UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-39081

BioNTech SE

(Exact name of Registrant as specified in its charter)

Federal Republic of Germany
(Jurisdiction of incorporation or organization)

An der Goldgrube 12
D-55131 Mainz
Germany
(Address of principal executive offices)

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Securities registered or to be registered, pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each Representing one ordinary share	BNTX	The Nasdaq Stock Market LLC
Ordinary shares, no par value, with a notional amount attributable to each ordinary share of €1*	—	The Nasdaq Stock Market LLC*

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of business covered by the annual report.

Ordinary shares, no par value, with a notional amount attributable to each share of €1 outstanding as of March 30, 2022, no par value: 246,807,808

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐	Emerging growth company	☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards † provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

* Listed not for trading or quotation purposes, but only in connection with the registration of American Depositary Shares representing such ordinary shares pursuant to the requirements of the Securities and Exchange Commission. The American Depositary Shares are registered under the Securities Act of 1933, as amended, pursuant to a separate registration statement on Form F-6 (File No. 333-233898).

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GENERAL INFORMATION

In this annual report on Form 20-F ("Annual Report"), "BioNTech," the "Group," the "Company," "we," "us," and "our" refer to BioNTech SE and its consolidated subsidiaries, except where the context otherwise requires.

In response to the fact that our consolidated financial statements are published in Euro, the selected consolidated financial data is presented in Euro as well. Amounts in U.S. dollar are translated into Euro using the exchange rates as per period end or average exchange rates for the periods indicated as published by the German Central Bank (*Deutsche Bundesbank*).

All references in this Annual Report to "$" mean U.S. dollars and all references to "€" mean Euros.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements concerning our business, operations and financial performance and condition as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements that are not of historical facts may be deemed to be forward-looking statements. Many of the forward-looking statements contained in this Annual Report can be identified by the use of forward-looking words such as "believes", "estimates", "anticipates", "expects", "plans", "intends", "may", "could", "might", "will", "should", "aims" or other similar expressions that convey uncertainty of future events or outcomes.

These forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause our actual results of operations, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These forward-looking statements are based on assumptions regarding our present and future business strategies and the environment in which we expect to operate in the future. Important factors that could cause those differences include, but are not limited to:

- our expected revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY® in the United States for individuals 16 years of age and above and in the European Union as authorized for use under full and conditional marketing approval, respectively, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners;
- our pricing and coverage negotiations for our COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments;
- the extent to which a COVID-19 vaccine continues to be necessary in the future;
- competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, safety, side-effect profile and durability of immune response;
- the timing and ability of us and our collaborators to obtain regulatory approval for our COVID-19 vaccine and our product candidates, and to commercialize our approved and investigational product candidates, if approved;
- the pricing and reimbursement of our COVID-19 vaccine and our product candidates, if approved;
- the rate and degree of market acceptance of our COVID-19 vaccine and our product candidates, if approved;
- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding: the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to identify research opportunities and discover and develop product candidates;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our product candidates;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance;
- unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us;
- our estimates of our expenses, future revenue and capital requirements and our needs for or ability to obtain additional financing;
- our ability to identify, recruit and retain key personnel;

- our and our collaborators' ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, our ability to protect and defend against potential claims of others' intellectual property, and the scope of such protection;
- the development of and projections relating to our competitors or our industry;
- the amount of and our ability to use net operating losses and research and development credits to offset future taxable income;
- our ability, and that of our collaboration partners' ability as applicable, to manage our development and expansion;
- regulatory developments in the United States and foreign countries;
- our ability to effectively scale our production capabilities and manufacture our products, including our COVID-19 vaccine, and our product candidates;
- our expectations with respect to the timing and amount of any dividends and any potential repurchases of our outstanding ADSs;
- our expectations regarding the timing of customer payments for delivered COVID-19 vaccine;
- our ability to implement, maintain and improve effective internal controls; and
- other factors not known to us at this time.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements contained in this Annual Report speak only as of the date of this report, and unless otherwise required by law, we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Consolidated Financial Data

Not applicable.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business is subject to various risks, including those described below. You should consider carefully the risks and uncertainties described below and in our future filings. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. Additionally, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Investing in the ADSs involves various risks. You should carefully read and consider the matters discussed in this Annual Report under the heading "Risk Factors," which include the following risks:

- Our revenue depends heavily on sales of our COVID-19 vaccine, and our future revenues from our COVID-19 vaccine are uncertain.
- Our reported commercial revenue is based on preliminary estimates of COVID-19 vaccine sales and costs from Pfizer Inc., or Pfizer, as Pfizer's fiscal quarter for subsidiaries outside the United States differs from ours and creates an additional time lag. These estimates are likely to change in future periods, which will impact our reported financial results.
- We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine and/or variant-specific formulations to obtain permanent regulatory approval in the United States, the United Kingdom, the European Union, or other countries where it has been authorized for emergency use or granted conditional marketing approval.
- Significant adverse events may occur during our clinical trials or even after receiving regulatory approval, which could delay or terminate clinical trials, delay or prevent regulatory approval or market acceptance of any of our product candidates.
- We face significant competition from other makers of COVID-19 vaccines and may be unable to maintain a competitive market share for our COVID-19 vaccine.
- We have only recently built our marketing and sales organization. If we are unable to continue to increase our marketing and sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate product sales revenue.

- Other companies or organizations may challenge our intellectual property rights or may assert intellectual property rights that prevent us from developing and commercializing our COVID-19 vaccine or our product candidates and other technologies.
- Even if we obtain full regulatory approval for our COVID-19 vaccine and product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community necessary for commercial success.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. If our operating results fall below expectations, the price of the ADSs representing our shares could decline.
- We may require substantial additional financing to achieve our goals, and a failure to obtain this capital on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.
- We have in the past identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we fail to remediate our material weakness, we may not be able to report our financial results accurately or to prevent fraud.
- As a "foreign private issuer," we are exempt from a number of rules under the U.S. securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.
- We face risks related to health epidemics and pandemics, such as COVID-19, that could adversely affect our operations.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control. Clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which can affect our ability to fund our company and would have a material adverse impact on our business.
- mRNA drug development has substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.
- Our approved product and product candidates are based on novel technologies and they may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of the third-party manufacturers we work with encounter such difficulties, our ability to supply materials for clinical trials or any approved product could be delayed or stopped.
- If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our COVID-19 vaccine or our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.
- We have experienced and may continue to experience significant volatility in the market price of the ADSs representing our ordinary shares.
- Our principal shareholders and management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

Risk Factors

Our business is subject to various risks, including those described below. You should consider carefully the risks and uncertainties described below and in our future filings. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. Additionally, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Risks Related to our COVID-19 vaccine and the Commercialization of our Pipeline

Our revenue depends heavily on sales of our COVID-19 vaccine, and our future revenues from our COVID-19 vaccine are uncertain.

Our COVID-19 vaccine was granted emergency use authorization in the United States and the United Kingdom, and conditional marketing approval in the European Union, in December 2020, followed by emergency or limited use authorization in a number of other countries and approval for use in certain other countries. Prior to this, we had not sold or marketed any products in our pipeline. As a result, a majority of our total revenues, and all of our product revenues, in 2021 are attributable and in 2022 will be attributable to sales of our COVID-19 vaccine. There is intense competition in the field of COVID-19 vaccines, including with other vaccines that have been authorized and those in late-stage clinical development. Our future revenues from sales of our COVID-19 vaccine depend on numerous factors, including:

- competition from other COVID-19 vaccines, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response;
- the extent of the spread of COVID-19 infection;
- the extent to which a COVID-19 vaccine continues to be necessary beyond the current pandemic, including when it becomes an endemic virus;
- the durability of immune response generated by our COVID-19 vaccine, which has not yet been demonstrated in clinical trials;
- our ability to receive full regulatory approvals, where we currently have emergency use authorizations or equivalents;
- our ability to expand our geographic customer base;
- our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments;
- the extent to which SARS-CoV-2 mutates and the efficacy of our COVID-19 vaccine in preventing COVID-19 infection from mutated strains;
- the ability of countries and jurisdictions to store and distribute doses of our COVID-19 vaccine to end users at cold temperatures;
- the safety profile of our COVID-19 vaccine, including if previously unknown side effects or increased incidence or severity of known side effects as compared to those seen during clinical trials are identified with our COVID-19 vaccine with widespread global use after approval;
- future intellectual property litigation involving COVID-19 vaccines, particularly if such litigation involves our COVID-19 vaccine; and
- our manufacturing and distribution capabilities for our COVID-19 vaccine.

While our COVID-19 vaccine has established a competitive commercial profile, we cannot ensure it will maintain its competitive position as competing vaccines become approved, and we cannot accurately predict the revenues our COVID-19 vaccine will generate in future periods or for how long our COVID-19 vaccine will continue to generate material revenues. If our revenues, market share and/or other indicators of market acceptance of our COVID-19 vaccine do not meet the expectations of investors or securities analysts, the market price of the ADSs representing our ordinary shares may decline. In addition, if one or more of the factors above negatively affects our COVID-19 vaccine sales, our business and financial condition could be materially harmed.

Our reported commercial revenue is based on preliminary estimates of COVID-19 vaccine sales and costs from Pfizer that are likely to change in future periods, which may impact our reported financial results.

Our reported commercial revenue is based on preliminary estimates from Pfizer, and other assumptions and judgments that we have made, which may be subject to significant uncertainties. Our commercial revenue are preliminary estimates in part due to a difference in Pfizer's fiscal quarter for subsidiaries outside the United States, which consequently creates an additional time lag between the recognition of revenues and the payment receipt. Although our revenue

recognition policy is based on facts and circumstances known to us and various other assumptions that we believe to be reasonable under the circumstances, our actual results may deviate from such reported revenue.

We depend on Pfizer to determine and provide estimates of the costs and profits to be shared with us in the countries where it is commercializing our COVID-19 vaccine under our collaboration agreement with Pfizer for our COVID-19 vaccine, which we refer to as the Pfizer Agreement. Because the information supplied by Pfizer is preliminary and is subject to change, the commercial revenue we report based on such information is also subject to finalization. This is particularly true for vaccine sales outside of the United States, where Pfizer has a different reporting cycle than ours. As a result, we may not have the complete sales and costs results outside of the United States for months not covered by the reporting period, but we are nonetheless required to report estimated figures.

For example, for the year ended December 31, 2021, Pfizer provided us profit figures for our COVID-19 vaccine sales in the United States using standard U.S. transfer prices and manufacturing and shipping cost variances (as far as those have been identified) that could be subject to adjustment (e.g., due to changes in manufacturing costs or the price of our COVID-19 vaccine). Pfizer also provided estimated profits for COVID-19 vaccine sales outside of the United States that were preliminary in nature, as Pfizer's subsidiaries outside of the United States do not have a fiscal year end of December 31. These estimated figures are likely to change as we receive final data from Pfizer for the year ended December 31, 2021 in accordance with the reporting cycle of its ex-U.S. subsidiaries and as actual costs become known. Further, to the extent that Pfizer does not provide such preliminary information in the future, our provisional sales figures for territories outside of the United States will be subject to an even greater level of estimates and judgments. Any changes to the preliminary data we report herein may have an impact on our reported revenues and expenses, profitability or financial position.

Our COVID-19 vaccine is sensitive to temperature, shipping and storage conditions and could be subject to risk of loss or damage.

Our COVID-19 vaccine is, and other product candidates we develop could be, sensitive to temperature, storage and handling conditions. In particular, while we have improved the required shipping and storage conditions of our COVID-19 vaccine, it must be shipped and stored at cold temperatures. Loss in supply of our COVID-19 vaccine and our product candidates could occur if the product or product intermediates are not stored or handled properly. Shelf life for our product candidates may vary by product, and it is possible that supply of our COVID-19 vaccine or our product candidates could be lost due to expiration prior to use. This has in the past led, and could in the future, lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or for commercial purposes. Such distribution challenges may make our COVID-19 vaccine a less attractive product than other COVID-19 vaccines that do not require as cold storage, and our COVID-19 vaccine may become increasingly less competitive as additional other vaccines become authorized for emergency use. If we, our partners and customers are unable to adequately manage these issues, we may be exposed to product liability claims and the market opportunity for our COVID-19 vaccine may be reduced, each of which could adversely affect our business prospects and our financial condition could be materially harmed.

If we discover safety issues with our products, including our COVID-19 vaccine, that were not known at the time of approval, commercialization efforts for our products could be negatively affected, approved products could lose their approval or sales could be suspended, we could be subject to product liability claims, and our business and reputation could be materially harmed.

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, including the review of additional safety information. Our COVID-19 vaccine is being more widely used by patients as an authorized product than it was used in clinical trials and therefore side effects and other problems may be observed after emergency use authorization that were not seen or anticipated, or were not as prevalent or severe, during clinical trials. We cannot provide assurance that newly discovered or developed safety issues will not arise. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that did not arise in the clinical trials of the product or that initially appeared to be unrelated to the vaccine itself and only with the collection of subsequent information were found to be causally related to the product. Any such safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition. The subsequent discovery of previously unknown problems with a product could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market. The reporting of adverse safety events involving our products or public speculation about such events could cause the price of the ADSs representing our ordinary shares to decline or experience periods of volatility.

Unexpected safety issues, including any that we have not yet observed in our clinical trials for our COVID-19 vaccine or in real world data, could lead to significant reputational damage for us and our product development platforms going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

Failure to comply with continuing regulatory requirements by us or our collaboration partners could adversely impact regulatory approvals for our products, result in product recalls or suspensions, subject us to fines and/or other types of liabilities.

If we or our collaborators fail to comply with applicable continuing regulatory requirements, including good industry practices, such as good manufacturing practices (GMP), we or our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals for specific drugs, product recalls and seizures, operating restrictions and/or criminal prosecutions. In addition, the manufacturers we engage to make our products and the manufacturing facilities in which our products are made are subject to periodic review and inspection by the U.S. Food and Drug Administration, or the FDA, and foreign regulatory authorities. If problems are identified during the review or inspection of these manufacturers or manufacturing facilities, it could result in our inability to use the facility to make our product or a determination that inventories are not safe for commercial sale. Any of these factors could adversely affect our business prospects and our financial position could be materially harmed.

We may be unsuccessful in adapting our COVID-19 vaccine or developing future versions of our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus, and even if we are successful, a market for vaccines against these variants may not develop.

Our COVID-19 vaccine was developed based upon the genetic sequence of the ancestral SARS-CoV-2 virus that was first detected. The SARS-CoV-2 virus continues to evolve, and new strains of the virus or those that are already in circulation may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains observed to date. Our vaccine may not be as effective in protecting against existing and future variant strains of the SARS-CoV-2 virus as it is against the ancestral virus. While we continue to monitor emerging SARS-CoV-2 strains, undertake preclinical investigations into the immunogenicity of BNT162b2 against new variants, and develop a modified versions of BNT-162b2, these efforts may be unsuccessful, and failure to adapt our vaccine to variants of the SARS-CoV-2 virus could lead to significant reputational harm and adversely affect our financial results. It is also possible that we may expend significant resources adapting our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus, but that a market for this adapted vaccine does not develop or demand does not align with our projections or cost expenditures. Moreover, even if we are successful in developing an adapted vaccine and there is a market for this new vaccine, in the future there may be a new strain of the virus and our adapted vaccine may not be as effective in protecting against such future variant strain.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, and/or delayed payments from government authorities could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford certain treatments, including our COVID-19 vaccine and other product candidates we may develop and sell. In addition, because our mRNA product candidates represent an entirely new therapeutic modality, we cannot accurately estimate how future products we may develop and sell would be priced, whether reimbursement could be obtained, or any potential revenue. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment in any of our products. Additionally, even if pricing terms with governmental authorities are agreed upon, there may be delayed or denied payments.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products in particular in the United States, including genetic medicines. In the United States, the principal decisions about

reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States but have not been approved for reimbursement in certain European countries.

Outside the United States, certain countries, including a number of member states of the European Union, set prices and reimbursement for pharmaceutical products, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaborators, our revenues from sales by us or our collaborators, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world but have been most drastic in the European Union. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. For example, the U.S. government recently released a "blueprint," which is a plan to reduce the cost of drugs. The blueprint contains certain measures that the HHS is already working to implement. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace.

The imposition of export controls on our COVID-19 vaccine in the European Union or in other jurisdictions could severely and adversely impact our manufacturing activities, commercial activities and financial results.

Governments of the jurisdictions in which we or our partners produce our COVID-19 vaccine may prohibit us from delivering orders of our COVID-19 vaccine to customers in other jurisdictions.

The European Union and other regions have imposed, or threatened to impose, export controls that would limit or block the delivery of COVID-19 vaccines manufactured in or outside their territories in instances where manufacturers have been delayed or have not fully satisfied their delivery obligations to such governments. The European Union ended this export authorization scheme as of December 31, 2021, however if they reenact this scheme, we may be prohibited from exporting commercial supply of the vaccine from our manufacturing site in Germany to non-EU countries (and Pfizer may likewise be prohibited from exporting out of its manufacturing site in Belgium). Such restrictions may have a material impact on our manufacturing or distribution activities, and the commercialization of our COVID-19 vaccine.

Our ability to continue to generate income from sales of our COVID-19 vaccine is uncertain, due to government interest and public perception regarding a vaccine, as well as the evolving nature of the disease more generally.

As a result of the emergency pandemic situations in many countries, there is a heightened risk that a COVID-19 vaccine may be subject to adverse actions by governmental entities in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions. In the U.S., the Defense Production Act of 1950, as amended (the "Defense Production Act"), gives the U.S. government rights and authorities that may directly or indirectly

diminish our own rights or economic opportunities with respect to our COVID-19 vaccine. Our current and potential third-party service providers may be impacted by government entities potentially invoking the Defense Production Act or other potential restrictions to all or a portion of services they might otherwise offer. The current presidential administration has communicated its intent to continue using the Defense Production Act to expand manufacturing capacity of vaccine and vaccine supplies as well as COVID-19 tests and testing supplies.

Additionally, we may need to, or we may be required by governmental or non-governmental authorities to, set aside specific quantities of doses of our COVID-19 vaccine for designated purposes or geographic areas. We face challenges related to the allocation of supply of our COVID-19 vaccine, particularly with respect to geographic distribution.

Furthermore, public sentiment regarding commercialization of a COVID-19 vaccine, the safety and efficacy of our COVID-19 vaccine, other COVID-19 vaccines and treatments, the COVID-19 pandemic generally, as well as public perception of the severity of SARS-CoV-2 virus may limit or negate our ability to generate income from sales of our COVID-19 vaccine. We believe that social media is increasingly being used to communicate information and misinformation about the COVID-19 pandemic and our and other COVID-19 vaccines. If social media posts and other communications contain negative, inaccurate or misleading information about our COVID-19 vaccine, demand for our COVID-19 vaccine may be diminished and we may suffer reputational damage.

The COVID-19 disease itself is very unpredictable, each variant comes with varying levels of transmissibilty and severity. Consequently, the burden of the disease may wane or dissipate such that our and other COVID-19 vaccines may be less essential from an individual and public health perspectives.

We face significant competition with other makers of COVID-19 vaccines and may be unable to maintain a competitive market share for our COVID-19 vaccine.

A large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates and certain other vaccines have been authorized for emergency use or approved in various countries. For example, Moderna, Inc.'s and Johnson & Johnson's vaccine candidates have been approved for emergency use in the United States, United Kingdom, European Union and other countries and other vaccines have been approved for emergency use in other jurisdictions. While we are not aware of all of our competitors' efforts, other vaccine candidates developed by the Gamaleya Research Institute of Epidemiology and Microbiology, the University of Oxford/AstraZeneca plc, CanSino Biologics Inc., the Vector Institute, Novavax, Inc., China National Pharmaceutical Group (Sinopharm)/Beijing Institute of Biological Products and Wuhan Institute of Biological Products, Sinovac Biotech Ltd., Bharat Biotech International Limited and other companies are in late stages of clinical development or have been authorized for emergency use or approved in certain countries. Our competitors pursuing vaccine candidates may have greater financial, product candidate development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to invest heavily to accelerate discovery and development of their vaccine candidates.

Our efforts to successfully commercialize our COVID-19 vaccine may fail if competitors develop and commercialize COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe side effects, have broader market acceptance, are more convenient to administer or distribute or are less expensive than any vaccine candidate that we have developed or we may develop.

We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine to obtain permanent regulatory approval in jurisdictions where it has been authorized for emergency use or granted conditional marketing approval.

Our COVID-19 vaccine has been granted full U.S. FDA approval for individuals 16 years and older, emergency or limited use authorization in a number of countries and approval for use in certain other countries. Our COVID-19 vaccine has not yet been approved by regulatory authorities in many of such countries. We and Pfizer intend to continue to observe our COVID-19 vaccine and other variants of a COVID-19 vaccine candidate in global clinical trials. It is possible that subsequent data from these clinical trials may not be as favorable as data we submitted to regulatory authorities to support our applications for emergency use authorization, marketing or conditional marketing approval or that concerns with the safety of our COVID-19 vaccine will arise from the widespread use of our COVID-19 vaccine outside of clinical trials. Our COVID-19 vaccine may not receive approval outside of the emergency use setting in the countries where it is not currently approved, which could adversely affect our business prospects.

We are developing other product candidates in an environment of rapid technological and scientific change, and our failure to effectively compete would prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to compete successfully.

The pharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and other public and private research organizations are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling drug products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop drugs in the future. We also expect to face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of conditions for which we are trying, or may in the future try, to develop drugs. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively, than any products we develop.

We anticipate competing with the largest pharmaceutical companies in the world, many of which are all currently conducting research in the fields of infectious diseases, immuno-oncology, rare genetic diseases and cancer immunotherapies. Some of these companies have greater financial and human resources than we currently have. In addition to these large pharmaceutical companies, we may directly compete with fully-integrated biopharmaceutical companies and other immunotherapy-focused oncology companies, as well as a number of companies focused on immunotherapies or shared tumor antigen and neoantigen therapeutics, some of which have entered into collaboration and funding agreements with larger pharmaceutical or biotechnology companies.

If we successfully develop other product candidates, and obtain approval for them, we will face competition based on many different factors, including:

- the safety and effectiveness of our products relative to alternative therapies, if any;
- the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration;
- the timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the price of any approved immunotherapy;
- reimbursement coverage; and
- intellectual property position.

Our competitors may develop or commercialize products with significant advantages over any products we develop based on any of the factors listed above or on other factors. In addition, our competitors may develop collaborations with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors therefore may be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

The market opportunities for certain of our product candidates may be small due to the rarity of the disease, or limited to those patients who are ineligible for or have failed prior treatments. As the target patient populations for some

of our programs are small, we may never achieve or maintain profitability without obtaining regulatory approval for additional indication.

The FDA often approves new cancer therapies initially only for use by patients with relapsed or refractory advanced cancer. We expect to seek approval initially of certain of our product candidates in this context. Subsequently, for those products that prove to be sufficiently beneficial, we would expect to seek approval in earlier lines of treatment and potentially as a first-line therapy but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. We are also developing product candidates for the treatment of rare diseases.

Our projections of the number of people who have or will have the diseases we may be targeting may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our products, if approved, because the potential target populations may be small, we may never achieve or maintain profitability without obtaining regulatory approval for additional indications.

We have only recently built our marketing and sales organization. If we are unable to continue to increase our marketing and sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate product sales revenue.

We have only recently developed our sales, distribution or marketing capabilities in Germany and Turkey, and, other than for our COVID-19 vaccine, we have not historically designed our preclinical studies and clinical trials with specific commercialization or marketing considerations in mind. To successfully commercialize our COVID-19 vaccine and any other products that may result from our development programs, we will need to continue developing sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. We may enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our current and future collaborators do not commit sufficient resources to commercialize our COVID-19 vaccine and our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product sales revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our ability to maintain profitability depends in part on our and our collaborators' ability to penetrate global markets, where we would be subject to additional regulatory burdens and other risks and uncertainties associated with international operations that could materially adversely affect our business.

Our ability to maintain profitability will depend in part on our ability and the ability of our collaborators to commercialize any products that we or our collaborators may develop in markets throughout the world. Commercialization of products in various markets could subject us to risks and uncertainties, including:

- obtaining, on a country-by-country basis, the applicable marketing authorization from the competent regulatory authority;
- the burden of complying with complex and changing regulatory, tax, accounting, labor and other legal requirements in each jurisdiction that we or our collaborators pursue;
- reduced protection for intellectual property rights;
- differing medical practices and customs affecting acceptance in the marketplace;
- import or export licensing requirements;
- governmental controls, trade restrictions or changes in tariffs;
- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- longer accounts receivable collection times;

- longer lead times for shipping;
- language barriers;
- foreign currency exchange rate fluctuations;
- the impact of public health epidemics and pandemics, such as the COVID-19 pandemic, on employees and the global economy;
- reimbursement, pricing and insurance regimes; and
- the interpretation of contractual provisions governed by local laws in the event of a contract dispute.

We do not have prior experience in all of these areas, and the experience we do have in some of these areas is limited. Our collaborators may have limited experience in these areas as well. Failure to successfully navigate these risks and uncertainties may limit or prevent market penetration for any products that we or our collaborators may develop, which would limit their commercial potential and our revenues.

Even if we obtain regulatory approval for our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, treatment centers and others in the medical community necessary for commercial success.

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients, and third- party or governmental payors accepting immunotherapies in general, and our products in particular, as medically useful, cost-effective and safe.

Any product that we bring to the market may not gain market acceptance by physicians, trial participants, third-party payors, and others in the medical community. Additionally, ethical, social and legal concerns about genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. If these products do not achieve an adequate level of acceptance, we may not generate significant product sales revenue and may not be able to achieve or maintain profitability. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the ability to offer our products, if approved, at competitive prices;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered;
- relative convenience and ease of transportation, storage and administration;
- any restrictions on the use of our products, if approved, together with other medications;
- the willingness of the target patient population to try new therapies, such as mRNA vaccines and therapies, and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third- party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our programs.

In addition, if any of our products are approved for marketing, we or a collaborator will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such

product, and will need to continue to comply (or ensure that our third-party providers comply) with current good manufacturing practices, or GMP, and current good clinical practices, or GCP, for any clinical trials that we or a collaborator conduct post-approval. In addition, there is always the risk that we or a collaborator or regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid in the United States, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time- consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse healthcare providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our product candidates in the United States, the European Union and other selected jurisdictions. If we obtain approval for our product candidates in any particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the marketplace. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The advancement of healthcare reform legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any product candidates we or our collaborators develop and may adversely affect the prices for such product candidates.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. Considerable uncertainty remains regarding the implementation and impact of the ACA.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. The Tax Cuts and Jobs Act of 2017, or the TCJA, includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." CMS proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on October 13, 2017, an executive order was signed terminating the cost-sharing reduction, or CSR, subsidies that reimburse insurers under the ACA. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Another executive order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. With the current presidential administration and Congress, there may be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of, the ACA. However, it remains to be seen whether new legislation modifying the ACA will be enacted and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. The implications of a potential repeal or replacement of the ACA, for our and our collaborators' business and financial condition, if any, are not yet clear.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. These reductions will remain in effect through 2025 unless additional congressional action is taken.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities, and affect our ability to commercialize any products for which we obtain marketing approval.

We expect that additional healthcare reform measures or proposals will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. In the event that the pricing structures for healthcare products, such as the product candidates we are developing, change materially and limit payments for such product candidates, our business will be adversely impacted as our products may no longer be commercially viable based on their expected net present value; we may have invested significant resources in products that cannot be commercially developed; or we may determine that assets that have reached an early phase of development cannot or will not be taken into further development, notwithstanding their clinical viability. In addition, development assets or clinical programs that are part of our collaborations may no longer be deemed commercially viable to pursue based on our collaborators' assessments of the impact of any proposed, announced, or legislated pricing reforms.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval, and may affect our overall financial condition and ability to develop product candidates.

European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the member states of the European Union.

We intend to seek approval to market our product candidates in both the United States and in other selected jurisdictions. If we obtain approval for our product candidates in a particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations that could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

In addition, in most countries outside the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and, generally, prices tend to be significantly lower in the European Union. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our collaborators and the potential profitability of any of our product candidates in those countries would be negatively affected.

Risks Related to our Financial Condition and Capital Requirements

We have incurred significant losses in the past and we may incur significant losses in the future, which makes it difficult to assess our future viability.

Historically, we have incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. As of December 31, 2020, our accumulated losses amounted to €409.6 million. Those loses have been compensated by the profit generated during the year ended December 31, 2021 and our retained earnings as of December 31, 2021 amounted to €9,882.9 million. Prior to December 2020 we funded our operations primarily from private placements of our ordinary shares, issuances of ordinary shares (including in the form of American Depositary Shares, or ADSs) in connection with our public offerings, generation of proceeds under our collaboration agreements, secured bank loans and issuance of a convertible note. Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Consequently, we have progressed from earning revenues primarily from research and development to earning revenues from commercial sales. We plan to invest heavily in R&D as we make a strong drive to build out our global development organization and diversify our therapeutic area footprint. Additionally, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. Even for those products for which we have obtained regulatory approval or emergency use authorization, our future revenues will depend upon the size of any markets in which our product candidates have received approval or authorization to market, our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. If achieved, profitability is difficult to maintain over time and is highly dependent on various factors. Our future financial results will depend, in part, on the rate of our future expenditures, the extent to which we experience long-term success of our commercial products and our ability to obtain funding through equity or debt financings, sales of assets, collaborations or grants.

We expect to continue to incur significant and increasing operating expenses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or increase our manufacturing capacity or capability;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as a public company and our product development and commercialization efforts, including expansion of sites in Germany and new sites in the United States, and potentially others globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;
- develop our sales, marketing, and distribution infrastructure for our COVID-19 vaccine and any other products for which we may obtain marketing approval or emergency use authorization;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- acquire other companies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. If our operating results fall below expectations, the price of the ADSs representing our shares could decline.

Our financial condition and operating results have varied in the past and will continue to fluctuate from one financial period to the next due to a variety of factors, many of which are beyond our control.

Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this report:

- the size and timing of orders for our COVID-19 vaccine;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the occurrence of adverse events during our clinical trials or post marketing authorization;
- our ability to develop and manufacture our product candidates and commercialize and manufacture our COVID-19 vaccine at commercial scale;
- our ability to manage our growth;
- our ability execute our corporate objectives;
- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by us and our collaborators;
- the ability of our collaborators to develop and successfully commercialize products developed from our suite of therapeutic classes;
- our relationships, and any associated exclusivity terms, with collaborators;
- our contractual or other obligations to provide resources to fund our product candidates, and to provide resources to our collaborators or to the collaborations themselves;
- the extent to which we repurchase outstanding ADSs under our share repurchase plan;
- risks associated with the international aspects of our business outside Germany, including the conduct of clinical trials in multiple locations and potential commercialization in such locations;
- our ability to minimize and manage product recalls or inventory losses caused by unforeseen events, cold chain interruption or testing difficulties;
- our ability to report our financial results accurately and in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, defend and enforce our intellectual property rights;
- our ability to prevent the theft or infringement, misappropriation or other violation of our intellectual property, trade secrets, know- how or technologies;
- our and our collaborators' ability to defend against claims of infringement of the intellectual property rights of third parties;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaborators' ability to obtain and devote additional capital that may be necessary to develop and commercialize products under our collaboration agreements, including our COVID-19 vaccine;
- our ability to minimize and manage product liability claims arising from the use of our COVID-19 vaccine and our product candidates and other future products, if approved;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- our ability to use our net operating loss carryforwards to offset future taxable income.

Each of the factors listed above may be affected by the COVID-19 pandemic's or its impact on the global community and the global economy.

Due to the various factors mentioned above, and others, the results of any of our periods should not be relied upon as indications of our future operating performance. Our operating results may fluctuate significantly from one reporting period to the next, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause the price of the ADSs to decline. While as a general matter we intend to periodically report on the status of our product candidate pipeline, including articulating anticipated next steps in the form of development plans or potential data readouts, we may not always be able to provide forward-looking guidance on the timing of those next steps. In addition, we do not control the timing of disclosures of any milestones related to any of our programs that are managed by our collaborators. Any disclosure by a collaborator of data that are perceived as negative, whether or not such data are related to other data that we or others release, may have a material adverse impact on the price of the ADSs or overall valuation. The price of the ADSs may decline as a result of unexpected clinical trial results in one or more of our programs, including adverse safety events reported for any of our programs.

Profitability is difficult to maintain over time and highly dependent on various factors.

Our ability to continue to generate revenue and maintain profitability depends on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our product candidates. Although we generate revenue from sales of our COVID-19 vaccine and additional limited revenue from other sales transactions, the amount of long-term revenue from such sales, including the sales of our COVID-19 vaccine, is uncertain at this time. Our ability to generate future revenues from other pharmaceutical product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining U.S. and non-U.S. marketing approvals for product candidates for which we complete clinical trials;
- seeking and obtaining market access and favorable pricing terms in the United States, the European Union, and other key geographies;
- furthering the development of our own manufacturing capabilities and manufacturing relationships with third parties in order to provide adequate (in amount and quality) products and services to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as a treatment option;
- launching and commercializing product candidates for which we obtain marketing approval and reimbursement, either through collaborations or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;
- addressing any competing technological and market developments, in particular, declining demand for any of our approved products;
- implementing additional internal systems and infrastructure;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, defending, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Additionally, we have incurred significant costs associated with the commercialization of our COVID-19 vaccine. Our expenses could increase beyond our expectations if we are required by the FDA, the EMA, or other regulatory agencies to perform clinical and other trials or make changes to our manufacturing or quality systems in addition to those that we currently anticipate. Accordingly, such costs could adversely affect our future profitability.

The amount of and our ability to use, net operating losses and research and development credits to offset future taxable income may be subject to certain limitations and uncertainty. In addition, pending and future tax audits within our group, disputes with tax authorities and changes in tax law or fiscal regulations could lead to additional tax liabilities. We are subject to routine tax audits by the respective local tax authorities. Any additional tax liability could have an adverse effect on our business, financial conditions, results of operations or prospects.

In Germany, we have unused tax loss carryforwards for corporate taxes for German non tax group entities, though we have not recognized deferred tax assets related to such loss carryforwards for International Financial Reporting Standards, or IFRS, reporting purposes until December 31, 2021. Deferred tax assets are recognized for unused tax losses only to the extent that it is probable that taxable profit will be available against which the losses can be utilized. In general, net operating loss, or NOL, carryforwards in Germany do not expire. Furthermore, under current German tax laws, certain substantial changes in the Company's ownership and business may further limit the amount of NOL carryforwards that can be used annually to offset future taxable income.

For the German tax group we incurred tax losses up to and including December 31, 2020. Even though we recognized deferred tax assets on a majority of German tax loss carry forwards in 2020 which were fully utilized in 2021, they are, however, subject to review and possible adjustment by the German tax authorities.

In addition, we have U.S. federal and state NOL carryforwards due to our subsidiaries in the United States, which may be subject to limitations on use after an ownership change.

We may not be able to utilize a material portion of our historic or current NOLs or credits in either Germany resulting from our German tax group or non tax group entities in Germany or the United States until these have been finally assessed by the tax authorities or when the limitation period has passed. In addition, the rules regarding the timing of revenue and expense recognition for tax purposes in connection with various transactions are complex and uncertain in many respects, and, if challenged, our recognition may be subject to a revised assessment. In the event any such challenge is sustained, our NOLs could be materially reduced or we could be determined to be a material cash taxpayer for one or more years which could have an adverse effect on our business, financial conditions, results of operations or prospects.

Furthermore, our ability to use our NOLs or credits is conditioned upon our attaining profitability and generating taxable income. Taxable income exceeding NOLs will be subject to taxation resulting tax liabilities. As described above, we have incurred significant net losses in every year since our inception other than 2018 and 2021 and anticipate that in the future, we may incur significant losses for some of the group entities. Our ability to utilize our NOL or credit carryforwards in the United States and for some German group entities is uncertain.

Under German tax laws, we are obligated to withhold a percentage of wage tax and social security contributions on personnel expenses if contract services providers are considered to be our internal employees and remit those withholdings to German tax authorities and social security institutions. Late payments may subject us to penalties and fees.

Under German tax and social security laws, we are obligated to withhold a percentage of payments we make to third parties in consideration of the services provided, in case these are considered employment payments, and remit those withholdings to German tax authorities and social security institutions. As a result of an internal review, we discovered that especially in the most recent years, where a significant volume of service providers have been engaged to ensure research, development, manufacturing and general supply capabilities of our COVID-19 vaccine, we and certain of our subsidiaries did not withhold, report and remit certain wage taxes and social security contributions in connection with the contract service providers where some have been engaged in a manner comparable to internal employees as required to be withheld under German tax and social security laws, and have not made the requisite recordings in our and their financial books and records in relation to such wage taxes and social security contributions. We notified the tax authorities of these possible late payments. No administrative offense or criminal proceeding have been opened as of the date of this report.

It is not possible to seek the refund of these wage taxes or social security contributions from either the German Tax authorities of social security institutions after filing returns. In Germany, employers are considered secondarily liable for wage taxes.

In addition value added taxes on invoices received by contract services providers, who are considered internal employees, has to be considered non-deductible and needs to be repaid to the German Tax authorities. There is a possibility to reclaim the VAT repaid to the German Tax authorities from the service provider. As of December 31, 2021 the majority of these amounts have been refunded. However, there is a possibility that the relevant input VAT claims against the

contract service providers, may in some instances, not be enforceable as a result of a contract service provider no longer existing, the lapse of time or any other facts preventing the enforcement of such claims.

We may require substantial additional financing to achieve our goals, and a failure to obtain this capital on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

As of December 31, 2021, we had cash and cash equivalents of €1,692.7 million. Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. We may require additional capital to obtain regulatory approval for, and to commercialize, future product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Due to the high uncertainty of the length of time and activities associated with discovery and development of our product candidates, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the terms of any other strategic transactions, including relating to any acquisitions, into which we enter;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement, misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs; and
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily through the sale of equity securities, revenue from collaborations, and revenue from sales of our COVID-19 vaccine, and we cannot be certain that additional funding will be available on favorable terms, or at all. We are currently generating product sales or royalty revenue to finance our operations, however should this change in the future we expect to finance our future cash needs through a combination of product sales, public or private equity offerings, debt financings, collaborations, licensing arrangements, and other marketing or distribution arrangements. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all, including as a result of the impact that the COVID-19 pandemic and other global events, such as political upheavals, may have on the capital markets.

Negative clinical trial data or setbacks, or perceived setbacks, in our programs or with respect to our technology could impair our ability to raise additional financing on favorable terms, or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our shareholders' rights.

Further, to the extent that we raise additional capital through the sale of ADSs, ordinary shares or securities convertible or exchangeable into ordinary shares, share ownership interests will be diluted. We have entered into three credit facilities with an aggregate drawing capacity of €23.0 million which are all drawn down as of December 31, 2021, and for all of which first scheduled repayments have occurred. Subsequent to the end of the reporting period, on February 25, 2022 we agreed to repay two of the credit facilities amounting to €19.5 million. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to security interests in our assets and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements, sales of assets, collaborations, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations, cause the price of the ADSs to decline, and negatively impact our ability to fund operations.

We will need to continue to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, legal, compliance and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. In addition, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities.

As a growing biotechnology company, we are actively pursuing drug classes, platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing products for, and fully understanding the regulatory and manufacturing pathways to, all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to effectively implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our COVID-19 vaccine and our product candidates, if approved, will depend in part on our ability to effectively manage the current and future development and expansion of our company.

We have incurred increased costs as a result of operating as a public company, and our management has been required to devote substantial time to new compliance initiatives. We are subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm the business.

As a public company, we incur significant legal, accounting and other expenses. The federal securities laws, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies, including

requirements to file annual and event-driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations result in substantial legal and financial compliance costs and have made some activities time-consuming and costly. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, including the attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with Section 404, we document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have needed to continue to dedicate internal resources, have engaged outside consultants, and have adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting. We will continue to implement steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that in the future neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

The Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act contains significant corporate governance and executive compensation related provisions that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives.

In the past we have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we identify material weaknesses in the future and fail to remediate such material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.

Our management is responsible for establishing and maintaining internal control over financial reporting, disclosure controls, and compliance with the other requirements of the Sarbanes-Oxley Act and the rules promulgated by the SEC thereunder. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with international financial reporting standards. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected by the company's internal controls on a timely basis.

Prior to our initial public offering, we operated as a private company that was not required to comply with the obligations of a public company with respect to internal control over financial reporting. We had historically operated with limited accounting personnel and other resources with which to address our internal control over financial reporting.

We and our auditors identified a material weakness in 2019 which constituted a material weakness in our internal control over financial reporting in both design and operation. As of December 31, 2021, this material weakness has been fully remediated, as verified by our external auditors.

If we identify material weaknesses in the future and are unable to successfully remediate such material weaknesses or successfully supervise and rely on outside advisors with expertise in these matters to assist us in the preparation of our financial statements, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of the ADSs to decline.

We have various international trade obligations including customs value calculation, customs tariff number classification and other related securities requirements. Late payments to customs authorities may subject us to penalties and fees.

Our supply chain, production and distribution network across the globe creates an increasing level of complexity in customs and foreign trade processes. The requirements for internal control systems are increasing and must be developed simultaneously. The risk management system for customs and foreign trade, which we are continuously improving, determines which stakeholders, goods, and means of transport should be examined and to what extent. These risks include the potential for non-compliance with customs value calculation, customs tariff number classification, trade restrictions, security regulations as well as the potential failure to facilitate international trade.

We are, and will likely continue to be, subject to various audits that arise from time to time, including customs and potential future foreign trade audits.

As a result of an internal review, we discovered that especially in the most recent years, where a significant increase of shipments took place, international trade obligations such as correct customs value calculation of our and certain of our subsidiaries have not been applied correctly and we have made the requisite recordings in our financial books and records in relation to such customs duties. We notified the customs authorities of these possible late payments. No administrative offense or criminal proceeding have been opened as of the date of this report. The expenses are partially subject to reimbursement under our collaboration agreement with Pfizer.

As a "foreign private issuer," we are exempt from a number of rules under the U.S. securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.

We are a "foreign private issuer," as defined in the rules and regulations of the SEC, and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As a foreign private issuer, we file an Annual Report on Form 20-F within four months of the close of each fiscal year ending December 31 and reports on Form 6-K relating to certain material events promptly after we publicly announce these events. Additionally, we rely on a provision in Nasdaq's Listed Company Manual that allows us to follow German company law and European law applicable to European stock corporations in general, the German Stock Corporation Act (*Aktiengesetz*), the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), or the SE Regulation, and the German Act on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE)*) (*SE-Ausführungsgesetz-SEAG*), in particular with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq.

For example, we are exempt from regulations of Nasdaq that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors;
- require non-management directors to meet on a regular basis without management present;
- adopt a code of conduct and promptly disclose any waivers of the code for directors or executive officers that should address certain specified items;
- have an independent compensation committee;
- have an independent nominating committee;

- solicit proxies and provide proxy statements for all shareholder meetings;
- review related party transactions; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares.

As a foreign private issuer, we are permitted to follow home country practice in lieu of the above requirements. We therefore continue to follow German corporate governance practices in lieu of the corporate governance requirements of Nasdaq in certain respects. In particular, we follow German corporate governance practices in connection with the distribution of annual and interim reports to shareholders, the application of our code of conduct to our Supervisory Board, executive remuneration disclosure, proxy solicitation in connection with shareholders' meetings, and obtaining shareholder approval in connection with the establishment of, or material amendment to, certain equity-based compensation plans.

In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act, both of which are also applicable to U.S. companies listed on Nasdaq. As we are a foreign private issuer, however, our audit committee is not subject to additional requirements of Nasdaq applicable to listed U.S. companies, including an affirmative determination that all members of the audit committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer.

Due to the above exemptions for foreign private issuers, our shareholders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the United States, some investors may find the ADSs less attractive as a result, and there may be a less active trading market for the ADSs.

We face risks related to catastrophic global events including natural disasters, political crises, or public health epidemics and pandemics, such as COVID-19, that could adversely affect our operations.

Our business could be adversely impacted by the effects of catastrophic global events including natural disasters such as an earthquake, fire, hurricane, tornado, flood or significant power outage; public health crises such as the COVID-19 pandemic; political crises, such as terrorist attacks, war and other political instability, including the ongoing geopolitical tensions related to Russia's actions in Ukraine, resulting sanctions imposed by the United States and other countries and retaliatory actions taken by Russia in response to such sanctions; or other catastrophic events.

In particular, the COVID-19 pandemic may negatively impact our operations in the future and could also affect our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate. Certain of our programs have experienced delays in the clinical development process as a result of the COVID-19 pandemic. In addition, we have modified our business practices, in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. This partial disruption, even temporary, may severely impact our operations and overall business by delaying the progress of our clinical trials and preclinical studies. Our operations, including research and manufacturing, could also be disrupted due to the potential impact of staff absences as a result of self-isolation procedures or extended illness.

Our suppliers, licensors or collaborators could also be disrupted by conditions related to COVID-19, or other pandemics and epidemics, possibly resulting in disruption to our supply chain, clinical trials, partnerships or operations. If our suppliers, licensors, contract research organizations, or CROs, or collaborators are unable or fail to fulfill their obligations to us for any reason, our business could be adversely affected. Our customers could also be disrupted by conditions related to COVID-19 or other epidemics, possibly through deferring purchasing decisions or delaying research programs.

Although we have generated revenues from sales of our COVID-19 vaccine, there remains uncertainty regarding other potential effects of COVID-19 on our business. For example, if a new variant of COVID-19 emerges for which existing vaccines, including our COVID-19 vaccine, are ineffective, infections may become even more widespread or result in an economic downturn that could affect demand for our products and services or our ability to raise capital, which could have a material adverse effect on our business, operating results and financial condition.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. We currently maintain insurance coverage for losses relating to property damage and an interruption of our development, manufacturing or commercialization efforts. With the grant of the first marketing approvals for our COVID-19 vaccine we have acquired additional insurance coverage for losses relating to transportation and storage of our COVID-19 vaccine and product liability claims arising from its use, and the coverage or coverage limits of our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop.

Additionally, operating as a public company has made it more expensive for us to obtain director and officer liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Supervisory Board, our Management Board, or our board committees.

Risks Related to our Business

Our business is dependent on the successful development, regulatory approval and commercialization of product candidates based on our technology platforms. If we and our collaborators are unable to obtain approval for and effectively commercialize our product candidates for the treatment of patients in their intended indications, our business would be significantly harmed.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and we may not be able to obtain approvals for the commercialization of product candidates we may develop. Any product candidates we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable global health authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and our collaborators must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective, including in the target populations. Successful completion of clinical trials is a prerequisite to submitting a biologics license application, or BLA, or a new drug application, or NDA, to the FDA, a Marketing Authorization Application, or MAA, to the EMA, and similar marketing applications to comparable global regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. Although our COVID-19 vaccine has received emergency use authorization or approval in certain countries, it is possible that it will not receive widespread regulatory approval and that none of our other product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and may need to rely on third-party CROs, regulatory consultants or collaborators to assist us in this process. Although we expect to submit BLAs for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products, and other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals in the United States, the European Union and elsewhere, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in

marketing approval policies and standards of care during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA, EMA and comparable regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that the data are insufficient for approval and require additional preclinical, clinical or other trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays or non-approval may result if an FDA panel of experts, referred to as an Advisory Committee, or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process.

Regulatory agencies also may approve a product candidate for fewer or more limited indications or patient populations than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

The FDA, EMA and other regulatory agencies review the Quality or Chemistry, Manufacturing and Controls, or CMC, section of regulatory filings. Any aspects found unsatisfactory by regulatory agencies may result in delays in clinical trials and commercialization. In addition, the regulatory agencies typically conduct pre-approval inspections at the time of a BLA, MAA or comparable filing. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the potential mRNA product candidate.

If we experience delays in obtaining, or if we fail to obtain, approval of any product candidates we may develop, the commercial prospects for those product candidates will be harmed, and our ability to generate revenues will be materially impaired. Additionally, even if we are successful in obtaining marketing approval for product candidates, because our preclinical studies and clinical trials have not been designed with specific commercialization considerations, the commercial prospects for those product candidates could be harmed, and our ability to generate revenues could be materially impaired.

mRNA drug development has substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.

To our knowledge, other than our COVID-19 vaccine and MRNA-1273, no mRNA immunotherapies have been approved or received emergency use authorization or conditional marketing authorization to date by the FDA, the EMA or other comparable regulatory authority. Successful discovery and development of mRNA-based (and other) immunotherapies by either us or our collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. Our product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic or clinical holds, or fail to reach the market for many reasons, including:

- discovery efforts aimed at identifying potential immunotherapies may not be successful;
- nonclinical or preclinical study results may show product candidates to be less effective than desired or have harmful or problematic side effects;
- clinical trial results may show the product candidates to be less effective than expected, including a failure to meet one or more endpoints or have unacceptable side effects or toxicities;
- manufacturing or distribution failures or insufficient supply of GMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make our product candidates commercially unattractive;
- our improvements in the manufacturing processes may not be sufficient to satisfy the clinical or commercial demand of our product candidates or regulatory requirements for clinical trials;
- changes that we make to optimize our manufacturing, testing or formulating of GMP materials could impact the safety, tolerability and efficacy of our product candidates;
- pricing or reimbursement issues or other factors could delay clinical trials or make any immunotherapy uneconomical or noncompetitive with other therapies;

- the failure to timely advance our programs or receive the necessary regulatory approvals, or a delay in receiving such approvals, due to, among other reasons, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, BLA, MAA or the equivalent application, discussions with the FDA or the EMA, a regulatory request for additional nonclinical or clinical data, or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding; and
- the proprietary rights, products and technologies of our competitors may prevent our immunotherapies from being commercialized.

Currently, mRNA is considered a gene therapy product by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and may cause certain side effects, mRNA-based medicines are designed not to irreversibly change cell DNA. Side effects observed in other gene therapies, however, could negatively impact the perception of immunotherapies despite the differences in mechanism. In addition, the regulatory pathway in the United States and may other jurisdictions for approval is uncertain. Currently, our COVID-19 vaccine is not classified as a gene therapy. The pathway for an individualized therapy, such as our iNeST mRNA-based immunotherapy where each patient receives a different combination of mRNAs, remains particularly unsettled. The number and design of the clinical and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for gene therapy products or therapies that are not individualized or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and submit an application for marketing approval by a regulatory authority varies significantly from one pharmaceutical product to the next and may be difficult to predict.

Our product candidates may not work as intended, may cause undesirable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

As with most biological products, use of our product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. The potential for adverse events is especially acute in the oncology setting, where patients may have advanced disease, have impaired organ function, compromised immune and other systems and may be receiving numerous other therapies. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or comparable regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, competent authorities of EU member states, ethics committees, the institutional review boards, or IRBs, at the institutions in which our studies are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials. The FDA or comparable regulatory authorities could also order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Monitoring the safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize our product candidates.

In our ongoing and planned clinical trials, we have contracted, and are expected to continue to contract, with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. Additionally, the COVID-19 pandemic continues to have an impact on our ability to monitor trial safety related to, for example, staff shortages (i.e., due to contracting COVID-19 and/or the global shortage in healthcare professionals), re-assignment of staff to treat COVID-19 patients, restricted clinical site access, etc. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA, the EMA or other comparable regulatory

authority delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved on a commercial basis, could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

In addition, even if we successfully advance one of our product candidates into and through clinical trials, such trials will likely only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trials may not be sufficient to determine the effects and safety consequences of taking our product candidates over a multi-year period.

If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our product candidates or our immunotherapy approach generally prove to be unsafe, our technology platforms and pipeline could be affected, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all and would have an adverse effect on our business.

Much of our pipeline is in preclinical development and these programs could be delayed or not advance into the clinic. Before we can initiate clinical trials for product candidates, we must complete extensive preclinical studies, including IND-enabling Good Laboratory Practice toxicology testing, that support our planned Investigational New Drug applications, or INDs, in the United States or similar applications in other jurisdictions. We must also complete extensive work on CMC activities (including collecting yield, purity and stability data) to be included in the IND filing. CMC activities for a new category of medicines such as mRNA therapies require extensive manufacturing processes and analytical development, which are uncertain and lengthy. For instance, batch failures have occurred as we scale up our manufacturing and may occur in the future. In addition, we have had in the past, and may in the future have, difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our preclinical or clinical product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical or clinical trials of such product candidates. For example, we cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control. Clinical trials of our product candidates may be delayed, certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, and we may have difficulty recruiting patients to participate in clinical trials, any of which can affect our ability to fund our company and would have a material adverse impact on our business.

Clinical testing is expensive and complex and can take many years to complete. Its outcome is inherently uncertain. We may not be able to initiate, may experience delays in, or may have to discontinue clinical trials for our product candidates. We and our collaborators also may experience numerous unforeseen events during, or as a result of, any clinical trials that we or our collaborators conduct that could delay or prevent us or our collaborators from successfully developing our product candidates, including:

- the FDA, other regulators, IRBs or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we have optimized in the past and may in the future optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to additional studies (including bridging and bioequivalence studies) or potentially significant changes in our clinical trial designs, requiring additional cost and time, and, as a consequence, lead to a delay in plans for progressing one or more product candidates;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- in an effort to optimize product features, we have made in the past and may continue to make changes to our product candidates after we commence clinical trials of a medicine which may require us to repeat earlier stages of clinical testing or delay later-stage testing of the medicine;
- clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs;
- differences in trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- preclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- our product candidates may have undesirable side effects or other unexpected characteristics. One or more of such effects or events could cause regulators to impose a clinical hold on the applicable trial, or cause us or our investigators, IRBs or ethics committees to suspend or terminate the trial of that product candidate or any other of our product candidates for which a clinical trial may be ongoing;
- the number of trial participants required for clinical trials of any product candidates may be larger than we anticipate, identification of trial participants for such trials may be limited, enrollment in these clinical trials may be slower than we anticipate due to perceived adverse effects, limited patient populations, competitive trials, the COVID-19 pandemic or other reasons, or participants may withdraw from clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- despite robust sponsor oversight, our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or withdraw from the trial, which may require that we add new clinical trial sites;

- regulators may elect to impose a clinical hold, or we, our investigators, IRBs or ethics committees may elect to suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to an unacceptable benefit-risk ratio;
- with respect to infectious disease vaccine trials in particular, we have to wait for particular level of infection in the placebo arm in order to assess protection provided by vaccine, and we cannot control the rate of exposure or infection which can make timing uncertain;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- safety or efficacy concerns regarding our product candidates may result from any concerns arising from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours; and
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the FDA or other regulatory authorities, ethics committees, or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the DSMB. We may in the future be delayed in gaining clearance from the FDA or other regulators to initiate clinical trials through, among other things, the imposition of a clinical hold in order to address comments from such regulators on our clinical trial design or other elements of our clinical trials. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; unforeseen safety issues or adverse side effects; failure to demonstrate a benefit, or adequate benefit-risk ratio, from using a product candidate; failure to establish or achieve clinically meaningful trial endpoints; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. We must also complete extensive work on CMC activities that require extensive manufacturing processes and analytical development, which are uncertain and lengthy.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA and regulatory authorities in other jurisdictions have limited experience with commercial development of several of our technologies. The FDA may require an Advisory Committee to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be certain.

Moreover, the FDA and other regulatory authorities have indicated that, prior to commencing later stage clinical trials for our mRNA-based product candidates, we will need to scale up and further refine assays to measure and predict the potency of a given dose of these product candidates. Any delay in the scaling and refining of assays that are acceptable to the FDA or other regulatory authorities could delay the start of future clinical trials. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data for our clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Significant additional preclinical or nonclinical testing and studies or clinical trial delays for our product candidates also could allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in the development of our product candidates may harm our business, financial condition and prospects significantly.

If we or our collaborators encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We depend on enrollment of participants in our clinical trials for our product candidates. In the past, our collaborators have found, and we or our collaborators may in the future find, it difficult to enroll trial participants in our clinical studies, which could delay or prevent clinical studies of our product candidates. The COVID-19 pandemic has introduced additional challenges in enrolling patients into many of our clinical trials. Identifying and qualifying trial participants to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit trial participants to participate in testing our product candidates. Delays in enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific a therapeutic area, or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our product, or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of trial participants, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical trials in a timely manner. Patient and subject enrollment is affected by factors including:

- severity of the disease under investigation;
- complexity and design of the study protocol;
- size of the patient population;
- eligibility criteria for the study in question;
- proximity and availability of clinical study sites for prospective trial participants;
- availability of competing therapies and clinical trials, including between our own clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor trial participants adequately during and after treatment;
- ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and trial participants' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain participant informed consent;
- major changes in the approval status of competitor investigational products during the clinical trial period;
- impacts of the COVID-19 global pandemic; and
- the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of trial participants available to us because some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a third party. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Moreover, because in some cases our product candidates represent a therapeutic novelty in contrast to more traditional methods for disease treatment and prevention, potential trial participants and their doctors may be inclined to use conventional therapies or other investigational therapies rather than enroll trial participants in any future clinical trial involving more novel product candidates. Additionally, if new product candidates, such as gene editing therapies, show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If

such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our clinical trials.

In particular, certain conditions for which we plan to evaluate our current product candidates are rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly. As discussed above, each of the foregoing risks is exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

Clinical trials of our product candidates are currently being conducted in several countries, and we plan to commercialize our product candidates, if approved, globally. Accordingly, we are subject to additional risks related to operating in multiple countries, including:

- differing regulatory requirements in such countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in Germany and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- taxes, including withholding of payroll taxes;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of Germany;
- workforce uncertainty in countries where labor unrest is more common;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable regulations in other jurisdictions;
- challenges enforcing our contractual and intellectual property rights, especially in those countries that do not respect and protect intellectual property rights to the same extent as Germany and the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or public health epidemics or pandemics.

The extent to which the COVID-19 pandemic continues to impact our operations, including our clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. In the future, similar events could affect our ability to manufacture and commercialize our product candidates.

These and other risks associated with our international operations and our collaborations with our collaborators may materially adversely affect our ability to attain or maintain profitable operations.

Interim top-line and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to disclose publicly regarding a particular study or clinical trial is based on what is typically extensive information, and our securityholders may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by our securityholders or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

Results of earlier studies and trials of our product candidates may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our tumor-specific cancer immunotherapy candidates and any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates.

Our planned clinical trials or those of our collaborators may be less efficacious or may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could delay or terminate clinical trials, or delay or prevent regulatory approval or market acceptance of any of our product candidates.

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials.

These product candidates may fail to show the desired safety and efficacy profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Some of our product candidates are being developed or are intended to be co-administered with other developmental therapies or approved medicines. For example, autogene cevumeran (BNT122) is being developed to be co-administered with checkpoint inhibitors. Such combinations may have additional side effects, which may be difficult to predict in future clinical trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting trial participants to any of our clinical trials, trial participants may withdraw from trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other regulatory authorities, ethics committees or an IRB may impose a clinical hold on, or suspend or terminate, clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, an unfavorable benefit-risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

If we are not successful in discovering, developing and commercializing additional product candidates beyond our current portfolio, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our efforts will focus on the clinical trials and potential approval of our existing product candidates, a key element of our strategy is to discover, develop and potentially commercialize additional products beyond our current portfolio to treat various conditions and in a variety of therapeutic areas. We intend to do so by investing in our own drug and target discovery efforts, exploring potential collaborations for the development of new products, and in-licensing technologies. Identifying new product candidates requires substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Even if we identify product candidates that initially show promise, we may fail to develop and commercialize such products successfully for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional products, our potential for growth may be impaired.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified senior management and scientific personnel.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent upon members of our management and scientific teams. We may not be able to retain these persons due to the competitive environment in the biotechnology industry, as well as a current global shortage of these highly qualified individuals. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We are also aware of physical threats made against certain of these people. In response to these threats, we have deployed personal protection for such employees and increased our security generally. We currently do not have "key person" insurance on any of our employees.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval and commercialization strategy. Our consultants and

advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly grown our workforce through the use of contractors and part-time workers. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will be critical to our success as well. Competition for skilled personnel, including in mRNA research, clinical development, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, failure to succeed in preclinical studies or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have an adverse effect on the results of our operations.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants, despite our robust efforts to prevent such misconduct through sponsor oversight. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Employee litigation and unfavorable publicity could negatively affect our future business.

From time to time our employees may bring lawsuits against us regarding injury, creating a hostile work place, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years, there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment- related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related claims, our business could be negatively affected.

The illegal distribution and sale by third parties of counterfeit versions of our COVID-19 vaccine could have a negative impact on our financial performance or reputation.

Third parties have in the past and may continue to illegally distribute and sell counterfeit versions of COVID-19 vaccines. Counterfeit products are frequently unsafe or ineffective, and may even be life-threatening. Counterfeit medicines may contain harmful substances or the wrong dosage. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit products, increased levels of counterfeiting, or unsafe COVID-19 vaccines could materially affect public confidence in our COVID-19 vaccine or other product candidates. It is possible that adverse events caused by unsafe counterfeit vaccines will mistakenly be attributed to our COVID-19 vaccine. In addition, thefts of inventory at warehouses, plants or while in-transit, which are subsequently improperly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation, and our business. Public loss of

confidence in the integrity of our COVID-19 vaccine as a result of counterfeiting or theft could have a material adverse effect on our business, results of operations, and financial condition.

We and our collaborators or other contractors or consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

Our internal computer systems and those of our current and any future collaborators, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, cybersecurity threats, war, and telecommunication and electrical failures. If any such material system failure, accident or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from one or more ongoing or completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, because of our approach to running multiple clinical trials in parallel, any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in many stages of development. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under the EU General Data Protection Regulation, or the GDPR, relevant law of an EU member state, HIPAA, and other relevant state and federal privacy laws in the United States. To the extent that any disruption or security breach were to result in a loss of, or damage to, data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

While we have not experienced any material system failures, accidents or security breaches to date, we and a vendor have separately in the past been subject to a security breach resulting in us unknowingly making payments to third parties that were able to gain unauthorized access to our and the vendor's email systems. Additionally, in December 2020, we were informed by the EMA that the agency was subject to a cyber attack and that some documents relating to our regulatory submission for our COVID-19 vaccine candidate, which was stored on an EMA server, had been unlawfully accessed. None of our systems were breached in connection with this incident and we are unaware that any study participants were identified through the data being accessed.

We have put systems and procedures in place to minimize the likelihood of such incidents reoccurring; however, we cannot guarantee that third parties will not be able to gain unauthorized access to or otherwise breach our systems in the future. Any such unauthorized access or breach could adversely affect our business, results of operations and financial condition.

Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We recognize the need for, and are in the early stages of, developing disaster recovery, business continuity and document retention plans that would allow us to be operational despite casualties or unforeseen events including natural disasters such as an earthquake, fire, hurricane, tornado, flood or significant power outage; public health crises such as the COVID-19 pandemic; political crises, such as terrorist attacks, war and other political instability, including the ongoing geopolitical tensions related to Russia's actions in Ukraine, resulting sanctions imposed by the U.S. and other countries and retaliatory actions taken by Russia in response to such sanctions; or other catastrophic events. Without disaster recovery, business continuity and document retention plans, if we encounter difficulties or disasters with our manufacturing facilities, our distribution facilities, at our corporate headquarters or those of third parties we rely on, our critical systems, operations and information may not be restored in a timely manner, or at all, and this could have an adverse effect on our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of our current or future product candidates.

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and an even greater risk related to any commercialized products, such as our COVID-19 vaccine. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;

- loss of revenue;
- substantial monetary awards to patients, healthy volunteers or their children;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

We carry clinical trial insurance, including product liability insurance, which we believe to be sufficient in light of our current commercial operations and clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We have expanded our insurance coverage to include product liability claims arising from the use of our COVID-19 vaccine; however, the amount of coverage we have obtained may not be adequate, and we may be unable to maintain product liability insurance for our COVID-19 vaccine on commercially reasonable terms in the future. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of the ADS to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If our products become subject to a product recall it could harm our reputation, business and financial results.

The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of certain commercialized products. In the case of the FDA, the authority to require a recall of a biologic product must be based on an FDA finding that a batch, lot of other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, some governmental bodies outside the United States have the authority to require the recall of any product candidate in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues.

Recalls of any of our product candidates would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall announcement could harm our reputation with customers and negatively affect our sales, if any.

Our ability to effectively monitor and respond to the rapid and ongoing developments and expectations relating to environmental, social and governance ("ESG") matters, including related social expectations and concerns, may impose unexpected costs or result in reputational or other harm that could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline.

There are rapid and ongoing developments and changing expectations relating to ESG matters and factors such as the impact of our operations on the environment, access to our COVID-19 vaccine, corporate governance, our practices relating to product stewardship, management of business ethics, human rights diligence in our supply chain, and human resource development, which may result in increased regulatory, social or other scrutiny on us. Regarding climate risks, we are expected to address climate risks due to our own contribution to climate change (inside-out perspective), risks due to physical effects of climate change as well as transition risks (outside-in perspective), and interactions between both perspectives ("dual materiality"). If we are unable to adequately recognize and respond to such developments and governmental, societal, investor and NGO expectations relating to such ESG matters, we may miss corporate opportunities, become subject to additional scrutiny, incur unexpected costs or experience damage to our reputation or our various brands. If any of these events were to occur, there may be a material adverse effect on our business, financial condition, cash flows and results of operations and the market value of our common shares may decline.

We have observed that in addition to the importance of their financial performance, companies are increasingly being judged by their performance on ESG matters. A variety of organizations measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. We may fail to comply with standards or best practices put forth by such organizations or by governmental or regulatory bodies. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. In light of investors' increased focus on ESG matters, there can be no certainty that we will manage such issues successfully, or that we will

successfully meet society's expectations as to our proper role. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

Risks Related to the Manufacturing of our COVID-19 Vaccine, our Product Candidates and Future Pipeline

Our mRNA product candidates are based on novel technologies and any product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of the third-party manufacturers we work with encounter such difficulties, our ability to supply materials for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our COVID-19 vaccine and our product candidates are novel and complex. Due to the novel nature of this technology and limited experience at larger scale production, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. In an effort to optimize product features, we have in the past and may in the future make changes to our product candidates in their manufacturing and stability formulation and conditions. This has resulted in the past, and may in the future result, in our having to resupply batches for preclinical, clinical, or commercial activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our product candidates could materially delay our or our collaborators' ability to continue the clinical trial for that product candidate or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical, clinical or commercial supply.

For example, in March 2021 we received product quality complaints related to our COVID-19 vaccine in Hong Kong. A thorough investigation into these complaints concluded that the reported product quality complaints were due to the combination of a deficient container closure process, or crimping, at one specific contract manufacturing organization when such containers were later shipped at ultra-cold conditions created by shipping on dry ice. The investigation did not identify any safety issues related to the product quality complaints. We and our COVID-19 vaccine collaboration partner, Fosun, in Hong Kong subsequently supplied replacement COVID-19 vaccine vials, but we cannot assure you that we will not experience similar product quality complaints in the future.

Our rate of innovation is high, which has resulted in, and will continue to cause a high degree of, technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of, new manufacturing infrastructure or may adversely affect third-party relationships.

The process to generate mRNA medicines is complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. We may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply. Additionally, for individualized therapies, we may encounter issues with our ability to timely and efficiently manufacture product given the on-demand requirements of such therapies, thereby potentially impacting clinical and commercial supply.

As we continue developing new manufacturing processes for our drug substance and drug product, the changes we implement to the manufacturing process may impact, in turn, specification and stability of the drug product. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials or an inability to supply sufficient commercial quantities of drug product. Our mRNA product, if approved, and product candidates may prove to have a stability profile that leads to an unfavorable shelf life. This poses risk in supply requirements, wasted stock and higher cost of goods.

We are dependent on a number of equipment providers who are also implementing novel technology. Further, we have developed our own custom manufacturing equipment for certain of our product candidates. If such equipment malfunctions or we encounter unexpected performance issues, we could encounter delays or interruptions to clinical and commercial supply.

Due to the number of different programs, we may have cross contamination of products inside of our factories, CROs, external contract manufacturing organizations, or CMOs, suppliers or in the clinic that affect the integrity of our

products. Additionally, for some programs the manufacturing scale is extremely small compared to the standard volumes of supply, such that we run the risk of contaminating the process each time we reopen a container to use remaining supplies.

As we scale the manufacturing output for particular programs, we plan to continuously improve yield, purity and the pharmaceutical properties of our product candidates from IND-enabling studies through commercial launch, including shelf life stability and solubility properties of drug product and drug substance. Due to continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after the change in process, more time is required for pharmaceutical property testing, such as six- or 12- month stability testing. That may require resupplying clinical or commercial material, or making additional GMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

We are utilizing a number of raw materials and excipients that are either new to the pharmaceutical industry or are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our COVID-19 vaccine and our product candidates. Further, now and in the future, one or more of our programs may have a single source of supply for raw materials and excipients. Some of our suppliers are located in countries (e.g. the United States) different from our manufacturing sites (i.e. Germany). Export restrictions could lead to unplanned interruptions in manufacturing and thus impacting supply of both clinical and commercial material.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our mRNA product candidates. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release mRNA product candidates until the manufacturing or testing process is rectified.

Our product and product intermediates are extremely temperature sensitive, and we may learn that any or all of our products are less stable than desired. We may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our product candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions. As we are transporting intermediate products with holding times in refrigeration (TIR) and allowed times out of refrigeration (TOR) across long distances and crossing boarders, traffic issues and customs delays could lead to the loss of batches which would need to be replaced.

Certain of our product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of the third-party manufacturers with whom we contract encounter these types of difficulties, our ability to provide our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

We custom design and manufacture certain product candidates that are unique and tailored specifically for each patient. Manufacturing unique lots of these product candidates is susceptible to product loss or failure due to issues with:

- logistics associated with the collection of a patient's tumor, blood or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next-generation sequencing of the tumor mRNA;
- biopsy of a sufficient quantity of cancerous tissue to allow for proper sequencing and identification of tumor-specific mutations;
- identification of appropriate tumor-specific mutations;
- the use of a software program, including proprietary and open source components, which is hosted in the cloud and a part of our product candidate, to assist with the design of the patient-specific mRNA, which software must be maintained and secured;
- effective design of the patient-specific mRNA that encodes for the required neoantigens;
- batch-specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch that may not have been foreseen;

- quality control testing failures;
- unexpected failures of batches placed on stability;
- shortages or quality control issues with single-use assemblies, consumables or critical parts sourced from third-party vendors that must be changed out for each patient-specific batch;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the site of patient care;
- the ability to define a consistent safety profile at a given dose when each participant receives a unique treatment; and
- our reliance on single source suppliers.

We also continue to evolve our own custom manufacturing equipment. This equipment may not function as designed, which may lead to deviations in the drug product being produced. This can lead to increased batch failure and the inability to supply patients enrolled in the clinical trial. If our clinical development plans are expanded, due to the custom nature of the equipment and single-use assemblies, we may not be able to supply this expanded need reliably without significant investments. In addition, there will be considerable time to scale up our facilities or build new facilities before we can begin to meet any commercial demand if one or more of our product candidates are approved. This expansion or addition of new facilities could also lead to product comparability issues, which can further delay introduction of new capacity.

As certain of our product candidates are manufactured for each individual patient, we will be required to maintain a chain of identity with respect to each patient's tissue sample, sequence data derived from such tissue sample, analyze results of such patient's genomic analysis and the custom manufactured product for each patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in product mix-up, adverse patient outcomes, loss of product, or regulatory action, including withdrawal of any approved products from the market. Further, as our product candidates are developed through early-stage clinical studies to later-stage clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture and delivery processes will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Our inability to manufacture sufficient quantities of our COVID-19 vaccine or any of our product candidates, or our failure to comply with applicable regulatory requirements, would materially and adversely affect our business.

Manufacturing is a vital component of our individualized immunotherapy approach, and we have invested significantly in our manufacturing facilities, including the acquisition of a manufacturing site in Marburg, Germany. All internal manufacturing is performed under GMP guidelines. We also rely on a network of CMOs for the manufacture of our COVID-19 vaccine. We do not rely on any external CMOs for the manufacture of our individualized product candidates and at this time, and we have limited redundancy among our facilities. Due to the individualized nature of our product candidates, we do not maintain product reserves. If any of our or our external CMOs' manufacturing facilities experience difficulties, including related to manufacturing, product release, shelf life, testing, storage and supply chain management or shipping, our clinical development programs may be delayed or suspended until we or our external CMOs can resume operations. We may also be required to incur significant expenditures to resolve such difficulties.

Our facilities are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities.

If we or our external CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA or comparable regulatory authorities in other jurisdictions, we may not be able to rely on our or our external CMOs' manufacturing facilities for the manufacture of our product candidates. If the FDA, the EMA or another comparable regulatory authority finds our facilities inadequate for the manufacture of our COVID-19 vaccine or our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our COVID-19 vaccine or our product candidates.

Additionally, we may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our COVID-19 vaccine or our product candidates to patients in clinical trials, or to provide products for the treatment of patients, once approved, would be jeopardized.

We are subject to regulatory and operational risks associated with the physical and digital infrastructure at both our internal manufacturing facilities and at those of our external service providers.

The designs of our facilities are based on current standards for biotechnology facilities. They have been reviewed and approved by local German authorities and have also received GMP manufacturing licenses. We have designed our facilities to incorporate a significant level of automation of equipment with integration of several digital systems to improve efficiency of operations. We have attempted to achieve a high level of digitization for clinical and commercial manufacturing facilities relative to industry standards. While this is meant to improve operational efficiency, this may pose additional risk of process equipment malfunction and even overall manufacturing system failure or shutdown due to internal or external factors including, but not limited to, design issues, system compatibility or potential cybersecurity breaches. This may lead to delay in supply or shutdown of our facilities. Any disruption in our manufacturing capabilities could cause delays in our production capacity for our drug substances or drug products, impose additional costs, or may require us to identify, qualify and establish an alternative manufacturing site, the occurrence of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

As we expand our development and commercial capacity, we may establish additional manufacturing capabilities and expand to other locations or geographies, which may lead to regulatory delays or prove costly. If we fail to select the correct location, complete the construction in an efficient manner, recruit the required personnel, and generally manage our growth effectively, the development and production of our product candidates could be delayed or curtailed. Additional investments may be needed if changes in our manufacturing process lead to required changes in our infrastructure.

Our COVID-19 vaccine and certain of our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. In addition, some such suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under GMP by biopharmaceutical firms. These suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we have experienced and we may in the future experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

We are subject to significant regulatory oversight with respect to manufacturing our product candidates. Our manufacturing facilities or the manufacturing facilities of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet GMP requirements set forth in regulations promulgated by the FDA, the EMA and other comparable regulatory authorities could result in significant delays in and costs of our products.

The manufacturing of immunotherapies for clinical trials or commercial sale is subject to extensive regulation. GMP requirements govern manufacturing processes and procedures, including record-keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in our products and product candidates. Poor control of the GMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in loss of potential product sales revenue, cost overruns and delays to clinical timelines for our clinical programs, which could be extensive. Such production process issues include but are not limited to:

- critical deviations in the manufacturing process;
- facility and equipment failures;
- contamination of the product due to an ineffective quality control strategy;
- facility contamination as assessed by the facility and utility environmental monitoring program;
- ineffective process, equipment or analytical change management, resulting in failed lot release criteria;
- raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers;
- ineffective product stability;
- failed lot release or facility and utility quality control testing;
- ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and
- failed or defective components or consumables.

We must supply all necessary documentation in support of a BLA or other marketing authorization application on a timely basis and must adhere to the FDA's, the EMA's and other countries' GMP requirements, which are enforced, in the case of the FDA, in part through its facilities inspection program.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with GMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, approval continue delivery of our commercial product or to commercialize our product candidates may not be granted. Inspections by regulatory authorities may occur at any time during the development or commercialization phase of products. The inspections may be product-specific or facility-specific for broader GMP inspections or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may influence the ability of our third-party manufacturers or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying programs.

The manufacturing process for any products that is subject to the FDA's, the EMA's and other regulatory authorities' approval processes, and we may need to contract with manufacturers who we believe can meet applicable regulatory authority requirements on an ongoing basis. If we or our third-party manufacturers are unable to reliably manufacture to specifications acceptable to the FDA, the EMA or other regulatory authorities, we or our collaborators may not obtain or maintain the approvals we or they need to release and deliver such products. Even if we or our collaborators obtain regulatory approval for any of our immunotherapies, there is no assurance that either we or our CMOs will be able to manufacture our product candidates to specifications acceptable to the FDA, the EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we may not have direct control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CMOs are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CMOs' facilities. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaborators) and our overall business operations. Our potential future dependence upon others for the manufacture of our products, product candidates and raw materials may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The FDA, the EMA and other regulatory authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other regulatory authorities may require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Our CMOs have, in the past, experienced lot failures and some may have experienced product recalls. Lot failures or product recalls with respect to product produced by either our own facilities or those of our third-party manufacturers could cause us and our collaborators to delay clinical trials, product launches or product supply, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While we train and qualify all personnel around the appropriate handling of our products and materials, we may not be able to control for or ultimately detect intentional sabotage or negligence by any employee or contractor.

Risks Related to our Reliance on Third Parties

We have entered into several arrangements with a related party for the performance of nonclinical research programs, and these arrangements present potential conflicts of interest.

We have had a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (*Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH*), or TRON, a non-profit limited liability company engaged in biopharmaceutical research, for the performance of nonclinical research. For more information about our relationship with TRON, see Item 7.B. Major Shareholders and Related Party Transactions in this Annual Report on Form 20-F, below.

The existence or appearance of a conflict of interest could depress the price of the ADSs or attract scrutiny from shareholders, regulators or other stakeholders. Additionally, any conflicts of interest would create the risk that our officers may favor their personal interests over those of our shareholders.

We rely on third parties in the conduct of significant aspects of our preclinical studies and clinical trials and intend to rely on third parties in the conduct of future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

We currently rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, collaborators, medical institutions and clinical investigators, to conduct various and significant elements of our clinical trials. We currently rely, and expect to continue to rely, on third parties to conduct certain research and preclinical testing activities. In some cases, these third parties may terminate their engagements with us. If we need to enter into alternative arrangements, it would delay our discovery or product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial.

Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs are required to comply with regulations, including GCP, for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to ensure that the data and results are scientifically credible and

accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We also are responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the FDA, the regulatory authorities of the EU member states, and comparable regulatory authorities of other jurisdictions for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable regulatory authorities of other jurisdictions may require us to perform additional clinical trials before approving our marketing applications. We cannot be sure that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements of GMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we have designed, and in the future intend to design the clinical trials for certain of our product candidates, our collaborators will design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will conduct all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials results in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed;
- form relationships with other entities, some of which may be our competitors;
- have human errors; or
- be subject to cyberattacks.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform preclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

We also rely on other third parties to transport, store and distribute the required materials for our clinical trials. In the past, certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, if approved, producing additional losses and depriving us of potential product sales revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace. Each of the risks set forth above may be exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

Our existing collaborations, or any future collaboration arrangements that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of the collaboration and adversely affect our ability to develop and commercialize our product candidates.

We have entered into collaborations under which our collaborators have provided, and may in the future provide, funding and other resources for developing and commercializing our product candidates. We expect to enter into additional

collaborations to access additional funding, capabilities and expertise in the future. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators may not perform or prioritize their obligations as expected;
- the clinical trials conducted as part of such collaborations may not be successful;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the collaborators' focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaborations with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development or commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates, or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain, protect, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, the development of our product candidates may be delayed, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business;
- we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex; and
- our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in the United States.

If our collaborations do not result in the successful development and commercialization of programs, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone, earn-out, royalty or other contingent payments under the collaborations. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, in general our collaborators have the right to terminate their agreements with us for convenience. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this report apply to the activities of our collaborators.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.

Our research and product development programs and the potential commercialization of any product candidates we develop alone or with collaborators will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements with others in connection with the development and potential commercialization of current and future product candidates or the development of ancillary technologies. We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether or not we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, of the FDA or comparable regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

Current or future collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. Additionally, we may be restricted under existing collaboration agreements from entering into future agreements on certain terms or for certain development activities with potential collaborators. For example, we have granted exclusive rights or options to Pfizer for certain targets, and under the terms of our respective collaboration agreements with them, we will be restricted from granting rights to other parties to use our mRNA technology to pursue potential products that address those targets. Similarly, our collaboration agreements have in the past and may in the future contain non-competition provisions that could limit our ability to enter into collaborations with future collaborators.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate or technology for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense. If we elect to increase our expenditures to fund research, development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all.

We have entered into in-licensing arrangements and may form or seek to enter into additional licensing arrangements in the future, and we may not realize the benefits of such licensing arrangements.

We are a party to licenses that give us rights to third-party intellectual property, including patents and patent applications, that are necessary or useful for our business. In particular, we have obtained licenses from Actuitas Therapeutics, CellScript LLC and its affiliate, mRNA RiboTherapeutics, Inc., to patent rights claiming certain uses of modified RNA, as well as licenses from certain other parties for intellectual property useful in pharmaceutical formulations. We may enter into additional licenses to third-party intellectual property in the future.

The success of products developed based on in-licensed technology will depend in part on the ability of our current and future licensors to prosecute, obtain, maintain, protect, enforce and defend patent protection for our in-licensed intellectual property. Our current and future licensors may not successfully prosecute the patent applications we license. Even if patents were issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. In addition, we sublicense our rights under various third-party licenses to our collaborators. Any impairment of these sublicensed rights could result in reduced revenues under our collaboration agreements or result in termination of an agreement by one or more of our collaborators.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative relationships;
- our diligence obligations with respect to the use of the licensed intellectual property and technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions, trade secrets, know-how and other intellectual property resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology; and
- including amounts to be paid pursuant to royalty obligations, including the triggering of royalty obligations and amounts to be paid pursuant thereto.

If disputes over intellectual property that we have in-licensed or other related contractual rights prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we, our co-owners or our licensors fail to adequately protect, defend, maintain or enforce this intellectual property, our ability to commercialize products could suffer.

If we commit certain material breaches and fail to remedy them (if such breach is curable), we are required to repurchase shares held by the Bill & Melinda Gates Foundation.

If we commit a specified material breach under the letter agreement with the Bill & Melinda Gates Foundation, or BMGF, and such breach remains uncured after a specified period of time (if curable), we are required to either (i) repurchase the shares held by BMGF or locate a third party to purchase the shares from BMGF, in either case at a price that is the greater of the original purchase price or the fair market value of the shares at the time of repurchase, or (ii) if we cannot meet the requirements under (i) (e.g., because we do not have sufficient cash reserves), then we must use our best efforts to effect BMGF's withdrawal right as soon as practicable, which may mean acquiring the shares in tranches over time. If we are required to repurchase BMGF's shares, our financial position could be materially and adversely affected.

We rely on third parties to manufacture certain of our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.

Although we expect to continue using our own clinical manufacturing facilities, we also rely on outside vendors to manufacture supplies and process our product candidates. We have only recently begun to manufacture our COVID-19 vaccine on a commercial scale and may not be able to achieve commercial- scale manufacturing and processing for our product candidates, if approved, and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may not be able to develop commercially viable products other than our COVID-19 vaccine.

In addition, our reliance on a limited number of CMOs exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or other regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new

manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory authority questions, if any;

- our CMOs might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- CMOs may not be able to execute our manufacturing procedures appropriately;
- our future CMOs may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration and corresponding state agencies and by regulatory authorities in other jurisdictions to ensure strict compliance with GMP and other government regulations and corresponding standards in other jurisdictions. We do not have control over CMOs' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made in the manufacturing process for our products;
- our CMOs could breach or terminate their agreement with us; and
- our CMOs would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above.

Each of these risks could delay our clinical trials, the approval, if any, of our COVID-19 vaccine or product candidates by the FDA or regulatory authorities in other jurisdictions or the commercialization of our COVID-19 vaccine or product candidates, or result in higher costs or deprive us of potential product sales revenue. In addition, we will rely on third parties to perform release tests on our COVID-19 or our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We are dependent on single source suppliers for some of the components and materials used in, and the processes required to develop, our COVID-19 vaccine and our product candidates.

We currently depend on single source suppliers for some of the components and materials used in, and manufacturing processes required to develop, our COVID-19 and our product candidates. We cannot ensure that these suppliers or service providers will remain in business, or have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our COVID-19 vaccine and our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our COVID-19 vaccine and our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our COVID-19 vaccine and product candidates.

In addition, as part of the FDA's approval of our product candidates, we will also require FDA review of the individual components of our process, which include the manufacturing processes and facilities of our single source suppliers.

Our reliance on these suppliers, service providers and manufacturers subjects us to a number of risks that could harm our reputation, business and financial condition, including, among other things:

- delays to the development timelines for our product candidates;
- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of components from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers' prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted

Risks Related to our Intellectual Property

If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our COVID-19 vaccine or our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.

Our commercial success depends in part on our ability to obtain, maintain, protect, defend and enforce patent and other intellectual property, including trade secret and know-how, protection for our COVID-19 vaccine and for our product candidates, proprietary technologies and their uses, as well as our ability to operate, develop, manufacture and commercialize our COVID-19 vaccine or one or more of our product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of our competitors or any other third parties, including any non-practicing entities or patent assertion entities. We generally seek to protect our intellectual property position by filing and/or licensing patent applications in the United States and abroad related to our product candidates, proprietary technologies (including methods of manufacture) and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent that the issued claims cover third parties' activities in the countries in which they are performed. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office, or the USPTO, courts in the United States or the patent offices and courts in other jurisdictions, including Europe, nor can we be certain that any claim in our issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will adequately cover our COVID-19 vaccine or our product candidates, or otherwise afford sufficient protection against competitors with similar technology, nor can there be any assurance that issued patents will not be infringed, designed around, invalidated or held unenforceable. Furthermore, we may not be able to apply for patents on certain aspects of our current or future products or product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent protection we obtain may not be sufficient to prevent substantial competition.

Even claims of issued patents may later be found invalid or unenforceable, or may be modified or revoked in proceedings before various patent offices or in courts in the United States, Europe or other jurisdictions. The degree of future protection for our intellectual property and other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately obtain, maintain, protect, defend and enforce our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or future licensors or collaborators will be successful in prosecuting, obtaining, protecting, maintaining, enforcing or defending patents and patent applications necessary or useful to protect our products or product candidates, proprietary technologies (including methods of manufacture) and their uses. These risks and uncertainties include, from time to time, the following:

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patenting process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- claims of issued patents that we own (solely or jointly) or have in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- other parties may have designed around our patent claims or developed technologies that may be related or competitive to our COVID-19 vaccine or to our product candidates or other technologies, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent filings, either by claiming the same or overlapping methods, products, reagents, tools or devices or by claiming subject matter that could dominate one or more of our patent claims;
- any successful opposition to claims of any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of our COVID-19 vaccine or our product candidates and other technologies, or the successful commercialization of any product candidates and other technologies that we may develop;
- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we, our co-owners or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;
- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);
- a court or other patent proceeding, such as an inter partes review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; existing legislation (for example, in the United States, the Public Readiness and Emergency Preparedness Act, etc.) may be interpreted, and new legislation may be passed, to permit third-party use of patented technologies relating to a public health concern (for example, the COVID-19 pandemic), with little or no compensation to the patent holder(s); and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing competitors a better opportunity to create, develop and market competing product candidates.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. The standards that the USPTO and its counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and other countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. Moreover, there are periodic changes in patent law, as well as discussions in the U.S. Congress and in international jurisdictions about modifying various aspects of patent law. There is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable. More generally, the laws of some countries do

not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for granting, maintaining, protecting, defending and enforcing our intellectual property rights.

Furthermore, the patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost or in a timely manner. It is possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, if any of these parties were to breach such agreements and improperly disclose such output before a patent application is filed, this could jeopardize our ability to seek patent protection. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, priority date, scope, term, validity or enforceability so that any patents that may issue or that we may license may be challenged in the courts or patent offices in the United States, Europe and other jurisdictions. Once granted, patents may remain open to a variety of challenges, including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings, and furthermore, may be challenged as a defense in any enforcement action that we might bring; for example, various third parties have filed opposition papers challenging our issued EP patent number 2714071, which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. While the claims of our issued EP patent 2714071 were upheld after opposition, there is currently a pending appeal against the opposition decision. Such challenges may result in loss of exclusivity or in patent claims being narrowed, terminated, disclaimed, invalidated, assigned to others or held unenforceable, any or all of which could limit our ability to stop others from using or commercializing similar or identical products, or limit the scope and/or term of patent protection of our products and product candidates and/ or eliminate it altogether, thus hindering or removing our ability to limit third parties from making, using or selling products or technologies that are similar or identical to ours, and/or reduce or eliminate royalty payments to us from our licensees. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or our product(s) or product candidates, or which effectively prevent others from commercializing competitive technologies and products. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our owned and in-licensed patent and other intellectual property rights depends on our ability to detect infringement, misappropriation and other violation of such patents and other intellectual property. It may be difficult to detect infringers, misappropriators and other violators who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement, misappropriation or other violation in a competitor's or potential competitor's product or service, and in some cases we may not be able to introduce obtained evidence into a proceeding or otherwise utilize it to successfully demonstrate infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Furthermore, patents or other intellectual property rights that we may be able to secure for our COVID-19 vaccine or our other COVID-19 vaccine candidates could be restricted or preempted if governments determine that they will not enforce, or will require compulsory licensing of, technologies useful to address the COVID-19 pandemic.

In addition, proceedings to enforce or defend our owned or in-licensed patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. If any of our owned or in-licensed patents covering our product candidates or other technologies are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product

candidates or other technologies, our competitive position could be harmed or we could be required to incur significant expenses to protect, enforce or defend our rights. If we initiate lawsuits to protect, defend or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management, technical personnel, and other employees even if the eventual outcome is favorable to us.

The degree of future protection for our intellectual property and other proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product(s), our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we, our co-owners or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;
- any of the claims of patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the claims of patents we own or license and, if challenged, a court would hold that such patent claims are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our ability to issue patents, or otherwise on our business;
- our competitors do not conduct research, development, testing or commercialization activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies, product(s) or product candidates that are separately patentable; and
- our or our collaborators; development and commercialization activities, including our manufacturing processes, or products will not infringe patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

Other companies or organizations may challenge our intellectual property rights or the intellectual property rights of our partners or may assert intellectual property rights that prevent us or our partners from developing and commercializing our COVID-19 vaccine or our product candidates and other technologies.

We practice in new and evolving scientific fields, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the fields. We own and in-license patent applications and issued patents that describe and/or claim certain technologies, including products, reagents, formulations, tools and methods including uses and manufacturing methods, or features or aspects of any of these. These issued patents and pending patent applications claim certain compositions of matter and methods relating to the discovery, development, testing, manufacture and commercialization of therapeutic modalities and our delivery technologies, including lipid nanoparticles, or LNPs. If we, our co-owners or our licensors are unable to obtain, maintain, protect, defend or enforce patent protection with respect to our product candidates and other technology and any products or product candidates and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

As the scientific fields mature, our known competitors and other third parties have filed, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents, and will continue to file, patent applications claiming inventions in the fields in the United States and abroad. This may limit, interfere with or eliminate our ability and our partners' ability to make, use, sell, import or otherwise exploit our COVID-19 vaccine or our product candidates or other technologies. There is uncertainty about which patents will issue, and, if they do, as to when, to whom and with what claims. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

We, our co-owners, our partners or our licensors may in the future become a party to patent proceedings or priority disputes in the United States, Europe or other jurisdictions. The Leahy-Smith America Invents Act, or the America Invents Act, includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent through USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. We expect that our competitors and other third parties will institute litigation and other proceedings, such as interference, reexamination and opposition proceedings, as well as inter partes and post-grant review proceedings against us and the patents and patent applications that we own and in-license. For example, various third parties have filed oppositions challenging our issued EP patent 2714071 which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. While the patent was upheld through the opposition proceedings, one of the opposing parties has appealed that decision.

With regard to COVID-19 vaccines, while we are not currently a party to any pending or threatened lawsuits, both Moderna and our partner Pfizer have been named as defendants in ongoing COVID-19 vaccine patent litigation lawsuits. We cannot guarantee that we will not become subject to COVID-19 vaccine patent infringement lawsuits in the future. In addition, should Pfizer not prevail in its ongoing COVID-19 vaccine patent infringement lawsuit, Pfizer may seek to require us to indemnify Pfizer for losses suffered therefrom as well as any losses from future COVID-19 vaccine patent infringement lawsuits it does not prevail in.

We expect that we will continue to be subject to similar proceedings or priority disputes, including oppositions, in Europe or other foreign jurisdictions relating to patents and patent applications in our portfolio.

If we, our co-owners, our partners or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes, including any derivations, post-grant review, inter partes review or oppositions, to which we or they are subject, we may lose valuable intellectual property rights through the narrowing or loss of one or more patents owned or in-licensed, or our owned or in-licensed patent claims may be narrowed, invalidated or held unenforceable. In many cases, the possibility of appeal exists for either us or our opponents, and it may be years before final, unappealable rulings are made with respect to these patents in certain jurisdictions. The timing and outcome of these and other proceedings is uncertain and may adversely affect our business if we are not successful in defending the patentability and scope of our pending and issued patent claims. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management, technical personnel and other employees and could have a material adverse impact on our business and our ability to successfully compete against our current and future competitors.

There are many issued and pending patent filings that claim aspects of technologies that we may need for our mRNA products or product candidates, or other product candidates, including patent filings that relate to relevant delivery technologies. There are also many issued patents that claim targeting genes or portions of genes that may be relevant for immunotherapies we wish to develop. In addition, as evidenced by the lawsuits brought against Moderna and Pfizer, there may be issued and pending patent applications that may be asserted against us in a court proceeding or otherwise based upon the asserting party's belief that we may need such patents for the development, manufacturing, testing and commercialization of our COVID-19 vaccine or of our product candidates. Thus, it is possible that one or more organizations, ranging from our competitors to non-practicing entities or patent assertion entities, has or will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If those organizations refuse to grant us a license to such patent rights on reasonable terms, if we fail to invalidate relevant patents, or if a court or other governing

body determines that we need such patent rights that have been asserted against us and we are not able to obtain a license on reasonable terms or at all, we may be unable to perform research and development or other activities or market products covered by such patents, and we may need to cease the development, manufacture, testing and commercialization of one or more of the product candidates we may develop. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

We may not be successful in obtaining, maintaining, protecting or defending the necessary intellectual property rights to allow us to identify, develop product candidates, and test product components and manufacturing processes for our development pipeline.

We currently have rights to certain intellectual property through our owned and in-licensed patents and other intellectual property rights, relating to identification, development and testing of our product candidates or other technologies. As our pipeline may involve additional product candidates that could require the use of intellectual property and other proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license or use such intellectual property and proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these intellectual property and other proprietary rights may be held by others. We may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary, on reasonable terms, or at all, for product candidates and other technologies that we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

We sometimes collaborate with academic institutions and/or utilize services of CROs and CMOs. in certain aspects of our research or development under written agreements with these parties. These agreements may not ensure protection of intellectual property rights in developed technology, or may fail to provide us with sufficient control of or access to such intellectual property rights. For example, agreements with these academic institutions typically provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. However, these institutions may not honor our option and right of first negotiation for intellectual property rights or we may otherwise be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program or otherwise continue to develop certain product candidates or other technologies. CROs and/or CMOs may control certain technologies that were utilized in and/or developed through work on our behalf, and may not pursue protection of such technologies, or may provide us with only non-exclusive rights in such technologies, so that relevant technologies may be shared with other parties including our competitors. In any relationship with a third party, there is a risk of disagreement over intellectual property rights (including inventorship or ownership of, rights to protect and/or enforce, and/or rights to use) in utilized or developed technologies.

Moreover, some of our owned patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain, or continue to maintain, exclusive rights to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, third parties that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain, protect, defend or enforce the existing intellectual property rights we have, we may have to abandon the development and commercialization of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The lifespans of our patents may not be sufficient to effectively protect our products or product candidates, technologies and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non- provisional filing date, assuming maintenance fees are timely paid after the patent has issued. Most foreign jurisdictions also provide a 20-year nominal patent term, though many require payment of regular, often annual, annuities to maintain pendency of an application or viability of an issued patent. In some jurisdictions, one or more options for extension of a patent term may be available, but even with such extensions, the lifespan of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent term has expired, we may be subject to competition from third parties that can then use the inventions included in such patents to create competing products and technologies. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The USPTO can also require, in certain circumstances, that the expiration date of a subject patent be shortened by the filing of a terminal disclaimer over one or more patents that may expire sooner than the subject patent. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. If any patents that we own or in-license expire, we would not be able to stop others from using or commercializing similar or identical technology and products, and our competitors could market competing products and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process for a drug product subject to the provisions of the Hatch-Waxman Act. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. For example, we did not extend any patent for our COVID-19 vaccine. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are heavily reliant upon licenses to certain intellectual property and other proprietary rights from third parties that are important or necessary to the development and commercialization of our technology and product(s) or product candidates, and we expect to enter into similar license agreements in the future. Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Our licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop, test, or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in any or all of our licenses.

Where we obtain licenses from, or collaborate with, third parties, in some circumstances we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from, or that arises through collaboration with, such third parties, or such activities, if controlled by us, may require the input of such third parties. In some cases, patent prosecution (including

preparation and filing) of our in-licensed intellectual property or of intellectual property developed through collaboration, is controlled solely by the licensor or collaborator. We may also require the agreement and/or cooperation of our licensors and collaborators to protect, enforce, utilize, or defend any in-licensed patent rights, and such agreement and/or cooperation may not be provided. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, protected, enforced or defended in a manner consistent with the best interests of our business. Any patents or patent applications that we in-license may be challenged, narrowed, circumvented, invalidated or held unenforceable, or our licensors may not properly maintain such patents or patent applications and they may expire. If our licensors fail to obtain, maintain, defend, protect or enforce the intellectual property we license from them, we could lose our rights to the intellectual property and our competitors could market competing products using the inventions in such intellectual property. In certain cases, we control the prosecution of patents included from in-licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our collaborators. If we and our licensors or collaborators disagree over IP protection strategies for relevant technologies, disputes may arise, and we could lose access to or control over protection of technologies important to our business. If so, we may not be able to adequately protect our product(s) or product candidate(s), including not being able to prevent a competitor or other third party from developing the same product(s) or product candidate(s) for the same or a different use. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, any failure to satisfy obligations or any material breach under any of our licenses to third-party intellectual or any disagreements between us and our licensor(s) could potentially give the licensor(s) the right or reason to terminate the license or to exercise the option of a non-exclusive license, which would allow our competitors to have access to the same intellectual property and technology licensed to us. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone and royalty payment, exclusivity and other obligations on us. If we fail to comply with our obligations under these agreements, including royalty payments, or we are subject to a bankruptcy, the licensor may have the right to terminate the license agreement, in which event we would not be able to develop, market and commercialize product(s) or product candidates covered by the license agreement. In spite of our best efforts and even if we disagree, our licensors might still conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop, test and commercialize the product(s) or product candidates covered by these license agreements. In the event that any of our license agreements were to be terminated by the licensor, we may need to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all. If these license agreements are terminated, or if the underlying patents or other intellectual property fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market and commercialize, products similar or identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing license agreements in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described in this section. If we, our co-owners or our licensors fail to adequately protect this intellectual property, our ability to develop, test, market and commercialize our product(s) or product candidates could suffer. Moreover, if disputes over intellectual property that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop, test, market and commercialize the affected product(s) or product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Some of our in-licensed intellectual property has been discovered through government-funded programs and thus may be subject to federal regulations such as "march-in" rights and certain reporting requirements, and compliance with such regulations may limit our exclusive rights and our ability to contract with manufacturers.

Certain intellectual property rights that have been in-licensed, including patent applications and patents that we in-license from the University of Pennsylvania, the Louisiana State University, the Broad Institute, the National Institute of Health (NIH), Genevant, and Cellscript, have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights may include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions

covered by that Act for any governmental purpose. In addition, the U.S. government may have the right, under certain limited circumstances, to require the licensor to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also collectively referred to as "march-in rights"). The U.S. government may also have the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture the products substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. We may not be able to obtain a waiver of this preference for U.S. industry, and this preference may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or in-licensed future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. If we are unable to secure an exemption to these manufacturing requirements, if we comply with them, or if we are unable to comply with them, we may experience a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our current proprietary position for certain products and product candidates depends upon our owned or in-licensed patent filings covering components, manufacturing-related methods, formulations and/or methods of use, which may not adequately prevent a competitor or other third party from using the same product candidate for the same or a different use.

Composition of matter patent protection is generally considered to be desirable because it provides protection without regard to any particular method of use or manufacture or formulation. While we have pursued or obtained patent protection covering components of certain product candidates and tests, manufacturing-related methods, formulations and/or methods of use, we have not yet obtained patent protection for all components of certain product candidates and tests, manufacturing-related methods, formulations and/or methods of use. For instance, we do not currently have any claims in our owned or in-licensed issued U.S. patents that cover the overall construct used in our COVID-19 vaccine, or that used in our iNeST product candidates. We also cannot be certain that claims in any future patents issuing from our pending owned or in-licensed patent applications or our future owned or in-licensed patent applications will cover the composition of matter, tests, manufacturing-related methods, formulations and/or methods of use of our current or future product candidates. Method of use patents protect the use of a product for the specified method and formulation patents cover formulations to deliver therapeutics. These types of patents do not prevent a competitor or other third party from developing, testing, marketing or commercializing a similar or identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method of use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method of use patents, the practice is common and this type of infringement is difficult to prevent or enforce. Consequently, we may not be able to prevent third parties from practicing our inventions in the United States or abroad.

In addition, we cannot be certain that our proprietary technical information and related confidential documents that we have shared with our collaborators and/or have submitted to governmental agencies including regulatory agencies for evaluation and supervision of pharmaceutical products will not be disclosed or that competitors will not otherwise gain access to our such information. For example, a former employee of our COVID-19 vaccine collaborator, Pfizer, has reportedly misappropriated trade secrets on our COVID-19 vaccine. Certain documents relating to our COVID-19 vaccine were unlawfully accessed after a cyberattack on the European Medicines Agency (EMA) in December 2020. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we may not be able to prevent such third parties from using that technology or information to compete with us.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product(s) and product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop, test or market our product(s) and product candidates.

Because our products and product candidates are still in early stages of development, testing or commercialization, and one or more features of the products or product candidates, or related technologies such as their manufacture, formulation, testing or use, may still change, we cannot be confident that we are aware of all third-party intellectual property that might be relevant to products that we eventually hope to commercialize. Furthermore, even if all aspects of our product(s) or product candidate(s), or of other technology, were known, it is possible that third-party intellectual property, which may or may not currently be public, could develop in a manner (for example, through issuance of additional patents) that could impede our ability to make or use relevant products or product candidates, or other technology. Various third-party competitors practice in relevant spaces, and may have issued patents, or patent applications that will issue as patents in the future, that will impede or preclude our ability to commercialize products. Furthermore, while U.S. patent laws provide a "safe harbor" to our clinical product candidates under 35 U.S.C. § 271(e)(1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product, that exemption expires when an NDA or BLA is submitted. Accordingly, our COVID-19 vaccine was granted full FDA approval for individuals 16 years of age and older on August 23, 2021 (after BLA submission on May 18, 2021) and emergency use authorization for individuals 5 to less than 16 years of age, after both of which the 271(e)(1) safe harbor may no longer provide the same level of protection from third party patent infringement claims for that product. We may become exposed to one or more lawsuits from third parties who consider our COVID-19 vaccine to infringe their patents. More generally, given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we might want to submit an NDA or BLA at a time when one or more relevant third-party patents is in force. Thus, it is possible that at the time that we commercialize our product candidates, one or more third parties may have issued patent claims that cover our products or critical features of their production, testing or use. We may not be able to commercialize our products if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, our products or elements thereof, or their methods of manufacture, testing or use at the time that we seek to commercialize them. In such cases, we may not be in a position to develop, test or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enter into a license agreement with the intellectual property right holder(s). Such litigation or licenses could be costly or not available on commercially reasonable terms or at all, and design-around could be prohibitively expensive or impossible.

Additionally, with respect to our COVID-19 vaccine and our other COVID-19 product candidates and related technologies, it is unclear whether the U.S. government, or other governments around the world, will protect vaccine manufacturers for liability from infringement of third party intellectual property, at least during the period of the pandemic. Thus, it is possible that third parties may assert intellectual property rights against us relating to our COVID-19 vaccine, and that we will not be successful in arguing that commercialization of our COVID-19 vaccine is exempted from infringement and/or liability for infringement (for example, under 35 U.S.C. § 271(e)(1), discussed above, or under the Public Readiness and Emergency Preparedness Act, or the PREP Act, etc.). Furthermore, even if such commercialization is deemed protected from infringement during the period of pandemic crisis, once that period has passed, or as otherwise might be established, any such exemption may be terminated so that continuing commercialization could expose us to liability, and might even be precluded if third party(ies) who hold relevant intellectual property rights are able to secure injunction(s) or are unwilling to license to us on commercially feasible terms.

It is also possible that we have failed to identify relevant third-party patents that cover, or applications that will mature into patents that cover, one or more aspects of our platform or product(s) and product candidates. Given that, in most jurisdictions, a patent application is confidential when initially filed, and typically remains so until it is published about 18 months after the initial filing, it may not be possible for us to identify certain relevant filings in time to avoid using the technology that they claim. Additionally, the claims of pending patent applications can, subject to certain limitations, be amended over time, so that even patent applications whose claims did not cover our products or activities when published could be amended to cover one or more aspects of our platform or product candidates over time, and we might not be aware that such amendment had been made.

We may be involved in lawsuits or other legal proceedings to protect or enforce our intellectual property or the intellectual property of our licensors, or to defend against third-party claims that we infringe, misappropriate or

otherwise violate such third party's intellectual property, each of which could be expensive, time consuming and unsuccessful.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the USPTO and corresponding European and other non-U.S. patent offices.

Competitors and other third parties may infringe, misappropriate or otherwise violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time-consuming. In certain instances, we have instituted and may in the future institute inter partes review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties in the field of immunotherapy. We have a number of these opposition proceedings ongoing at the European Patent Office against third-party patents related to mRNA technologies; also, multiple oppositions have been filed against our EP patent number 2714071, which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. While the claims of our issued EP patent 2714071 were upheld after opposition, there is currently an appeal pending. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In addition, in a patent infringement proceeding, our owned or in-licensed patents may be challenged and a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product(s) and/or product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness, enablement or written description. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-U.S. patent offices and may result in the revocation, cancellation or amendment of any ex-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on a product and/or product candidate. Such a loss of patent protection would have a material adverse impact on our competitive position, business, financial conditions, results of operations and prospects.

Third parties, including our competitors to non-practicing entities or patent assertion entities, may assert that we are employing their intellectual property and other proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, testing, methods of manufacture or methods for treatment related to the use, development, testing, manufacture or commercialization of our COVID-19 vaccine or product candidates. As patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product(s) and/or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the testing or manufacturing processes of any of our product(s) and/or product candidates, any molecules formed during the testing and manufacturing processes or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to develop, test and commercialize such product and/or product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for testing or manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop, test and commercialize the applicable product and/or product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms, or at all, or may be non- exclusive.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the

prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same intellectual property and technology. Our defense of litigation, interference, derivation or similar proceedings may fail and, even if successful, may result in substantial costs and distract our management, technical personnel and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds we need to continue our clinical trials, and research programs, to license necessary technology from third parties or enter into development or manufacturing collaborations that would help us bring our product(s) and/or product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our management, technical personnel and other employees from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater resources in one or more aspects, or for other reasons. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may not be made available on commercially favorable terms, if at all, or may require substantial time and expense.

Such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same intellectual property and technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and product(s) and/or product candidates, which could limit our ability to generate revenues or achieve or maintain profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Moreover, certain of our collaborations provide, and we expect additional collaborations to provide, that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our collaborators to third parties for licenses to such third parties' intellectual property in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

In addition, in connection with certain license and collaboration agreements, we have agreed to indemnify certain third parties for certain costs incurred in connection with litigation relating to intellectual property rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any litigation or other intellectual property proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of the ADSs.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. We have systems in place to remind us to pay these fees and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies; however, we cannot guarantee that we will successfully pay these fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property, and we

cannot guarantee that they will do so. In such an event, our competitors might be able to enter the market with similar or identical products or technology, and this would have a material adverse impact on our business, financial condition, results of operations and prospects.

Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property rights, particularly patents that we own and in-license. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. Moreover, there are periodic changes in patent law. For example, after March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that have affected the way patent applications are prosecuted and also affect patent litigation. Such legislation and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, decisions by courts and governmental bodies in the United States and other jurisdictions may affect the value of patent applications, issued patents or other intellectual property that we own or in-licenses. For example, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, the USPTO, USPTO and other administrative agencies, and their equivalents in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to obtain, maintain, protect, defend or enforce our intellectual property in the future.

If we are unable to protect the confidentiality of ***our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent protection for some of our technology, product(s) and product candidates, we also seek to rely on trade secret protection and confidentiality agreements to maintain our competitive position and protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery development, testing, manufacturing and commercialization processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets and know-how may be difficult to protect.

We seek to protect these trade secrets, know-how and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants and require all of our employees and key consultants who have access to our trade secrets, proprietary know-how, information or technology to enter into confidentiality agreements. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. To the extent we become involved in litigation that may require discovery of our trade secrets, know-how and other proprietary technology, we seek to secure protective orders from the court that bind the parties with access to the discovered information. Despite our best efforts, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Any of these parties who may have access to our trade secrets, know-how and other proprietary technology may breach such agreements or orders. For example, a former employee of our COVID-19 vaccine collaborator, Pfizer, has reportedly misappropriated trade secrets on our COVID-19 vaccine. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or know-how is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. In addition, we cannot be

certain that our proprietary technical information and related confidential documents that we have shared with our collaborators and/or have submitted to governmental agencies including regulatory agencies for evaluation and supervision of pharmaceutical products will be kept confidential. For example, certain documents relating to our COVID-19 vaccine were unlawfully accessed after a cyberattack on the European Medicines Agency (EMA) in December 2020. If any of our trade secrets or know-how were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, financial condition and prospects

We may be subject to claims that we have wrongfully hired an employee from a competitor, or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, including alleged trade secrets of their former employers.

We have received confidential and proprietary information from third parties in the course of our research and other collaborations with others in the industry, academic institutions and other third parties. In addition, many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the confidential or proprietary information, trade secrets or know-how of others in their work for us, we may be subject to claims that we have inadvertently or otherwise used or disclosed confidential or proprietary information, trade secrets or know-how of these third parties, or that our employees, consultants, independent contractors or advisors have inadvertently or otherwise used or disclosed confidential information, trade secrets or know-how of such individual's current or former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management, technical personnel and other employees. Claims that we, our employees, consultants or advisors have misappropriated the confidential or proprietary information, trade secrets or know-how of third parties could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

In the future, we may be subject to claims that current or former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants, independent contractors, collaborators and other third parties who may be involved in the conception, development or reduction to practice of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives, develops or reduces to practice such intellectual property that we regard as our own. In addition, certain such agreements, even if successfully executed may distribute ownership or control of intellectual property rights between or among parties, for example based on subject matter, relationship to other intellectual property, and/or one or more aspects of development of the intellectual property; after the agreements are in place disputes may arise over such distribution principles or over proper treatment of particular developed intellectual property in accordance with them. Disagreements may be difficult or impossible to resolve, may be expensive to address, and may result in our failing to secure or maintain ownership in or control of intellectual property necessary or important to our business.

The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached. For example, we may have inventorship or ownership disputes arise from conflicting obligations of employees, consultants, independent contractors, collaborators or other third parties who are involved in developing and commercializing our product(s) and/or product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, operating results and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management, technical personnel and other employees.

Furthermore, the laws of some other countries do not protect intellectual property and other proprietary rights or establish ownership of inventions to the same extent or in the same manner as the U.S. laws. A majority of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between us and our employees or former employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up our management's, technical personnel's and other employees' time and efforts whether we prevail or fail in any such dispute. There is a risk that the compensation we provided to employees who assign patents to us may be deemed to be insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases, where employees' rights have not been assigned to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our business, results of operations and financial condition could be adversely affected.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product(s) and/or product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in Germany and the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States to the same extent as within the United States, or from selling or importing products made using our inventions in and to the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product(s) and/or product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, particularly outside of the United States. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents and other intellectual property or development, testing, marketing and commercialization of competing products in violation of our owned or in-licensed intellectual property and other proprietary rights generally. Proceedings to enforce our intellectual property rights in such jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours or collaborators may fail to use our

trade names or trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors and collaborators. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse or failure to use of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks, and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make COVID-19 vaccines or therapies, and/or personalized cancer immunotherapies that are similar to our COVID-19 vaccine and/or any product candidates we may develop and commercialize or utilize similar technologies that are not covered by the claims of the patents that we now or may in the future own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or in-license in the future will not lead to issued patents;
- claims of issued patents that we own or have exclusively in-licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research, development, testing or commercialization activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

We may not be able to develop or obtain approval for companion diagnostics required for commercialization of some of our product candidates.

Administration of some of our product candidates may require the use of immuno-assays and bioinformatic tools in which patients are screened for optimal target antigens of our product candidates. If safe and effective use of a biologic product depends on an in vitro diagnostic, then the FDA generally requires approval or clearance of the diagnostic, known as a companion diagnostic, concurrently with approval of the therapeutic product. To date, the FDA has generally required in vitro companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, for that diagnostic, which can take up to several years, simultaneously with approval of the biologic product. Similarly, in the European Union, an in vitro companion diagnostic may be placed on the market only if it

conforms to certain "essential requirements" and bears the Conformité Européene Mark, or CE Mark. The conformity assessment process to obtain the CE Mark can be lengthy and we may fail to demonstrate such conformity. Further, the applicable regulatory framework for in vitro diagnostics in the EU is expected to change beginning May 26, 2022 when a new EU regulation with stricter regulatory requirements for in vitro diagnostics will become applicable.

For our individualized immunotherapy candidates, the FDA and comparable regulatory authorities outside of the United States may require the development and regulatory approval of a companion diagnostic assay as a condition to approval. The FDA may require PMA supplemental approvals for use of that same companion diagnostic as a condition of approval of additional individualized therapeutic candidates. We do not have experience or capabilities in developing or commercializing companion diagnostics and plan to rely in large part on third parties to perform these functions. Companion diagnostic assays are subject to regulation by the FDA and other comparable regulatory authorities in other jurisdictions as medical devices and require separate regulatory approval prior to the use of such diagnostic assays with our individualized therapeutic candidates. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostic assays for use with our individualized therapeutic candidates, or are unable to obtain regulatory approval or experience delays in either development or obtaining regulatory approval, we may be unable to identify patients with the specific profile targeted by our product candidates for enrollment in our clinical trials. Accordingly, further investment may be required to further develop or obtain the required regulatory approval for the relevant companion diagnostic assay, which would delay or substantially impact our ability to conduct additional clinical trials or obtain regulatory approval.

Because we are developing some of our product candidates for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA, the EMA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.

There may not be pharmacologic therapies approved to treat the underlying causes of many diseases that we may address in the future. For instance, we and our collaborators are applying our technology to develop therapeutics in indications such as certain rare diseases, including some for which no or few clinical trials have been attempted. As a result, any future design and conduct of clinical trials of product candidates for the treatment of certain rare diseases may take longer, be more costly, or be less effective as part of the novelty of development in these diseases. Even if we decide to conduct clinical trials and the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we or our collaborators may conduct for our programs. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of licensure. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

The FDA, the EMA or other comparable regulatory authorities may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

If the results of our clinical trials are sufficiently compelling, we or our collaborators intend to discuss with the FDA and regulatory authorities in other countries the submission of a BLA or respective applications in other countries for our product candidates. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA for any of our product candidates. The FDA, the EMA or other regulatory agencies may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA, the EMA or other regulatory agencies may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA, the EMA or other regulatory agencies that are more accelerated than those available for regular approvals. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA, the EMA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, the EMA or comparable regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, the EMA or comparable regulatory authorities to support the submission of a BLA or other comparable submissions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, the EMA or comparable regulatory authorities will inspect our manufacturing facilities and may not approve our facilities or our manufacturing processes and controls; and
- the approval policies or regulations of the FDA, the EMA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We may not be able to file INDs with the FDA, clinical trial applications with the competent authorities of the member states of the European Union or similar applications with other comparable regulatory authorities to commence additional clinical trials on the timelines we expect, and even if we are able to, one or more of these regulatory authorities may not permit us to proceed.

The timing of filing on our product candidates is dependent on further preclinical, clinical and manufacturing success. We cannot be sure that submission of an IND or IND amendment with the FDA, a clinical trial application with the regulatory authorities of the EU member states or similar application with other comparable regulatory authorities will result in the FDA, the regulatory authorities of the EU member states or any comparable regulatory authority allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, clinical trial application or similar applications, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

Our strategy includes filing for orphan drug designation where available for our product candidates. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or greater in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application or a BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity. Similar rules apply in the European Union with respect to drugs or biologics designated as orphan medicinal products.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not protect the product effectively from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing

exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Similar considerations apply in the European Union with respect to drugs or biologics designated as orphan medicinal products. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

We may seek breakthrough therapy or fast-track designation for one or more of our product candidates, but we may not receive such designations. Even if we do, it may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that such product candidates will receive marketing approval.

We may seek a breakthrough therapy designation in the United States for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

We may also seek Fast Track Designation in the United States for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

We expect some of the product candidates we develop will be regulated as biologics in the United States and therefore they may be subject to competition from biosimilars approved through an abbreviated regulatory pathway.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved.

During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for a 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Some of our product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that our product candidates will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business.

There have been few approvals of gene therapy products in the United States and other jurisdictions, and there have been well-reported significant adverse events associated with their testing and use. Gene therapy products have the effect of introducing new DNA and potentially irreversibly changing the DNA in a cell. In contrast, mRNA is highly unlikely to localize to the nucleus, integrate into cell DNA, or otherwise make any permanent changes to cell DNA. Consequently, we expect that our product candidates will have a different potential side effect profile from gene therapies because they lack risks associated with altering cell DNA irreversibly. Further, we may avail ourselves of ways of mitigating side effects in developing our product candidates to address safety concerns that are not available to all gene therapies, such as lowering the dose of our product candidates during repeat dosing or stopping treatment to potentially ameliorate undesirable side effects.

Regulatory requirements governing gene and cell therapy products have evolved and may continue to change in the future, and the implications for mRNA-based therapies is unknown. For example, the FDA has established the Office of Tissues and Advanced Therapies within CBER to consolidate the review of gene therapy and related products, and convenes the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In the European Union, mRNA has been characterized as a gene therapy medicinal product. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us. Specifically, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification. Notwithstanding the differences between our mRNA product candidates and gene therapies, the classification of some of our mRNA product candidates as gene therapies in the United States, the European Union and potentially other counties could adversely impact our ability to develop our product candidates, and could negatively impact our platform and our business. For instance, a clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly may apply to our mRNA product candidates irrespective of the mechanistic differences between gene therapies and mRNA.

Adverse events reported with respect to gene therapies or genome editing therapies could adversely impact one or more of our programs. Although our mRNA product candidates are designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapy products caused by introducing new DNA and irreversibly changing the DNA in a cell could also be a risk for our mRNA investigational therapies, and as a result may delay one or more of our trials or impose additional testing for long-term side effects. Any new requirements and guidelines promulgated by regulatory review agencies may have a negative effect on our business by lengthening the regulatory review process, requiring us to perform additional or larger studies, or increasing our development costs, any of which could lead to changes in regulatory positions and interpretations, delay or prevent advancement or approval and commercialization of our product candidates or lead to significant post-approval studies, limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and advisory committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of some or all of our product candidates.

The regulatory landscape that will govern our product candidates is uncertain. Regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could

result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

The regulatory requirements to which our product candidates will be subject are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union, a special committee called the Committee for Advanced Therapies, or CAT, was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products, or ATMPs, to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As the regulatory landscape for our CAR-T cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product sales revenue to maintain our business.

We may be unable to obtain regulatory approval for our product candidates under applicable international regulatory requirements.

The denial or delay of such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In order to market our product candidates in any other jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory approval in other jurisdictions could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The European Union and other jurisdictions' regulatory approval processes involve all of the risks associated with the FDA approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

A third-party investigational drug used in combination with our product candidates may be unable to obtain regulatory approval, which may delay commercialization of our product candidates.

We are developing several of our product candidates to be used in combination with our and third-party drugs. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA or comparable regulatory authorities in other jurisdictions could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, the EMA or comparable regulatory authorities in other jurisdictions may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We also plan to evaluate current and future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, the EMA or comparable regulatory authorities in other jurisdictions. We will not be able to market any product candidate we develop in combination with an unapproved therapy if that unapproved therapy does not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, EMA or comparable regulatory authority approval.

If the FDA, the EMA or comparable regulatory authorities in other jurisdictions do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market any product candidate we develop.

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, and we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, including the review of additional safety information, and the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Similar requirements apply to holders of (conditional) approvals in other countries. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In other countries, advertising and promotional material may be subject to similar rules.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval or revoke a license;
- suspend any ongoing clinical studies;
- refuse to approve a pending BLA (or comparable approval) or supplements to a BLA (or comparable approval) submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

If any of our product candidates cause undesirable side effects, it could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential marketing approval. Product candidates we may develop may be associated with an adverse immune response or other serious adverse events, undesirable side effects or unexpected characteristics. In addition to serious adverse events or side effects caused by any of our product candidates, the administration process or related procedures also can cause undesirable side effects. If any such events occur, the clinical trials of any of our product candidates could be suspended or terminated.

If in the future we are unable to demonstrate that such adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any of our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled trial participants to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product sale revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations and prospects significantly.

Additionally, following regulatory approval of a product candidate, the FDA or other regulatory authority could require us to adopt a REMS or a risk management plan, or RMP, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry.

Furthermore, if we or others later identify undesirable side effects caused by any product that we develop, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals or revoke licenses of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients and their children; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any products we may identify and develop and could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are successful in gaining approval for any of our product candidates, we will continue to face significant regulatory oversight of the manufacturing and distribution of our products. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP and adherence to commitments made in the BLA or comparable approval. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

We may be subject to additional healthcare regulation and enforcement by the U.S. federal government and by authorities in the United States, the European Union and other jurisdictions in which we conduct our business.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various

federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act, and the Physician Payments Sunshine Act and regulations. Many states and other jurisdictions have similar laws and regulations, some of which may be broader in scope. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws enacted by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. The ACA amends the intent requirement of the federal Anti-Kickback Statute to provide that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it.
- The federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval from Medicare, Medicaid or other government payors. The ACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private).
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers.
- The U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices.
- The U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product.
- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations.
- State law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances which are also applicable to us, and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances.
- The U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents, as well as non-U.S. companies that are registered with the SEC, from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- Similar statutes, healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Due to the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in

government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union member states and other jurisdictions, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We are subject to certain anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as "trade laws," prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other collaborators from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, intellectual property (including patents) and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or collaborators, even if we do not explicitly authorize or have prior knowledge of such activities.

We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing, and cross-border transfer of personal information and our data privacy and security practices.

We receive, generate and store significant and increasing volumes of sensitive information, such as employee, personal and patient data.

We are subject to a variety of local, state, national and international laws, directives and regulations that apply to the collection, use, storage, retention, protection, disclosure, transfer and other processing of personal data, collectively referred to as "data processing", in the different jurisdictions in which we operate, including comprehensive regulatory systems in the United States and Europe. Legal requirements relating to data processing continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

Compliance with U.S. and international data protection laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition and results of operations.

The collection and use of personal data in the European Union had previously been governed by the provisions of the EU Data Protection Directive, which EU member states were required to implement. While the Data Protection Directive did not apply to organizations based outside the European Union, the GDPR has expanded its reach to include any business,

regardless of its location, that targets goods or services to residents in the European Union or that "monitors" their behavior in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of patients residing in the European Union. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Since we are located in the European Union, we are subject to the GDPR. Additionally, as the GDPR applies extraterritorially, we are also subject to the GDPR even where our data processing activities occur outside of the European Union if such activities involve the personal data of individuals located in the European Union and the above-mentioned applicable law triggers apply. GDPR regulations have imposed additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with non-compliance. We cannot guarantee that we are, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws, in which case we may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect our business. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with the GDPR and other international data protection regulations, especially with regard to clinical trial activities. For example, it is not clear if the authorities will conduct random audits of companies doing business in the European Union, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated, as enforcement practices vary from country to country. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects. If we fail to comply with the GDPR and the applicable national data protection laws of the EU member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions, which can result in monetary penalties of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. If any of these events were to occur, our business and financial results could be significantly disrupted and adversely affected.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, as well as regulatory penalties. In many jurisdictions, there are legal requirements to provide notice of breaches to affected individuals and/or regulators in certain circumstances. Such a notice could harm our reputation and our ability to compete. Regulators may also have the discretion to impose penalties without attempting to resolve violations through informal means. Although we have implemented security measures to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

If we or our third-party suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held

liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Risks Related to Ownership of the ADSs

We have experienced and may continue to experience significant volatility in the market price of the ADSs representing our ordinary shares.

Biopharmaceutical companies that are developing potential therapeutics and vaccines to combat COVID-19, including BioNTech SE, have experienced significant volatility in the price of their securities upon publication of preclinical and clinical data as well as news about their development programs. For example, during 2021 the closing sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market ranged from $85.73 to $447.23, with significant volatility occurring shortly after announcements related to regulatory and purchase announcements related to our COVID-19 vaccine and to other COVID-19 vaccines. Additionally, we have observed the trading price of the ADSs respond significantly to news and statements by us, government agencies, competing vaccine developers, financial analysts or others relating to other COVID-19 vaccines and COVID-19 therapeutics and the pandemic generally, even in cases in which we believe the news does not affect our business or vaccine specifically. Given the attention being paid to the COVID-19 pandemic and the public scrutiny of COVID-19 development and commercialization announcements, and given that our COVID-19 vaccine is among the first vaccines to receive emergency use authorization, we expect that the public announcements we and Pfizer intend to make in the coming months regarding additional supply agreements and any news regarding manufacturing and distribution of our COVID-19 vaccine or unanticipated side effects of our COVID-19 vaccine, whether or not accurate, will attract significant attention and scrutiny and that, as a result, the price of the ADSs representing our ordinary shares likely will continue to be volatile.

If we engage in future acquisitions, joint ventures or collaborations, it may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may not realize the benefits of these acquisitions, joint ventures or collaborations.

We may evaluate various acquisitions and collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition, joint venture or collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may utilize our cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Moreover, we may not be able to locate suitable acquisition or collaboration opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our Articles of Association designate specific courts in the United States as the exclusive forum for certain U.S. litigation that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us.

Our Articles of Association provide that the United States District Court for the Southern District of New York shall be the competent court of jurisdiction for the resolution of any litigation on the grounds of or in connection with U.S. federal or state capital market laws. In the absence of these provisions, under the Securities Act of 1933, as amended, or the Securities Act, U.S. federal and state courts have been found to have concurrent jurisdiction over suits brought to enforce duties or liabilities created by the Securities Act. This choice of forum provision will not apply to suits brought to enforce duties or liabilities created by the Securities Exchange Act of 1934, as amended, which already provides that such federal district courts have exclusive jurisdictions over such suits.

The choice of forum provision contained in our Articles of Association may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our executive officers, directors, or other employees, or impose additional litigation costs on shareholders in pursuing any such claims, particularly if the shareholders do not reside in or near the state of New York, which may discourage such lawsuits. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other U.S. or German courts will enforce our choice of forum provision. The enforceability of similar choice of forum provisions in other companies' governing documents has been challenged in recent legal proceedings, and it is possible that a court in the relevant jurisdictions with respect to us could find the choice of forum provision contained our Articles of Association to be inapplicable or unenforceable. If the relevant court were to find the choice of forum provision contained in our articles of association to be inapplicable or unenforceable, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition and operating results. The choice of forum provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The United States District Court for the Southern District of New York may also reach different judgments or

results than would other courts, including courts where a shareholder considering a U.S.-based action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

Holders of the ADSs may not be able to participate in any future preemptive subscription rights issues or elect to receive dividends in shares, which may cause additional dilution to their holdings.

Under German law, the existing shareholders of a company generally have a preemptive right in proportion to the amount of shares they hold in connection with any issuance of ordinary shares, convertible bonds, bonds with warrants, profit participation rights and participating bonds. However, our shareholders in a shareholders' meeting may vote, by a majority representing at least three-quarters of the share capital represented at the meeting, to waive this preemptive right provided that, from the company's perspective, there exists good and objective cause for such waiver.

The deposit agreement provides that the depositary need not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our future rights offerings and may experience dilution in their holdings. For example, ADS holders were unable to participate in our summer 2020 rights offering. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

The amount and frequency of our dividends and ADS repurchases may fluctuate.

The amount, timing and execution of our ADS repurchase program and the amount and timing of any dividends we pay may fluctuate based on our priorities for the use of cash for other purposes, and any ADS repurchases would be subject to the parameters contained in our repurchase plan. These purposes include operational spending, capital spending, acquisitions and repayment of debt. Additionally, we may choose to repurchase ADSs so that such ADSs may be used to settle outstanding and future equity awards granted to our employees. Changes in cash flows, tax laws and the price of the ADSs could also impact our ADS repurchase program. We are not obligated to repurchase any specific amount of ADSs, and the ADS repurchase program may be suspended or terminated at any time. Additionally, because we have entered into a Rule 10b5-1 trading plan governing the repurchases, we have no discretion over the particular sales made and are only able to set minimum price floors and maximum ADS count ceilings.

Our principal shareholders and management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

Our executive officers, directors, five percent shareholders, and their affiliates beneficially own a majority of our ordinary shares (including ordinary shares represented by ADSs) as of December 31, 2021, and will have the ability to influence us through their ownership positions. For example, these shareholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that shareholders may believe are in their best interest. Such insiders may also act in concert to waive rights to participate in rights offerings, as was done in our summer 2020 rights offering, which would have the effect of permitting the ADSs or shares underlying such waived rights to be offered to the public in an underwritten offering without contravening German law pricing requirements.

The large number of shares eligible for sale or subject to rights requiring us to register them for sale could cause the market price of the ADSs to drop significantly, even if our business is performing well.

We have filed a registration statement on Form S-8 under the Securities Act, to register all ordinary shares issued or issuable under our equity plans. Such Form S-8 registration statements and any other registration statements on Form S-8 we file in the future become effective upon filing, upon which shares registered under such registration statements become available for sale in the open market.

Additionally, certain sales of ADSs or our ordinary shares that we have made included holding period restrictions or registration rights. Sales of ADSs or our ordinary shares as restrictions end or pursuant to registration rights may make it more difficult for us to finance our operations through the sale of equity securities in the future at a time and at a price that

we deem appropriate. These sales also could cause the trading price of the ADSs to fall and make it more difficult to sell the ADSs on favorable terms.

Item 4. Information on the Company

A. History and Development of the Company

We are committed to improving the health of people worldwide with our fundamental research and development of immunotherapies. Scientific rigor, innovation and passion are our driving forces. BioNTech was founded by scientists and physicians to translate science into survival by combining fundamental research and operational excellence.

We were founded and incorporated on June 2, 2008 as Petersberg 91, V AG, a German stock corporation (Aktiengesellschaft). We changed our name to BioNTech AG on December 11, 2008. On March 8, 2019, we converted to a European stock corporation (Societas Europaea, or SE) under the laws of Germany and the European Union called BioNTech SE. We completed our initial public offering in October 2019. ADSs representing our ordinary shares are currently listed on the Nasdaq Global Select Market under the symbol "BNTX".

Our principal executive offices are located at An der Goldgrube 12, D-55131 Mainz, Germany. Our telephone number is +49 6131-9084-0. Our website address is http://www.biontech.de. The information contained on, or that can be accessed through, our website is not part of this document. Our agent for service of process in the United States is c/o BioNTech US Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139, +1 (617) 337-4701.

B. Business Overview

I. Overview

We are a fully integrated global biotechnology company specializing in the development of novel medicines at the intersection of immunology and synthetic biology. Since our founding in 2008, we have focused on harnessing the power of the immune system to address human diseases with unmet medical need and major health burden. Our fully-integrated model combines decades of research in immunology, translational drug discovery and development, a technology agnostic innovation engine, GMP manufacturing, and commercial capabilities to rapidly develop and commercialize potential vaccines and therapies to address a range of serious indications on a global scale.

A 21st Century Immunotherapy Powerhouse

We have built a broad toolkit across multiple technology platforms, including a diverse range of potentially first-in-class therapeutic approaches. This includes mRNA vaccines, cell and gene therapies, targeted antibodies, small molecule immunomodulators, Ribologicals, and next generation immunomodulators. Our approach has created a robust and diversified product pipeline across infectious disease and oncology, comprised of our first commercial product, BNT162b2

(COMIRNATY), the first ever approved mRNA therapy, over 17 clinical stage product candidates and more than 30 research programs.

Core to our business practices is ensuring that people all around the globe benefit from our efforts. As part of this effort, we intend to maintain our focus on high medical needs and democratizing access to novel medicines. We believe we are well positioned to develop and commercialize the next generation of immunotherapies with the potential to transform treatment paradigms for many severe diseases and substantially improve clinical outcomes for patients. BioNTech supports the United Nations Sustainable Development Goals (SDGs). Our research and product development efforts make a relevant contribution to supporting the third United Nations Sustainable Development Goal (SDG 3): ensuring healthy lives and promoting well-being for all people of all ages. This aligns with our commitment to global social responsibility.

Our first commercial-stage product is BNT162b2, our mRNA vaccine program to prevent COVID-19. We are co-developing BNT162b2 with Pfizer, Inc., or Pfizer, worldwide (ex-China) and with Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma in China. In early 2020, recognizing the onset of the COVID-19 pandemic as a global threat, we leveraged our technologies to address this global health challenge and developed BNT162b2, which became the first-ever approved mRNA-based product, and, to our knowledge, the fastest pharmaceutical product ever developed. Our efforts have resulted in more than one billion vaccinated people around the globe. BioNTech and Pfizer continue to execute on plans for global COVID-19 vaccine leadership with multiple new product launches, including label expansions, pediatric dosage forms and potentially variant-based vaccines.We believe our successful development of a first-in-class COVID-19 mRNA vaccine in less than one year validates our execution capabilities, the power of our technologies, and our commitment to social responsibility.

As of February 2022, our COVID-19 vaccine has been authorized or approved for emergency use or temporary use or granted marketing authorization in over 100 countries and regions around the world. In August 2021, our COVID-19 vaccine was the first to receive full FDA approval in the United States for use in individuals aged 16 and older. In 2021, we and Pfizer delivered more than 2.6 billion doses of our COVID-19 vaccine to more than 165 countries and regions worldwide, including approximately 1 billion doses to low- and middle-income countries. As of the beginning of March 2022, we and Pfizer have delivered more than 3.1 billion doses to more than 170 countries and regions, including approximately 1.3 billion does to low- and middle-income countries.

In our oncology clinical programs, to-date we have treated over 900 patients across more than 20 solid tumor types. We now have five ongoing randomized Phase 2 clinical trials, four of which started in 2021. We also started four first-in-human clinical trials in diverse therapeutic programs in 2021 and another first-in-human trial started in January 2022.

In addition to various data read-outs for our BNT162b2 program, we had several clinical data updates in our oncology programs in 2021, including presentations at major medical conferences. At the Society for Immunotherapy of Cancer (SITC) Annual Meeting 2021 we presented Phase 1 clinical data updates across six programs and four therapeutic platforms in two oral presentations and five posters. Data was presented for our FixVac programs (BNT111 and BNT112), our CAR-T cell immunotherapy (BNT211), our bispecific antibodies (BNT311 and BNT312, which are partnered with Genmab), and our small molecule immunomodulator (BNT411). For all six programs, the data presented demonstrated favorable safety profiles and promising signs of clinical activity. At the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) Congress 2021 we presented an additional data update for our CAR-T cell therapy BNT211 which showed additional evidence of clinical activity in most patients.

The broad success of our COVID-19 vaccine has paved the way to a new era of mRNA technology and synthetic biology. Our position today reflects a uniquely rich pipeline including multiple first-in-class approaches positioning us to re-imagine the therapeutic landscape, enable personalized care, and drive superior patient outcomes across diseases. The current capital allocation places us in an exceptional position to drive a multi-platform strategy and deliver a fully integrated global biotechnology company.

On the R&D front, we are focused on developing next generation COVID-19 vaccines to maintain leadership and pandemic preparedness as well as broaden the label of and access to the vaccine. We also plan to invest heavily to build out our global development organization, bringing in talent with clinical and regulatory expertise needed to rapidly advance our diversified clinical pipeline. Additionally, we are accelerating clinical development, bolstering mid- and late-stage oncology presence and broadening our pipeline through the start of new programs in oncology and infectious diseases. We are also taking the opportunity to diversify our therapeutic area footprint which will enable us to fully leverage the potential of all

technology platforms across autoimmune diseases, inflammatory diseases, cardiovascular disease, neurodegenerative diseases, and regenerative medicines.

M&A and business development efforts focus on strengthening technology platforms and digital capabilities through select strategic partnerships and acquisitions. We also plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing.

To support our future trajectory, growing the organization and expanding our team is of utmost importance. We are on the way to develop our global footprint in key regions including Europe, the United States, Asia and Africa. Additionally, investing in manufacturing capabilities for key technologies and deploying our pandemic response capabilities remain priorities for us.

II. The BioNTech Approach

We are focused on developing next generation immunotherapies by employing a multi-platform strategy, powered by a technology agnostic innovation engine, coupled with strong expertise in emerging technologies in mRNA and synthetic biology. With the approval or our COVID-19 vaccine to support the validation of mRNA vaccines as a new drug class, we believe that we are entering into a new era of mRNA technology. Our goal is to drive this transformation by applying the following principles:

- **Exploiting the full potential of the immune system.** Our broad pipeline includes mRNA-based vaccines, including cancer vaccines, antigen-specific tolerance vaccines and prophylactic infectious disease vaccines. In addition, our pipeline includes mRNA-based immune activators, antigen-targeting T cells and antibodies, and defined immunomodulators of various immune cell mechanisms. This portfolio is designed to mirror the evolution of the immune system to rely on multiple complementary pathways.

- **Advancing programs to combat major health burdens.** Our infectious disease product strategy is rooted in our global social responsibility and we aim to help democratizing global access to mRNA medicines. Our infectious disease toolkit includes multiple technology platforms, including mRNA vaccines, prophylactic infectious disease vaccines, and a new class of precision anti-bacterials, Synthetic Lysins.

- **Broadening the universe of patients benefiting from cancer immunotherapy.** We discover and exploit novel targets and target combinations. Our aim is to extend the utility of immunotherapy to patient populations that are not currently amenable or do not benefit from the targets of current immunotherapies.

- **Improving the success rate.** We engineer and develop highly potent drug candidates designed to be precise for the specific target. We further augment activity and counteract resistance mechanisms by combining compounds with non-overlapping, synergistic mechanisms of action, such as combining our FixVac immunotherapy, CARVac, with our novel CAR-T therapies.

- **Focusing on curative and individualized approaches.** The root cause of recurrence or for lack of tumor eradication is interindividual variability and cancer heterogeneity. Addressing this biological reality is one of the mandatory design aspects of the product candidates we develop. For example, each of our cancer immunotherapies incorporates multiple targets in order to account for this variability.

III. Multi-Platform Strategy: Technology Agnostic Innovation Engine

We have applied these guiding principles to a broad suite of therapeutic platforms optimized for a distinct mode of action, high precision targeting, high potency and efficacy. We expect each platform to yield a pipeline of drug candidates for further development. We believe this technology-agnostic combination of platforms and product candidates positions us to remain at the forefront of the shift toward an individually tailored, patient-centric therapeutic approach in oncology.

Similarly, in infectious disease, we are deploying our full suite of technologies and our immunotherapeutic understanding to develop mRNA vaccines against infectious diseases, such as COVID-19, in a manner that is designed to be faster and more easily scalable, and with more flexible constructs, than traditional vaccine development.

Our current immunotherapy product candidates that are being tested in clinical trials span four distinct drug classes:

- **mRNA Therapeutics.** We are utilizing messenger ribonucleic acid, or mRNA, to deliver genetic information to cells, where it is used to express proteins for therapeutic effect. In infectious disease, we are leveraging our mRNA technology to develop prophylactic infectious disease vaccines to address COVID-19, influenza, shingles, malaria, tuberculosis, HSV 2 and other infectious diseases. In oncology, we are developing a portfolio of immunotherapies that utilize four different mRNA formats and three different formulations to derive five distinct platforms for the treatment of cancer. All our platforms are in clinical testing for oncology: (i) our off-the-shelf shared antigen immunotherapy, or FixVac; with two FixVac product candidates currently being tested in randomized Phase 2 clinical trials, (ii) our individualized neoantigen specific immunotherapy, or iNeST, in collaboration with Genentech, Inc.; with two ongoing Phase 2 clinical trials (iii) our intratumoral immunotherapy in collaboration with Sanofi, S.A.; (iv) our mRNA encoding for specific cytokines, or RiboCytokines; and (v) our mRNA encoded antibodies, or RiboMabs, which entered clinical testing in January 2022.

- **Cell Therapies.** We are developing a range of cell therapies, including chimeric antigen receptor T cells, or CAR-T, neoantigen-based T cell therapies and T cell receptor, or TCR, therapies, in which the patient's T cells are modified or primed to target cancer-specific antigens. We are also combining our mRNA FixVac platform with our first CAR-T product candidates to enhance the persistence of CAR-T cells *in vivo*. Our first CARVac product candidate entered into clinical testing in solid tumors in February 2021, and our first neoantigen-targeted T cell therapy candidate entered into clinical testing in April 2021.

- **Antibodies.** In collaboration with Genmab A/S, we are developing next-generation bispecific antibodies that are designed to target immune checkpoints that modulate the patient's immune response to cancer. Our first two product candidates under this collaboration are in clinical testing including one randomized Phase 2 clinical trial which started in December 2021. We are also exploring additional targeted cancer antibody approaches utilizing our in-house capabilities.

- **Small Molecule Immunomodulators.** We use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation. The first program is a small molecule toll-like receptor 7, or TLR7, immunomodulator for the treatment of solid tumors that is currently in Phase 1 clinical testing.

We have leveraged these four drug classes to build a robust pipeline of over 20 product candidates in oncology and additional product candidates in infectious disease. Longer-term, we see applications for the technology in the fields of autoimmune diseases, inflammatory diseases, cardiovascular and neurodegenerative diseases, and regenerative medicines.

IV. Our Team and Culture

Our success is driven by people. We have expanded our team to more than 3,000 employees by attracting top talent globally and our diverse workforce represents more than 60 nations. The ambition and dedication of people that share our vision of engineering immunity to combat human diseases are the foundation to transform our vision into reality.

Our management team combines proven biotechnology entrepreneurs, world-renowned immunologists and sophisticated biopharma investors. We were founded in 2008 by our scientific founders, Prof. Ugur Sahin, M.D., Prof. Christoph Huber, M.D. and Prof. Özlem Türeci, M.D., with a seed investment of €150 million from the Strüngmann family, through its investment vehicle, AT Impf GmbH, and MIG Fonds, or MIG. Andreas and Thomas Strüngmann are serial entrepreneurs, having co-founded Hexal AG, a German pharmaceutical firm, which they built and sold to Novartis, along with their majority stake in Eon Labs, Inc., a U.S. public pharmaceutical firm, for a combined €5.6 billion (at the time, $8.3 billion). Helmut Jeggle and Michael Motschmann, on behalf of the Strüngmann family and MIG, respectively, along with Christoph Huber, were founding members of our Supervisory Board.

Our initial group of scientific founders have been joined by experienced pharmaceutical executives, immunologists and biotechnology specialty investors. Sean Marett, our Chief Business Officer and Chief Commercial Officer, led the business development teams at Evotec, and previously was an executive at GlaxoSmithKline in the United States. Dr. Sierk Poetting, our Chief Operating Officer, joined us from Sandoz, where he served as the Chief Financial Officer in North America. Ryan Richardson, our Chief Strategy Officer, joined us from J.P. Morgan Securities LLC, where he served as Executive Director, Healthcare Investment Banking. Jens Holstein, our Chief Financial Officer, joined as of July 1, 2021. Previously he served as Chief Financial Officer at MorphoSys AG. We have also attracted talented scientists such as Katalin Karikó, our Senior Vice President & Head of RNA Protein Replacement, who has more than 30 years of experience

working with RNA, has published more than 70 peer-reviewed papers and is co-inventor on mRNA-related patents, including a foundational patent relating to modified mRNA.

BioNTech has been supported since its inception by Prof. Rolf Zinkernagel, M.D., Ph.D. and Prof. Hans Hengartner, Ph.D., who serve on our Scientific Advisory Board. Prof. Zinkernagel is a Professor Emeritus at the University of Zurich, University Hospital, and former head of the Institute of Experimental Immunology in Zurich. He was awarded the Nobel Prize in 1996 for the discovery of how the immune system recognizes virus-infected cells. Prof. Hengartner is a world-renowned immunologist and Professor Emeritus at the Federal Institute of Technology ETH Zurich and the University of Zurich.

Our corporate culture has been one of our key success factors over the last decade and remains essential for our continued innovation engine and execution to bring new medicines to people. Both the Management Board and Supervisory Board recognize that maintaining our original culture, exemplified by "Project Lightspeed" that led to the rapid and successful development of our COVID-19 vaccine, is a fundamental component of our strategy for managing our expected future organizational growth.

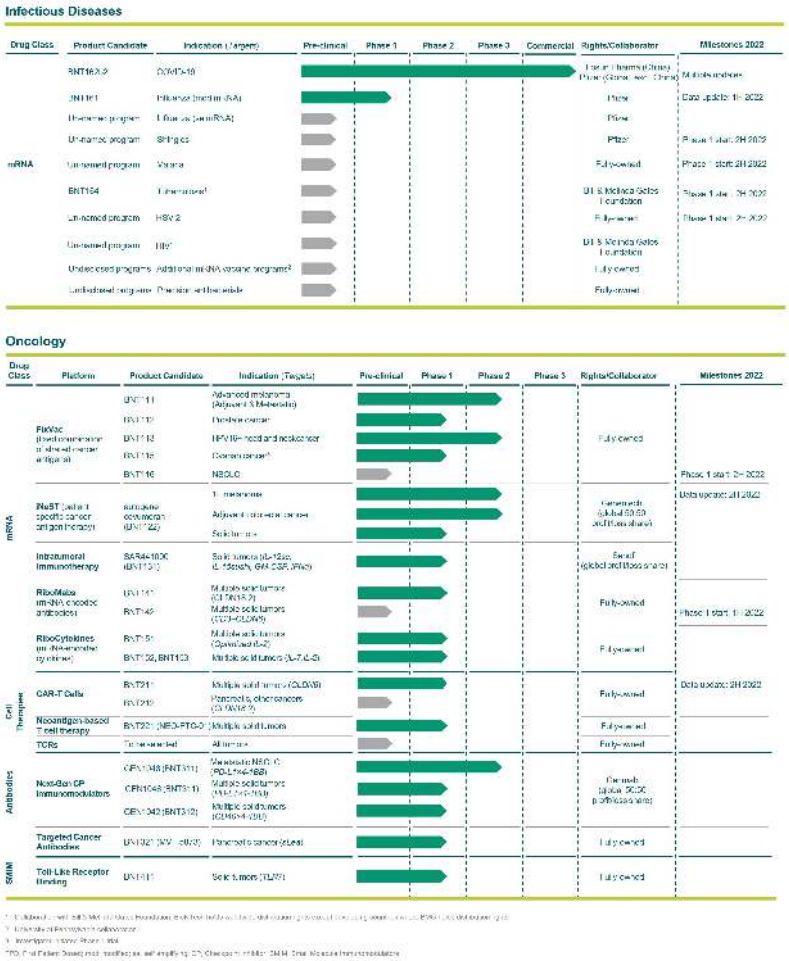
The importance of corporate culture has led to the establishment of the "Culture Campus", a project team within BioNTech, reporting directly to senior management, focused on codification, sensing, shaping, implementation, safeguarding, developing and communication of BioNTech´s corporate culture. The group has spent considerable efforts to identify the key components of our current culture through empirical social research, including employee focus groups, research, and structured feedback loops. Based on this data-driven process, we have identified key facts of our corporate culture - a strong sense of purpose, a focus on embracing contribution and responsiveness.

Scientific rigor, innovation and passion are driving our spirit. We encourage self-confidence among our employees, provide the ambition needed to be pioneers and break boundaries, and also take the time to celebrate our own achievements. Standing united is a key component of our culture, focusing on collaboration, teamwork, and a learning culture that views both successes and mistakes as opportunities for growth. Despite our significant growth, we are committed to staying agile, which is crucial to innovation, efficiency, and recognizing possibilities and opportunities. Last, we remain accountable, acting with integrity and making decisions based on sustainability, values and scientific data.

We have a high level of awareness within Germany as well as globally. Many employees have a high level of identification with our vision and draw inspiration from our strong corporate culture. Because of this, we are considered as an attractive employer globally both for scientific as well as operational and administrative roles.

V. Product and Pipeline of Product Candidates

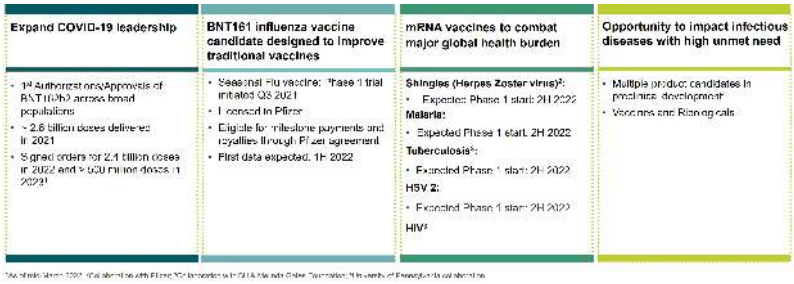
We are advancing our broad portfolio of product candidates derived from our four drug classes and multiple platforms focused on immunotherapies for the treatment of cancer and mRNA vaccines to prevent or treat infectious diseases.



A. Infectious Disease Programs

We are expanding our infectious disease pipeline of mRNA vaccines to address global health challenges. In addition to our COVID-19, influenza and shingles vaccine programs, which are partnered with Pfizer, we have active research and preclinical development programs against more than 10 additional distinct infectious diseases, spanning both vaccine and therapeutic approaches. As demonstrated with our COVID-19 vaccine, our infectious disease product strategy is rooted in our responsibility to make global and social impact with our medicines. Our goal is to advance and expand our infectious disease programs and pipeline to combat major health burdens while democratizing access to mRNA medicines.

We view the development of vaccines and therapeutics for infectious disease as a long-term growth pillar and we believe the technology behind our COVID-19 vaccine has potential against multiple other infectious diseases, as well as potential to play an important role in future pandemic preparedness. The Company's objective is to be a leader in mRNA vaccines for infectious disease. As with our COVID-19 vaccine, several of our infectious disease vaccines are based on our lipid-nanoparticle-formulated mRNA vaccine technology, which delivers precise genetic information of the immunogen to antigen-presenting cells and elicits potent immune responses. mRNA is transiently expressed, does not integrate into the genome and is degraded by physiological pathways. mRNA vaccines are molecularly well-defined and synthesized efficiently from DNA templates by *in vitro* transcription. mRNA production and lipid nanoparticle formulation are fast and highly scalable, which makes this technology suitable for the rapid development and supply of vaccines during pandemic scenarios.



First Commercial Product: COVID-19 Vaccine BNT162b2

Our mRNA-based COVID-19 vaccine product has been authorized or approved for emergency or temporary use or granted conditional marketing authorization in more than 100 countries and regions worldwide, including the United States and the European Union, as of December 2021. In August 2021 our vaccine received full FDA Biologics License Application, or BLA, approval for individuals 16 years of age and older. As of February 2022, based on data from the Centers for Disease Control and Prevention, or CDC, approximately six out of each ten doses administered in the United States were our COVID-19 vaccine. For Europe and the United States combined, our COVID-19 vaccine has accounted for approximately 70% of doses distributed as of February 5, 2022, according to "Our World in Data Coronavirus (COVID-19) Vaccinations."

We seek to drive long-term value in our COVID-19 vaccine program by increasing patient access through enhancing manufacturing and supply capacities, conducting a global clinical program to generate data to support additional label expansions, gaining regulatory advancement across further geographies, optimizing the formulation to simplify vaccine access worldwide, and by addressing waning immune responses and emerging SARS-CoV-2 variants.

As part of our commitment to global social responsibility, we and Pfizer are committed to working toward equitable and affordable access to COVID-19 vaccines for all people around the world and actively working with governments and health partners worldwide. As part of this commitment, we and Pfizer have pledged to provide two billion doses to low- and middle-income countries through the end of 2022, of which we supplied approximately 1 billion doses in 2021. By early March 2022, approximately 1.3 billion doses were delivered to these countries.

Under our collaboration with Pfizer, we are the Marketing Authorization Holder in the United States, European Union, the United Kingdom, Canada and other countries, and the holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany, and Turkey. Fosun Pharma has marketing and distribution rights in mainland China, Hong Kong special administrative region, or SAR, Macau SAR and the region of Taiwan.

Other Infectious Disease Programs

We are investing in mRNA vaccine programs to address diseases with major impact on global population health and on people in lower income countries. Besides our COVID-19 vaccine, we are partnering with Pfizer on the development of mRNA vaccines for influenza and shingles. We are also developing multiple other infectious disease programs to address high-need indications, such as malaria, tuberculosis, HSV 2 and HIV. The WHO estimates for malaria more than 200 million cases detected every year, with young children being the worst affected as they have no immunity against the pathogen. Additionally, the WHO estimates 10 million people contracted tuberculosis in 2019. HSV 2 has an estimated global incidence of more than 27 million cases in adults and an estimated 10,000 cases of neonatal HSV 2 infections annually. For HIV, the WHO estimates that more than 35 million people live with HIV today, two thirds of which are located in the WHO African region.

As part of our plan to develop sustainable vaccine production and end-to-end supply solutions on the African continent, we are exploring possibilities for establishing state-of-the-art mRNA manufacturing facilities in Africa, either with partners or on our own. Our efforts are supported by both the WHO and the Africa Centers for Disease Control and Prevention. The European Community and other organizations have also been involved in the early planning phase of the project and offered their support to identify and set-up needed infrastructure. Our malaria project is part of the 'eradicateMalaria' initiative, a program by the kENUP Foundation.

Since 2019, we have collaborated with the Bill and Melinda Gates foundation to develop human HIV and tuberculosis programs and provide affordable access to vaccines to low- and middle-income countries. In addition to mRNA vaccines, our infectious disease toolkit includes other multiple technology platforms, including Ribologicals and a new class of precision anti-bacterials, Synthetic Lysins, which we added to our research toolkit in 2021.

1. COVID-19 Vaccine Program - BNT162b2

In January 2020, it became clear that a novel Coronavirus (2019-nCoV) was the underlying cause of a pneumonia outbreak that had occurred in December 2019 in Wuhan, China. In early January 2020, the genetic sequence of the 2019-nCoV became available to the World Health Organization (WHO) and public (MN908947.3) and the virus was categorized in the Betacoronavirus subfamily. Sequence analysis revealed a closer relationship to severe acute respiratory syndrome (SARS) virus isolates than to other coronaviruses that infect humans, including the Middle East respiratory syndrome (MERS) coronavirus. SARS-CoV-2 infections and the resulting disease, COVID-19, spread globally affecting a growing number of countries and in March 2020, the WHO characterized the COVID-19 outbreak as a pandemic. Highly effective and safe vaccines and medications to prevent and treat COVID-19 were a high unmet medical need. Vaccination is the most effective medical countermeasure to decrease risk and mitigate spread of SARS-CoV-2. Immunization with a safe and effective COVID-19 vaccine is a critical component of the global strategy to reduce COVID-19-related illnesses, hospitalizations, and deaths and to help restore societal functioning.

In response to the COVID-19 pandemic, we initiated our COVID-19 vaccine development program, BNT162, leveraging our proprietary mRNA platform. In late January 2020, we assembled a global consortium of partners including Pfizer and Fosun Pharma, and in December 2020, BNT162b2 became the first COVID-19 vaccine and first mRNA product authorized for use in both the United States and the European Union. The authorizations were based on clinical results of BNT162b2 in a global Phase 3 trial. The study results demonstrated that BNT162b2 prevents symptomatic COVID-19 with a well-tolerated safety profile. Key characteristics of BNT162b2 are its broad immunogenicity profile that is both poly-epitopic and multi-effector. BNT162b2 induces high titers of neutralizing antibodies and robust CD4+ and CD8+ T cell responses that combine to prevent disease.

Based on a comprehensive data package that included the follow-up-data from the Phase 3 trial, the FDA subsequently approved the BLA for BNT162b2 to prevent COVID-19 in individuals 16 years of age and older, making BNT162b2 the first COVID-19 vaccine to be granted full approval by the FDA. Submissions to pursue regulatory approvals in those countries where emergency use authorizations or equivalent were initially granted are ongoing.

a) Commercial update

As of mid March 2022, we and our partner Pfizer have signed orders for approximately 2.4 billion doses to be delivered in 2022. This includes agreements with the governments in the United States, United Kingdom, Japan, Canada and the European Union. Further discussions for additional dose commitments are ongoing and the order book is expected to further grow. Based on our order book and the expected continued need for booster vaccinations and vaccinations in the pediatric population, we and Pfizer are well positioned to continue to be a global leader in vaccines for the prevention of COVID-19.

We and Pfizer have an agreement with the European Commission, or the EC, that includes supplying 600 million doses of our COVID-19 vaccine to the 27 EU member states by the end of 2021, and to supply 900 million doses in 2022 and 2023, with option to request up to an additional 900 million doses. This would also cover potential vaccines adapted to variants without additional costs, if a variant vaccine is determined to be needed and subsequently authorized or approved. All doses for the EC are planned to be manufactured in the EU. In December 2021, we and Pfizer announced an agreement with the EC and its member states, pursuant to which the EC exercised its option to purchase more than 200 million additional doses of vaccine. The 200 million doses are in addition to the 450 million doses already planned to be delivered in 2022, based on an agreement signed in May 2021. The number of doses to be delivered to EC member states in 2022 will now total more than 650 million doses. In sum, the total number of potential doses delivered to the EC, inclusive of all agreements, is expected to be up to 2.4 billion by end of 2023.

The U.S. government has secured a total of 600 million doses under a supply agreement with us and Pfizer, including doses for pediatric vaccinations, and excluding one billion doses to be supplied at a not-for-profit price for donation. The U.S. government also has the option to acquire an updated version of the vaccine that includes new formulations or addresses potential viral variants, if available and authorized.

We and Pfizer plan to provide the United States government with one billion doses at a not-for-profit price, to be provided by the end of the first half of 2022. The United States government will donate vaccine doses to low- and lower middle-income countries and organizations that support them. These doses are part of BioNTech's and Pfizer's previously announced pledge to provide two billion doses of the COVID-19 vaccine to low- and middle-income countries by the end of 2022.

b) Manufacturing

In 2021 we and Pfizer delivered an aggregate of over 2.6 billion doses of BNT162b2 vaccine to more than 165 countries and territories around the world. For 2022, we and Pfizer anticipate capacity to manufacture up to four billion doses.

We and Pfizer continue to work in collaboration with governments and health ministries around the world that will distribute the vaccine, subject to country authorization or approval and terms of supply agreements, to help ensure it can reach those most in need as quickly as possible. Together with Pfizer we have developed a global COVID-19 vaccine supply chain and manufacturing network, which now spans four continents and includes more than 20 manufacturing facilities.

Our manufacturing facility in Marburg is one of the largest mRNA vaccine manufacturing sites worldwide. The facility reached an annual capacity of up to 1 billion doses mRNA drug substance in 2021. The first batches of vaccines manufactured at the Marburg facility were delivered in mid-April 2021. For 2022 we and Pfizer plan to expand the global manufacturing capacity to four billion doses. The companies have developed a global COVID-19 vaccine supply chain and manufacturing network, which now spans four continents and includes more than 20 manufacturing facilities.

We and Pfizer are also leveraging Pfizer's manufacturing site in Puurs, Belgium, one of Pfizer's largest sterile injectable sites, for European supply and as back up supply to the primary manufacturing site for the U.S. market, which is in Kalamazoo, Michigan.

As our global footprint continues to grow we are also upscaling our manufacturing capacity by establishing new manufacturing sites.

We recently announced our manufacturing solution, named "BioNTainer", which will allow for mRNA vaccine preparation in bulk. BioNTainers will be equipped to manufacture a range of mRNA-based vaccines targeted to the needs of the African Union member states. The establishment of the first mRNA manufacturing facility in the African Union is expected to start in mid-2022 and the first BioNTainer is expected to arrive in Africa in the second half of 2022.

We plan to establish a fully-integrated mRNA manufacturing facility in Singapore with support from the Singapore Economic Development Board (EDB), as well as our first regional headquarters for South East Asia. The new facility will leverage cutting-edge manufacturing and digital infrastructure and will be equipped to produce a range of novel mRNA vaccines and therapeutics. The envisioned site will bring highly automated and end-to-end mRNA production capabilities. The facility, with an estimated annual capacity of several hundred million doses, will provide regional and global supply capacity, as well as a rapid response capability for South East Asia to address potential pandemic threats. We anticipate the site could be operational as early as 2023.

We have signed a letter of intent with The Biovac Institute (Pty) Ltd., a Cape Town-based, South African biopharmaceutical company, for the manufacture of vaccine for distribution within the African Union. Biovac will perform fill and finish manufacturing and distribution activities within our and Pfizer's global COVID-19 vaccine supply chain and manufacturing network. BioVac is to start manufacturing fill and finish of up to 100 million doses annually in 2022. All doses will exclusively be distributed within the 55-member states that make up the African Union.

In August 2021 we also signed a letter of intent with Eurofarma Laboratórios SA, a Brazilian biopharmaceutical company, to manufacture vaccine for distribution within Latin America. Eurofarma will obtain drug product from facilities in the United States, and manufacturing of finished doses is expected to commence in 2022. At full operational capacity, annual production is expected to exceed 100 million finished COVID-19 doses.

c) Clinical Research & Development and Regulatory

The Phase 3 clinical trial to evaluate safety, immune response, and efficacy of BNT162b2 began in July 2020 and enrolled more than 44,000 participants from approximately 150 clinical trials sites in the United States, Germany, Turkey, South Africa, Brazil and Argentina. We and Pfizer are conducting a robust booster development program to address waning efficacy and partial escape variants and to ensure continued protection by the vaccine.

Additionally, we and Pfizer continue to monitor protection offered by BNT162b2 against emerging SARS-CoV-2 variants. BNT162b2 offers a high level of protection against variants of concern, including Alpha, Beta, and Delta, and recent laboratory studies published in *Science* demonstrated three doses of BNT162b2 neutralize the SARS-CoV-2 Omicron variant.

We and Pfizer are evaluating variant-based versions of the vaccine, including Omicron-based candidates, and are also evaluating multivalent vaccines. The studies are part of ongoing efforts to address waning efficacy seen with Omicron and to determine the need for variant-based vaccines.

Efficacy and safety

In the final efficacy analysis of the global Phase 3 clinical trial, BNT162b2 met all of the study's primary efficacy endpoints. The results demonstrated that BNT162b2 can prevent symptomatic COVID-19 with a well-tolerated safety profile. BNT162b2 demonstrated 95% efficacy in the population group 16 years of age and older, including 94% efficacy in participants older than 65 years. The safety profile was favorable, with a low frequency of Grade 3 adverse events and mostly typical vaccine-related side effects.

Six-month follow-up data from the Phase 3 trial of BNT162b2 confirmed the favorable safety profile and showed continued high efficacy through up to six months following the second dose. BNT162b2 was 91.3% effective against COVID-19, measured seven days through up to six months after the second dose. The vaccine was also 96.7% effective against severe disease as measured seven days after the second dose. Safety data collected demonstrated a favorable safety and tolerability profile with an acceptable adverse-event profile. The data were published in the New England Journal of Medicine, or NEJM, in November 2021. An additional exploratory analysis of 800 trial participants enrolled in South Africa confirmed 100% efficacy against SARS-CoV-2 lineage B.1.351 (Beta variant), which was the prevalent variant at the time the analysis was conducted. These data support previous results from immunogenicity studies published in NEJM in April 2021 demonstrating that BNT162b2 induced a robust neutralizing antibody response to the Beta variant.

The global distribution of BNT162b2 has also generated a vast array of real-world vaccine effectiveness data in diverse populations. Vaccine effectiveness following the primary two doses demonstrated protection against symptomatic infections, asymptomatic infections, severe infections, hospitalizations and deaths in real world vaccine effectiveness trials, mirroring the high efficacy and confirming the safety observed in our Phase 3 clinical trial.

SARS-CoV-2 variants

BNT162b2 offers a high level of protection against variants of concern, including Alpha, Beta, and Delta. Recent laboratory studies demonstrated that three doses of BNT162b2 neutralize the SARS-CoV-2 Omicron variant.

To address emerging variants of concern, we and Pfizer are evaluating variant-based versions of the vaccine, including Omicron-based vaccine candidates, and are also evaluating bivalent vaccines, directed against the Omicron and Wuhan strains of SARS-CoV-2. The studies are part of ongoing efforts to assess durability of efficacy and to determine the need for variant-based vaccines. We are also developing an Early Warning System in collaboration with InstaDeep based on a new computational method that analyses worldwide available sequencing data and predicts high-risk variants of SARS-CoV-2.

In our ongoing Phase 3 clinical trial to evaluate a monovalent beta-variant specific vaccine the vaccine was administered to 300 vaccinated individuals as a third dose, and to 300 vaccine naïve individuals.

Additionally, we are conducting a clinical trial to evaluate a multivalent Delta/Alpha variant-encoding vaccine and monovalent vaccines encoding either the Delta or Alpha variant. The study is expected to enroll approximately 1,200 adults 18 to 85 years of age. In this trial participants receive a 30 µg dose of a multivalent Delta and Alpha version of the vaccine, or monovalent Delta or Alpha versions, six months after the second dose of the two-dose primary series of BNT162b2. Vaccine- and SARS-CoV-2-naïve participants in the study will receive two doses of the multivalent Delta and Alpha vaccine administered 21 days apart. Data from these trials, could support a flexible platform approach for product adaptation should it be needed.

In January 2022, we and Pfizer published results from a laboratory study in *Science* demonstrating that serum antibodies induced by BNT162b2 neutralize the SARS-CoV-2 Omicron variant after three doses. Sera obtained from vaccinated individuals one month after receiving the booster dose neutralized the Omicron variant at levels comparable to those observed for the wild-type SARS-CoV-2 spike protein after two doses. One month after the third BNT162b2 dose, neutralizing antibody titers against the Omicron variant increased 23.4-fold relative to their levels 21 days after the second dose (geometric mean titer of 164 versus 7) and were comparable to neutralizing antibody titers against the wild-type virus at 21 days after two doses of BNT162b2 (geometric mean titer of 164 versus 160). Reduced neutralizing titers were demonstrated with the primary two-dose regimen against Omicron. Based on observations that approximately 85% of epitopes in the spike protein recognized by CD8+ T cells are not affected by the mutations in the Omicron variant, the companies believe two doses may still induce protection against severe disease. These data confirm previously announced initial study results.

We and Pfizer will continue to collect more laboratory data and evaluate real-world effectiveness to assess and confirm protection against the Omicron variant and inform the most effective path forward.

As part of our efforts to determine the potential need for variant-based vaccines, we and Pfizer started clinical trials to evaluate the safety, tolerability and immunogenicity of an Omicron-based vaccine in healthy adults 18 through 55 years of age. The study is evaluating approximately 2,150 participants across multiple cohorts examining different regimens of the current COVID-19 vaccine or an Omicron-based vaccine in both vaccine experienced and naive subjects. The study was expanded to include multiple new cohorts, including a cohort evaluating combination of an Omicron-based vaccine and BNT162b2, as well as an exploratory cohort evaluating a bivalent Omicron vaccine. We have scaled-up manufacturing and have started producing our Omicron-based vaccine at risk. The trial recruitment is on track and we expect to publish data in April 2022 supporting potential regulatory submissions for an Omicron-adapted vaccine.

Booster dose

Clinical data for BNT162b2 support a third dose booster of the vaccine to augment vaccine protection over time. A third booster dose of BNT162b2 has been shown to confer high neutralizing antibody titers against the SARS-CoV-2 wild type virus and also the Beta and Delta variants. Data demonstrate that the titers following a booster dose are higher than the levels observed after the two-dose primary series.

Real world data confirms that vaccine effectiveness decreases over time as the interval after the second dose increases, while vaccine effectiveness against hospitalization continues to be high. Waning vaccine effectiveness observed in the real-world setting coincided with the global spread of the Delta variant. Real world evidence also shows that high vaccine effectiveness is restored with a third dose booster, both against severe disease, as well as confirmed infection, including infections caused by the Delta variant.

In a Phase 1/2/3 booster trial of BNT162b2, a booster dose elicited significantly higher SARS-CoV-2 neutralizing antibody titers against the wild type strain compared to the levels observed after the two-dose primary series. These Phase 3 data announced in September 2021 included 306 participants 18 to 55 years of age who received a booster dose approximately six months after completing the two-dose primary regimen, with a median follow-up time of 2.6 months post-third dose. The booster dose titers against wild type virus were more than 5 times as high at one month after the third dose compared to 1 month after the two-dose primary series. The safety profile was favorable and similar to the safety profile after dose two of the primary series and generally consistent with other clinical data for BNT162b2.

Results from an ongoing Phase 3 clinical trial to evaluate the safety, tolerability and efficacy of a 30µg booster dose versus placebo in more than 10,000 participants demonstrated that a booster dose restored vaccine protection to the high levels achieved after the second dose, showing a relative vaccine efficacy of 95.6% compared to those who did not receive a booster dose. The participants were 16 years of age and older and had previously received two doses of BNT162b2 at least six months prior to randomization. These first results from a randomized, controlled COVID-19 vaccine booster dose trial were announced in October 2021. Multiple subgroup analyses showed efficacy was consistent irrespective of age, sex, race, ethnicity and co-morbidities. The adverse event profile was consistent with previous clinical safety data.

Based on these data from our booster trials, a third dose booster of BNT162b2 was authorized by the FDA for emergency use after completion of a primary series in individuals 18 years of age and older. In January 2022, the FDA expanded the Emergency Use Authorization of a booster dose to include individuals 12 years of age and older. The booster dose is the same dosage strength, 30 µg, as the dose approved in the primary series.

The EC approved a variation to the CMA for the administration of a third dose booster of BNT162b2 at least six months after the second dose in individuals 18 years of age and older, and of a third dose in individuals with severely weakened immune systems at least 28 days after their second dose. In February 2022 the EC approved a variation to the CMA to include the administration of BNT162b2 as a booster dose in adolescents 12 through 17 years of age. The data are also being submitted to other regulatory authorities worldwide.

In March 2022, the U.S. FDA expanded the EUA for the COVID-19 vaccine to include a second booster dose for individuals aged 50 years and older who have previously received a booster of any authorized or approved COVID-19 vaccine. The FDA also authorized a second booster dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine. The second booster is to be administered at least four months after the first booster and is the same formulation and strength as prior doses. The EUA expansion is based on two real-world data sets from Israel analyzed at a time when the Omicron variant was widely circulating showing evidence that additional boosters increase immunogenicity and lowers rates of confirmed infections and severe illness.

An analysis of Israeli Ministry of Health records was conducted for over 1.1 million adults 60 years of age and older who had no known history of SARS-CoV-2 infection and were eligible for an additional (fourth dose) booster. Rates of confirmed infections were 2 times lower and rates of severe illness were 4 times lower among individuals who received an additional booster dose administered at least four months after an initial booster (third) dose compared to those who received only one booster dose in this analysis.

Also included in the submission were results from an ongoing, open-label, non-randomized clinical trial in healthcare workers 18 years of age and older at a single study center in Israel who had been vaccinated with three doses showed that . Among the 154 (out of 700) participants who received an additional booster (fourth) dose at least four months following the initial booster, neutralizing antibody titers increased approximately 7-fold to 8-fold at two and three weeks after the additional booster (fourth) dose compared to five months after the initial booster (third) dose. There was also an 8-fold and 10-fold increase in neutralizing antibody titers against the Omicron variant (B.1.1.529) at one and two weeks after the additional booster dose, respectively, compared to five months after the initial booster. No new safety concerns were revealed in individuals who received an additional booster dose of the vaccine.

Label expansion

Data from a Phase 3 trial in adolescents aged 12 to 15 demonstrated that BNT162b2 had 100% efficacy and robust antibody responses in adolescents aged 12 to 15 with or without prior evidence of SARS-CoV-2 infection. The Phase 3 trial enrolled 2,260 adolescents in the United States. In the trial, 18 cases of COVID-19 were observed in the placebo group (n=1,129) versus none in the vaccinated group (n=1,131). Vaccination with BNT162b2 elicited high neutralizing antibody titers, demonstrating strong immunogenicity in a subset of adolescents one month after the second dose. BNT162b2 administration was generally well tolerated. Based on this data, BNT162b2 has received expanded emergency use authorizations, conditional marketing authorizations or equivalent for adolescents 12 years of age and older in the United States, European Union and Canada and additional countries.

We and Pfizer have submitted a supplemental Biologics License Application (sBLA) to the U.S. FDA to expand the approval of BNT162b2 to include individuals aged 12 through 15 years. The sBLA includes updated longer-term follow-up data from our pivotal Phase 3 clinical trial including 2,228 participants 12 through 15 years of age. In the trial, a two-dose series of BNT162b2, 30-µg per dose, was 100% effective against COVID-19, measured seven days through over four months after the second dose. This was during a time when the Delta variant was the dominant circulating strain. Among 30 confirmed symptomatic cases of COVID-19 in the trial, with and without evidence of prior infection with SARS-CoV-2, all cases of COVID-19 were in the placebo group (n=1,129) and no cases were in the BNT162b2 group (n=1,131). The adverse event profile was generally consistent with other clinical safety data for the vaccine, with a favorable safety profile observed in individuals with at least 6 months of safety follow-up after the second dose. We and Pfizer have also submitted these data to the EMA and intend to file these data with other regulatory authorities around the world.

To support the extension of the vaccine label to include children under 12 years of age, we and Pfizer are conducting a Phase 1/2/3 trial in children ages 6 months to under 12 years of age, which is enrolling up to 4,500 participants at more than 90 clinical trial sites. The trial was designed to evaluate the safety, tolerability, and immunogenicity of BNT162b2 on a two-dose schedule (approximately 21 days apart) in three age groups: ages 5 to under 12 years; ages 2 to under 5 years; and ages 6 months to under 2 years. Based on the Phase 1 dose-escalation portion of the trial, children ages 5 to under 12 years received a two-dose schedule of 10 µg each, while children under age 5 received a lower 3 µg dose for each injection in the Phase 2/3 study. The trial enrolled children with or without prior evidence of SARS-CoV-2 infection. Data from the Phase 2/3 trial data in this age group showed a favorable safety profile, robust immune responses and a vaccine efficacy rate of 90.7% in participants without prior SARS-CoV-2 infection, measured from seven days after the second dose, during a period when Delta was the prevalent strain.

Based on scientific evidence shared by the companies, including results from the Phase 2/3 children cohort that included approximately 4,500 children 5 to under 12 years of age (2,268 from the original group and 2,379 from the supplemental safety group), BNT162b2 received the first FDA EUA for a COVID-19 vaccine in children ages 5 through 11 years of age and the EC also approved the administration of BNT162b2 in children 5 to under 12 years of age, making it the first COVID-19 vaccine authorized in the European Union in this population.

Following a routine review by the external independent Data Monitoring Committee (DMC), we and Pfizer decided to amend the clinical study in children 6 months to under 5 years of age. The study will now include evaluating a third dose of 3 µg at least two months after the second dose of the two-dose series to provide high levels of protection in this young age group. While the study is ongoing and remains blinded, a pre-specified immunogenicity analysis was conducted on a subset of the study population one month following the second dose. Compared to the 16- to 25-year-old population in which high efficacy was demonstrated, non-inferiority was met for the 6- to 24-month-old population, but not for the 2- to under 5-year-old population in this analysis. No safety concerns were identified and the 3 µg dose demonstrated a favorable safety profile in children 6 months to under 5 years of age. We and Pfizer believe a three-dose regimen may provide a

higher level of protection in this age group. This is also supported by observations of three dose booster data in several other age groups that seem to meaningfully augment neutralizing antibody levels and real world vaccine protection for Omicron compared to the two dose regimen. The three dose protection data in children 6 months to under 5 years of age are expected to be available in early April 2022. The data will be submitted to the FDA and other regulators to support expansion of authorizations and approvals for this age group. We and Pfizer are also evaluating a third doses of the 10 µg formulation in children 5 to under 12 years of age.

Following a request from the FDA, we and Pfizer initiated a rolling submission seeking to amend the EUA to include children 6 months through 4 years of age in response to the urgent public health need in this population. The application was for authorization of the first two 3 µg doses of a planned three-dose primary series in this age group. Subsequently, we and Pfizer announced plans to extend the rolling submission. Data from the first two doses are being shared with the FDA and cases continue to accumulate and more data are being generated as rates of infection and illness remain high in this age group, especially given recent Omicron variant surge. The companies believe that waiting for the three-dose data is important as the companies believe three doses will provide a higher level of protection in this age group.

To ensure protection against COVID-19 in pregnant women we are conducting a global Phase 2/3 trial to evaluate the safety, tolerability and immunogenicity of BNT162b2 in preventing COVID-19 in healthy pregnant women 18 years of age and older. The study will also assess safety in infants of vaccinated pregnant women and the transfer of potentially protective antibodies to their infants.

In February 2022, the EU Product Information of COMIRNATY® was updated to include the use of the vaccine during pregnancy. A large amount of data from pregnant women vaccinated with BNT162b2 during the second or third trimester of their pregnancy has been analyzed and showed no increase in pregnancy complications. Although data in the first trimester of pregnancy are more limited, no increased risk of miscarriage was seen. The EU Product Information was also updated to include the use during breast-feeding. Data from women who were breast-feeding after vaccination have not shown a risk of adverse effects in breast-fed babies.

d) Formulation and Stability

Over the last year we have continued to further optimize our vaccine formulations as well as to improve storage and transport conditions to simplify access globally. The FDA and the EMA and other regulatory authorities worldwide have authorized the extension of the shelf-life of the COVID-19 vaccine from six to nine months when stored at -90ºC to -60ºC. Regulatory authorities worldwide have also approved that undiluted frozen vials of BNT162b2 may be transported and stored at conventional temperatures commonly found in pharmaceutical freezers (-25°C to -15°C or -13°F to 5°F) for a period of up to two weeks, and that thawed, undiluted vials may be transported and stored at fridge temperatures of 2°C to 8°C for up to one month (31 days).

The EC and the FDA have also authorized a new formulation of BNT162b2, that further simplifies vaccine handling. The new formulation also allows for longer storage, as vials can be stored for 10 weeks at refrigerator temperatures from 2°C to 8°C, and after first puncture, can be stored and transported at 2°C to 30°C and used within 12 hours. The new formulation was rolled out in November 2021 in the United States and in December 2021 in the EU. To date been deliveredto more than 50 countries.

e) Phase 2 Clinical Trial in China

Under our collaboration with Fosun, we are conducting a Phase 2 clinical trial of BNT162b2 in Jiangsu Province, China to assess the safety and immunogenicity of BNT162b2 and to support a future Biologic License Application in China.

2. Influenza Vaccine Program – BNT161

We are collaborating with Pfizer to develop an influenza vaccine based on our suite of mRNA platforms.

a. BNT161

On September 27, 2021, the first participants were dosed in a Phase 1 clinical trial to evaluate the safety, tolerability and immunogenicity of a single dose quadrivalent mRNA vaccine, BNT161, against influenza in healthy adults 65 to 85

years of age, with an FDA-approved standard quadrivalent influenza vaccine as a control. BNT161 encodes World Health Organization recommended strains. Data from the trial is expected in the first half of 2022.

b. saRNA influenza vaccine

We and Pfizer plan to start a clinical study to evaluate a self-amplifying mRNA, or saRNA, vaccine against influenza. This planned dose-finding study will evaluate the safety, tolerability, and immunogenicity of the saRNA vaccine against influenza in healthy adults 18 through 49 years of age.

3. Shingles Vaccine Program

In January 2022 Pfizer and BioNTech signed a new global agreement to develop the first mRNA-based shingles vaccine candidate. Under the terms of the agreement the companies will leverage a proprietary antigen technology identified by Pfizer's scientists and our proprietary mRNA platform technology used in the companies' COVID-19 vaccine. The goal is to develop an mRNA vaccine with a favorable safety profile and high efficacy, utilizing a scalable manufacturing technology to support global access. Clinical trials are planned to start in the second half of 2022.

4. Malaria Vaccine Program

We plan to develop an mRNA vaccine candidate to potentially prevent malaria and disease-associated mortality. We will assess multiple vaccine candidates featuring known targets such as circumsporozoite protein (CSP) as well as newly discovered antigens.

In 2019, according to the WHO, there were an estimated 229 million cases of malaria worldwide. The estimated number of malaria deaths stood at 409,000 in 2019. Children aged under 5 years are the most vulnerable group affected by malaria. In 2019, they accounted for 67% (274,000) of all malaria deaths worldwide. The WHO African Region carries a disproportionately high share of the global malaria burden. In 2019, 94% of malaria cases and deaths worldwide were reported on the African continent.

A clinical trial for an mRNA-based malaria vaccine is planned to start in the second half of 2022.

5. Tuberculosis Vaccine Program - BNT164

We have collaborated with the Bill and Melinda Gates Foundation since 2019 to develop vaccine candidates aimed at preventing tuberculosis infection and disease.

Tuberculosis is a worldwide leading cause of death due to an infectious disease, second only to COVID-19. In 2020, approximately 10 million people developed active tuberculosis and 1.3 million people died from this disease. The WHO estimates that 25% of the world's population is latently infected with Mycobacterium tuberculosis, the bacteria responsible for the disease, and approximately 5 to 10% of infected individuals will develop tuberculosis disease.

There is still a high unmet medical need for a safe, effective, and durable vaccine to prevent the development and spread of pulmonary tuberculosis.

The collaboration will initially develop first mRNA vaccine candidates targeting tuberculosis.

A clinical trial for a tuberculosis vaccine candidate is planned to begin in the second half of 2022, just two years after the tuberculosis program was initiated.

6. HSV 2 Vaccine Program

We are developing an HSV 2 vaccine candidate under our pre-clinical collaboration with the University of Pennsylvania.

HSV 2 affects an estimated 491 million (13%) people aged 15–49 years worldwide (2016 data).

A clinical trial is planned to start in the second half of 2022.

7. Anti-bacterials

We acquired PhagoMed, a biotechnology company based in Vienna, Austria in October 2021. The acquisition expands our infectious disease toolkit into synthetic lysins, a new class of Precision Anti-bacterials, which we believe have potential to address a wide range of pathogens and also the global challenge of anti-microbial resistance.

The acquisition includes PhagoMed's LysinBuilder technology, a proprietary *in silico* therapeutics platform designed to enable the rapid production of recombinant natural lysins which are optimized for potency, stability, and manufacturing yield.

8. Other Infectious Disease programs

We have a research collaboration with the University of Pennsylvania under which we have the exclusive option to develop and commercialize prophylactic mRNA immunotherapies for the treatment of up to 10 infectious disease indications.

Our infectious diseases portfolio also includes a HIV vaccine (in collaboration with the Bill & Melinda Gates foundation) and additional five undisclosed programs.

B. Oncology Programs

Our immuno-oncology strategy is based on pioneering approaches to modulate the immune response to treat cancer. We have multiple assets across different therapeutic classes with potential to tackle tumors using complementary strategies, either by targeting tumor cells directly, or by modulating the immune response against the tumor. Our oncology pillars include mRNA therapeutic vaccines, CAR-T immunotherapies, cell therapies, individualized neoantigen specific immunotherapies, RiboMabs, next-generation checkpoint immunomodulators, anti-tumor antibodies and small molecules. Many product candidates have the potential to be combined with other pipeline assets or previously approved therapies.

This diverse toolkit of different technologies and modes of action has potential to address a broad range of solid tumors in different disease stages, using both off-the-shelf and individualized approaches. We have assembled libraries of more than 300 proprietary or known shared antigens and has developed predictive algorithms capable of efficiently identifying multiple neoantigens on an individualized basis for any patient.

We drove strong clinical execution in 2021 with advancement of four immuno-oncology programs into randomized Phase 2 studies, and five first in human trial starts, bringing our clinical pipeline to a total of 16 product candidates in 20 ongoing clinical trials. Our clinical stage oncology pipeline now includes five randomized Phase 2 clinical trials: two FixVac programs (BNT111 and BNT113), two indications for the iNeST product candidate autogene cevumeran (BNT122, RO7198457), and the bispecific antibody checkpoint immunomodulator BNT311 (GEN1046). Also, a first-in-human trial was started in January 2022 for the first product candidate from our RiboMabs program, BNT141. We expect continued pipeline advancement and expansion in 2022.

1. mRNA Product Class in Oncology

a) FixVac

FixVac is our wholly owned, systemic, off-the-shelf mRNA-based cancer immunotherapy platform, from which we are developing several first-in-human and potential first-in-class product candidates. Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. FixVac product candidates feature our proprietary immunogenic mRNA backbone and proprietary RNA-LPX delivery formulation for intravenous administration, which are designed to enhance stability and translation as well as trigger both innate and adaptive immune responses. FixVac product candidates may be of clinical utility in combination with anti-PD1 in patients with a lower mutational burden, including those who have already experienced checkpoint inhibitor (CPI) therapy.

Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2
BNT111	Advanced melanoma			
BNT112	Prostate cancer			
BNT113	HPV16+ head and neck cancer			
BNT115*	Ovarian Cancer			
BNT116	NSCLC			

*BNT115 is being studied in an investigator-initiated and –sponsored Phase 1 trial

i. BNT111: Our FixVac Cancer Immunotherapy for the Treatment of Advanced Melanoma

We are developing our mRNA-based FixVac product candidate BNT111 for the treatment of advanced melanoma in patients with metastatic tumors. We are currently studying BNT111 in an ongoing Phase 1 trial and we started a randomized Phase 2 clinical trial in June 2021.

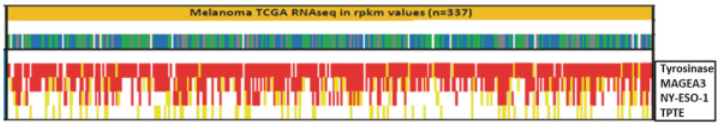
Our BNT111 Targets

BNT111 is designed to elicit an immune response to the following four antigens that have each been found to be associated with melanoma:

- New York esophageal squamous cell carcinoma 1, or NY-ESO-1, a well-known cancer-testis antigen that is also expressed in numerous cancers, including melanoma;

- melanoma-associated antigen A3, or MAGE-A3, which is not expressed in normal tissues, except the testis;
- tyrosinase, an enzyme that is required for melanin production and that is expressed at high levels in melanoma; and
- trans-membrane phosphatase with tensin homology, or TPTE, a novel cancer/testis antigen that we discovered internally.

Sequencing data from 337 melanoma tumors showed that at least one of these four antigens is detected in over 90% of such melanoma tumors.



BNT111 antigens detected in over 90% of melanoma tumors. The graphic above shows expression of BNT111 target antigens on a patient by patient basis. Each row at the bottom of the graphic represents an antigen, and each vertical line represents a patient, depicting whether or not that patient's tumor expressed each antigen. Red/yellow = antigen is expressed in patient's tumor; white = no expression.

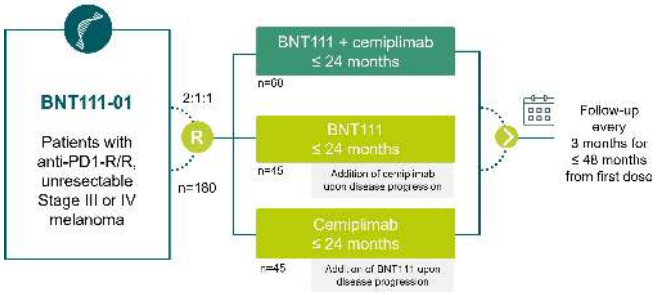
Our BNT111 Clinical Trials

Ongoing Phase 2 Trial with anti-PD-1 Therapy

In June 2021 we dosed the first patient in a randomized Phase 2 trial for the treatment of patients with advanced melanoma progressing during or after prior therapy with a PD-1 inhibitor. The trial, which we are conducting in collaboration with Regeneron, is a global, three-arm Phase 2 trial evaluating BNT111 in combination with cemiplimab (Regeneron and Sanofi's Libtayo®), versus both agents as monotherapy, in 180 patients with anti-PD-1-refractory/relapsed unresectable Stage III or IV melanoma. The primary endpoint is overall response rate in the BNT111 plus cemiplimab arm.

In 2021, BNT111 received two FDA designations. In November 2021, the FDA granted Fast Track Designation for BNT111 in combination with cemiplimab in patients with anti-PD-1-refractory/relapsed, unresectable Stage III or IV melanoma. In September 2021, the FDA granted Orphan Drug Designation for the treatment of stage IIB through IV melanoma.

Melanoma remains one of the deadliest types of skin cancer with a 5-year survival for Stage IV metastatic disease of only 22.5%. In the refractory or relapsed setting, survival can be as short as six months depending on risk factors. Up to 50% of patients progress after treatment with checkpoint inhibitors.



Trial design of BNT111 Global Phase 2 Clinical Trial in Anti-PD-1 Relapsed/Refractory Melanoma Patients

Ongoing Phase 1 Trial in Advanced Melanoma Patients (LIPOMERIT trial).

We are conducting a multi-center, open-label, first-in-human, Phase 1 dose escalation study evaluating the safety and tolerability of multiple intravenous administrations of BNT111 in patients with advanced melanoma. This is the first clinical trial worldwide in which an mRNA-based cancer immunotherapy is administered intravenously for systemic treatment.

The trial employed a conventional 3+3 design in which patients were dosed in groups of three at incrementally greater dosages until the maximum tolerated dose was identified, during the dose escalation phase, which was then followed by expanded dose cohorts. Patients were treated with doses from 7.2µg up to the highest administered dose of 400µg of total RNA.

November 2021 Data update from BNT111 Lipo-MERIT Trial

At SITC 2021, we presented additional data from the ongoing Phase 1 trial evaluating the safety and tolerability of BNT111 in patients with advanced melanoma with a focus on patients who had no evidence of disease (NED) who received BNT111 as monotherapy for 8 vaccinations. Overall, data demonstrated a favorable safety profile for BNT111, with similar safety in patients with evidence of disease (ED) and NED. Most treatment-related adverse events were pyrexia, followed by mostly mild-to-moderate flu-like systems. Overall, the rate of serious adverse events was low.

As of May 24, 2021, a T-cell response against at least one tumor associated antigen (TAA) was observed by post in vitro stimulation (IVS) ELISpot analyses in all 15 patients (9 ED patients and 6 NED patients) with available samples. A

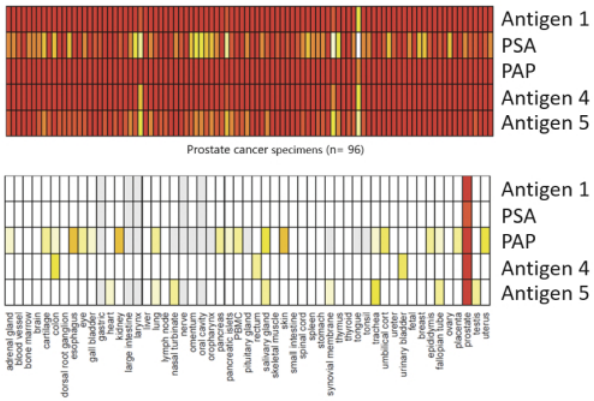
robust BNT111-induced T-cell responses as detected by ex vivo ELISpot was demonstrated in 14 of 22 (64%) patients with ED and 19 of 28 (68%) patients with NED against at least one tumor-associated antigen. A substantial proportion of patients presented de novo T-cell responses present only after vaccination. The median disease-free survival of patients with no evidence of disease was 34.8 months, highlighting that BNT111 monotherapy shows promising signals of prolonged disease control in patients with no evidence of disease.

ii. BNT112: Our FixVac Cancer Immunotherapy for the Treatment of Prostate Cancer

We are developing BNT112 for the treatment of prostate cancer.

Our BNT112 Targets

BNT112 is designed to elicit an immune response to five prostate cancer-specific antigens, including prostate-specific antigen, or PSA, a transmembrane protein that is expressed by virtually all prostate cancers, prostatic acid phosphatase, or PAP, and three additional tumor-associated antigens.



Our BNT112 Clinical Trials

Ongoing Phase 1/2 Clinical Trial (PRO-MERIT)

PRO-MERIT is a first-in-human, dose titration and expansion trial to evaluate safety, immunogenicity and preliminary efficacy of BNT112 monotherapy and in combination with cemiplimab in patients with prostate cancer. The study is a Phase 1/2, open-label, multicenter trial for localized and metastatic castration resistant prostate cancer patients (mCRPC) and patients with high-risk, localized prostate cancer (LPC) eligible for treatment with androgen deprivation therapy (ADT) followed by radical prostatectomy. The Phase 1/2 trial consists of two parts: dose titration (Part 1) and dose expansion (Part 2). The trial started end of 2019. In January 2021 we enrolled the first patient in the expansion part of the trial.

The primary objectives of this study are to establish the safety and tolerability profile of BNT112 monotherapy or in combination with cemiplimab (Parts 1 and 2), and to evaluate preliminary anti-tumor activity of BNT112 monotherapy and in combination with cemiplimab in patients with mCRPC based on ORR (Part 2). The secondary objectives of the trial are to examine the immunogenicity of BNT112 alone or in combination with cemiplimab, to evaluate anti-tumor activity based on levels of PSA, and to evaluate preliminary anti-tumor activity of BNT112 monotherapy and in combination with cemiplimab in patients with mCRPC based on ORR (Part 1) and in patients with newly diagnosed LPC.

Part 1 is a first-in-human, single arm design for mCRPC patients. It starts with an intra-patient dose titration in Cycle 1 for the initial safety assessment and recommended expansion dose range assessment. Part 2 consists of four arms (1A, 1B,

2 and 3), with similar intra-patient dose titration in Cycle 1, for both mCRPC and LPC indications, and targeting to enroll approximately 106 patients. Arms 1A and 1B are designed to treat mCRPC patients with a combination treatment (BNT112 and cemiplimab) and monotherapy (BNT112), respectively. Arms 2 and 3 are designed to treat LPC patients with a combination treatment (BNT112 and cemiplimab) and monotherapy (BNT112), respectively, plus a background medication of an androgen-deprivation therapy (e.g. goserelin acetate).

November 2021 Data update from BNT112 PRO-MERIT Trial

At SITC 2021, we presented data from the ongoing Phase 1/2 trial of BNT112 as a monotherapy and in combination with cemiplimab in patients with metastatic castration-resistant prostate cancer (mCRPC). As of June 2021, nine patients were treated with BNT112 monotherapy in Part 1, and five patients were treated in Part 2, in which patients received BNT112 only or in combination with cemiplimab. Overall, most adverse events that occurred in part 1 were mild or moderate. There were two instances of grade 3 hypertension leading to dose reductions; both patients recovered within 24 hours and these events did not meet the criteria of dose-limiting toxicities. All reported serious adverse events in part 1 were considered unrelated to BNT112. No safety signals or concerns were identified in part 1 or the ongoing part 2.

Additionally, data suggest that BNT112 induces robust immune responses, as de novo induction and expansion of pre-existing antigen-specific T-cell responses was observed in all patients with available Post-IVS-ELISpot. The data also demonstrated that all five tumor-associated antigens were immunogenic and T cell responses to each antigen were identified in at least 2 patients. Two patients with late-stage cancer treated with BNT112 monotherapy had decreases in prostate-specific antigen, a well-known prostate cancer biomarker. In summary, these data suggest that BNT112 has a tolerable safety profile with first signal of activity in patients with advanced prostate cancer.

iii. BNT113: Our FixVac Cancer Immunotherapy for the Treatment of HPV16+ Head and Neck Cancer

We are developing BNT113 for the treatment of HPV+ head and neck cancer.

Our BNT113 Clinical Trials

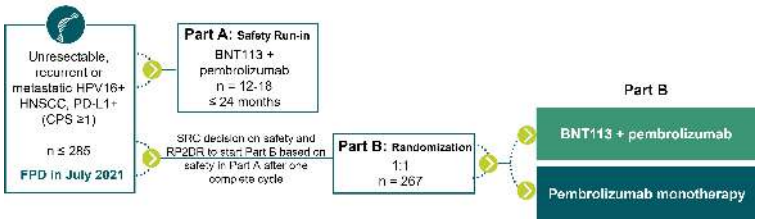
Ongoing BNT113 Phase 2 Trial

In July 2021 we dosed the first patient in an open-label, controlled, multi-site, interventional, 2-arm, Phase 2 trial evaluating BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ PDL1+ head and neck squamous cell carcinoma (HNSCC) expressing PD-L1. The trial is being conducted in the United States and the EU,

BNT113 has not previously been combined with anti-PD1 therapy, and the Phase 2 trial will start with a run-in portion (Part A) designed to demonstrate the safety of the combination of BNT113 and pembrolizumab. The trial will be advanced to Part B after safety and recommended Phase 2 dosage has been confirmed (after approximately 12 to 18 patients have completed one cycle in Part A).

Part B is planned to enroll a total of 267 patients. Primary endpoints include overall survival and objective response rate. Secondary endpoints include progression free survival, durable complete responses, duration of response, patient reported outcomes and quality of life measures.

HPV-associated cancers are increasing, with HPV16+ HNSCC typically occurring in younger people. Most patients with HPV16+ HNSCC are diagnosed at more advanced clinical stages. BioNTech sees a significant opportunity to improve the treatment landscape with BNT113 given that it has the potential to augment clinical responses in patients being treated with checkpoint inhibitors.



Trial design of BNT113 Phase 2 trial in HPV16+ and PD-L1+ HNSCC

Ongoing Phase 1/2 Basket Trial (Investigator-Sponsored)

BNT113 is being studied by the University of Southampton in an investigator sponsored open-label, Phase 1/2 dose escalation basket study with two different arms in approximately 44 patients with HPV16+ head and neck and other cancers. The first arm will perform dose escalation in patients with previously treated HPV16+ head and neck cancer using two dose cohorts to establish a safe, tolerable and recommended dose of BNT113. The second arm will perform dose escalation in patients with advanced HPV16+ cancers, including head and neck, anogenital, penile and cervical cancers, using a single cohort to establish a safe, tolerable and recommended dose.

iv. BNT114: Our FixVac Cancer Immunotherapy for the Treatment of Triple Negative Breast Cancer

We are studying eight antigens selected for BNT114 in a three-arm clinical trial as both a monotherapy and in combination with our individualized neoantigen specific vaccine in patients with triple negative breast cancers (TNBC).

Our BNT114 Targets

Patients are treated with individualized combinations of BNT114 antigens. BNT114 is designed to provide patients with an optimal combination of antigens and to elicit an immune response to selected antigens that are expressed in the patients' tumor.

Our BNT114 Clinical Trial

Phase 1 Clinical Trial (BNT114 monotherapy and in combination with our neoantigen vaccine)

In 2021 we completed the main study phase of an international, multi-center, open-label, three-arm Phase 1 study of BNT114 as a monotherapy and in combination with our individualized neoantigen specific immunotherapy in TNBC patients who had previously received the standard of care therapy (i.e., surgery, chemotherapy and/or radiotherapy).

Patients in the first arm receive BNT114, patients in the second arm receive a combination of optional BNT114 followed by individualized neoantigen specific immunotherapy and patients in the third arm receive BNT114 in combination with RNA-LPX encoding tetanus-toxoid-derived helper epitopes.

The trial results were summarized in a clinical trial report. A long-term follow-up period is ongoing until 2023 for patients receiving the individualized neoantigen specific vaccine only. Treatment with an on demand manufactured BNT114-vaccine was feasible in terms of timelines, logistics, and patient burden in a standard clinical healthcare setting. Main study data demonstrated that treatment with BNT114 had an acceptable safety and tolerability profile, which was in line with the known mode of action and was accompanied by transient increases in cytokine levels.

v. BNT115: Our FixVac Cancer Immunotherapy for the Treatment of Ovarian Cancer

We are developing BNT115 for the treatment of ovarian cancer. BNT115 is currently being studied in an ongoing investigator-initiated and -sponsored Phase 1 trial.

Our BNT115 Targets

BNT115 is designed to elicit an immune response to selected antigens that are found in epithelial ovarian cancers.

Our BNT115 Clinical Trial

Ongoing Phase 1 Trial (Investigator-Initiated and Sponsored)

BNT115 is being studied in an investigator-initiated and -sponsored, first-in-human, open label, Phase 1 dose escalation trial in 10 evaluable ovarian cancer patients eligible for standard-of-care treatment with (neo-) adjuvant chemotherapy. Eight doses of BNT115 will be administered prior to and in combination with the (neo-) adjuvant chemotherapy to induce an anti-tumor immune response. Systemic induction and/or expansion of BNT115 vaccine antigen-specific T cells, as well as intratumoral T cell infiltration, will be analyzed. The trial is currently recruiting.

vi. BNT116 : Our FixVac Cancer Immunotherapy for the Treatment of Non-small Cell Lung Cancer

We are developing BNT116 for the treatment of non-small cell lung cancer.

In March 2022, we announced the expansion of our strategic collaboration with Regeneron. Under the agreement, the combination of BNT116 and Libtayo is expected to be advanced into clinical development for the treatment of advanced NSCLC. We and Regeneron will jointly conduct trials to evaluate the combination in different patient populations.

Our BNT116 Targets

BNT116 is designed to elicit an immune response to 6 tumor- associated antigens that cover up to 100% of patients in all major histologic subtypes of Non-small cell lung cancer.

Our BNT116 Clinical Trial

Planned Phase 1 Trial

We expect to start a first-in-human clinical trial to evaluate the safety, tolerability and preliminary efficacy of BNT116 alone and in combination with Libtayo in patients with advanced non-small cell lung cancer in the second half of 2022.

b) Individualized Neoantigen Specific Immunotherapy (iNeST)

iNeSTs are individualized cancer immunotherapies that target specific neoantigens that are present on a patient's tumor. Our iNeST immunotherapies contain pharmacologically optimized uridine mRNA encoding up to 20 patient-specific neoantigens, delivered in our proprietary RNA-LPX formulation. Individual mRNA cancer vaccines use the patient's own tumor mutations to generate neoantigen specific CD4 and CD8 T cell responses in vivo. BioNTech believes this modality is well-suited for use in early-stage cancers and in the adjuvant setting. We are developing our iNeST autogene cevumeran in collaboration with Genentech.

i. Autogene cevumeran (BNT122): Our iNeST Cancer Immunotherapy for Multiple Potential Indications

We and our collaborator Genentech are developing autogene cevumeran (BNT122) for the treatment of metastatic cancers. We are currently conducting a randomized Phase 2 trial of autogene cevumeran in collaboration with Genentech in first-line melanoma in combination with pembrolizumab. In collaboration with Genentech, we are also studying autogene cevumeran as a monotherapy and in combination with atezolizumab in a Phase 1a/1b study of patients with locally advanced or metastatic solid tumors (including melanoma, non-small cell lung cancer, bladder cancer as well as other solid tumors). We are now moving into the adjuvant treatment space with a randomized Phase 2 trial in colorectal cancer patients, for which we announced first patient dosed in October 2021.

Our autogene cevumeran (BNT122) Targets

Autogene cevumeran (BNT122) is an individualized neoantigen-specific immunotherapy. Each autogene cevumeran dose includes up to 20 different neoantigens selected on a patient-by-patient basis. We believe that neoantigenspecific T cells induced by autogene cevumeran may be able to enhance the therapeutic efficacy of immune checkpoint blockade.

Our autogene cevumeran (BNT122) Clinical Trials

Ongoing Phase 2 Clinical Trial (First-line melanoma with pembrolizumab)

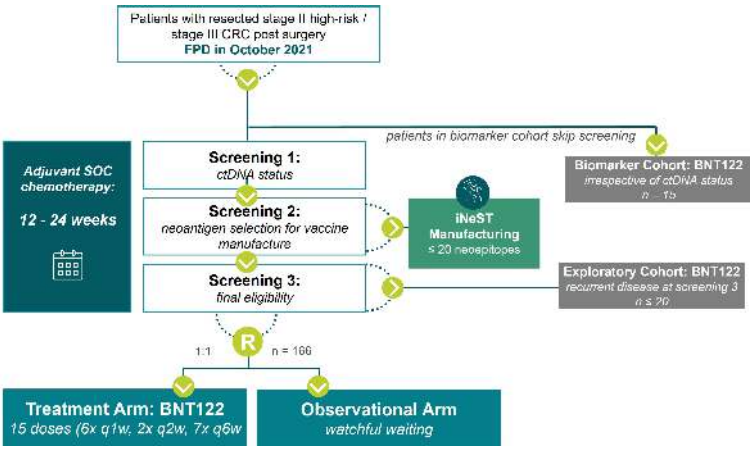
We and Genentech are investigating the safety and efficacy of autogene cevumeran (BNT122) in 126 patients with previously untreated metastatic melanoma in a Phase 2, open-label, multi-center, randomized clinical trial. Patients in the experimental arm will receive pembrolizumab by intravenous infusion every three weeks, plus a selected dose of autogene cevumeran at defined intervals. Patients in the active comparator arm will receive 200mg of pembrolizumab by intravenous infusion every three weeks. Patients in the comparator arm experiencing confirmed disease progression will be permitted to cross over to combination therapy with autogene cevumeran The primary endpoint is progression-free survival (PFS) of patients treated with autogene cevumeran compared with patients receiving pembrolizumab alone, according to RECIST v1.1. Secondary endpoints include objective response rate (ORR), overall survival (OS), duration of response (DOR) and safety.

We expect a data update in the second half of 2022.

Ongoing Phase 2 Trial in adjuvant colorectal cancer

In October 2021, the first patient was dosed in a randomized, multi-site, open-label Phase 2 trial in the adjuvant treatment of circulating tumor DNA (ctDNA) positive, surgically resected Stage II (high risk)/Stage III colorectal cancer. The trial plans to enroll about 200 patients to evaluate the efficacy of autogene cevumeran compared to watchful waiting after surgery and chemotherapy, the current standard of care for these high-risk patients. The primary endpoint for the study is disease-free survival (DFS). Secondary objectives include overall survival (OS) and safety. The trial has been initiated in the United States, Germany, Spain and Belgium.

The medical need for novel therapies to treat colorectal cancer, as the second deadliest cancer worldwide, remains high. The current standard of care in this indication is watchful waiting to see if tumors recur after removal of the primary tumor and adjuvant chemotherapy. A proportion of these patients are expected to have a recurrence of their tumor within 2-3 years after their surgery. For this clinical trial, patients at high risk for recurrence will be selected with a highly sensitive blood test detecting circulating tumor DNA (ctDNA).



Trial design of Autogene cevumeran (BNT122) Phase 2 Clinical Trial in Adjuvant Colorectal Cancer

Phase 1 Clinical Trial

In 2021 we completed enrollment in the Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial of Autogene Cevumeran. The trial was a non-registrational, signal seeking study in patients with locally advanced or metastatic solid tumors, including patients with melanoma, non-small cell lung cancer, bladder cancer, colorectal cancer, TNBC, renal cancer, head and neck cancer and sarcomas as well as other solid tumors. The study was designed to enroll both patients with and without prior checkpoint inhibitor regimens.

The primary objective of the study was to assess safety (including dose-limiting toxicities), and additional objectives included evaluation of immunogenicity and preliminary assessment of anti-tumor activity. The trial included a Phase 1a (monotherapy) dose escalation, a Phase 1b (combination) dose escalation, and multiple Phase 1b expansion cohorts. Patients received nine doses of the vaccine administered I.V. in weekly and bi-weekly intervals during the 12-week induction stage and every 24 weeks during the maintenance stage. In the Phase 1b portion of the trial, atezolizumab was administered on day one of each 21-day cycle.

Autogene cevumeran was manufactured on a per-patient basis including in-house determination of cancer mutation profiles, computational prediction of neoantigens, design, and manufacturing of autogene cevumeran based on liposomally formulated RNA (RNA-LPX). Each drug product contained up to 20 patient-specific neoantigens.

June 2020 Monotherapy Data Update Phase 1a/basket trial

At the 2020 AACR conference, we presented data from monotherapy dose-finding cohorts of our autogene cevumeran phase 1 trial in multiple solid tumors in which autogene cevumeran was observed to have a manageable safety profile and induced strong neoantigen-specific immune responses in patients with low and intermediate mutational load tumor types. This data related to 31 patients enrolled in cohorts with doses ranging from 25-100µg. Most patients enrolled had a low level of PD-L1 expression in the tumor. The majority of adverse events were Grade 1 or Grade 2 and included infusion related reaction (IRR), fatigue, cytokine release syndrome (CRS), nausea, and diarrhea. A single dose-limiting toxicity of Grade 3 CRS occurred at the 100µg dose level. None of the patients discontinued autogene cevumeran due to AEs. *Ex vivo* T cell responses were detected in approximately 86% of patients treated with autogene cevumeran as a monotherapy T cells against multiple neoantigens were detected in post-treatment tumor biopsies. Of 26 patients with

tumor assessment, one patient with gastric cancer and metastatic liver lesions had a durable best response of confirmed complete response and remained on study after 1.5 years (3.8%) and 12 patients had stable disease (46.2%).

June 2020 Combination Therapy Data Update Phase 1b/basket trial

At AACR conference 2020, we presented data from 142 patients enrolled in cohorts with doses ranging from 15µg to 50µg of autogene cevumeran in combination with 1200mg atezolizumab. The most common tumor types enrolled were NSCLC, TNBC, melanoma and colorectal cancer with a median of three lines of prior therapies (range 1-11). The patient population included both CPI experienced and inexperienced patients, and most patients enrolled had low level of PD-L1 expression in the tumor. The majority of adverse events were Grade 1 or Grade 2 including infusion related reaction (IRR), fatigue, nausea, cytokine release syndrome (CRS) and diarrhea. There were no dose limiting toxicities. Eight patients (5.6%) discontinued due to AEs related to study drugs. Autogene cevumeran induced a self-limiting increase of pro-inflammatory cytokines with each dose, consistent with the TLR agonist activity of RNA. *Ex vivo* T cell responses were observed in peripheral blood in 46 out of 63 (73%) patients. Induction of up to 5.7% MHC multimer-stained CD8+ T-cells with effector memory phenotype was observed in the peripheral blood. T cells against multiple neoantigens were detected in post-treatment tumor biopsies. One of 108 patients with tumor assessment had a complete response as their best response (0.9%), 8 patients had partial responses (7.4%), and 53 patients had stable disease (49.1%).

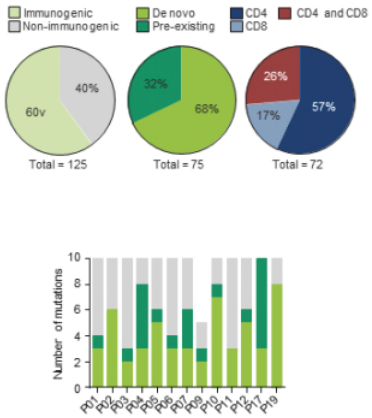
Based on data from our study of BNT121 (a prior iNeST precursor to autogene cevumeran) as an adjunct to surgery in patients with metastatic melanoma, we believe that autogene cevumeran is potentially well suited to control metastatic relapses in patients with a lower tumor burden. Additionally, autogene cevumeran as a monotherapy and in combination with atezolizumab has been observed to have a manageable safety profile to date and to induce significant levels of neoantigen-specific immune responses, even in late-stage, heavily pre-treated patients. Accordingly, we and our collaborator, Genentech, believe that autogene cevumeran is best suited for adjuvant and minimal residual disease settings.

Completed Phase 1 Clinical Trial (First Generation iNeST)

In 2017, we published the results of a 13-patient, first-in-human trial of our first-generation intranodal iNeST product candidate in patients with late-stage malignant melanoma. The objective of this clinical trial was to study the feasibility, safety, tolerability, immunogenicity and potential anti-tumoral activity of iNeST. All patients had stable disease at enrollment with a high risk for relapse.

All 13 patients developed T cell immune responses against multiple immunotherapy neoantigens at up to high single-digit percentages. As shown below, 60% of the selected neoantigens elicited a T cell response. The detected immune response comprised both CD4+ and CD8+ T cells and the majority of the response was induced *de novo*, which we believe to be an important requirement for an effective immune response and an added benefit beyond checkpoint inhibition alone.

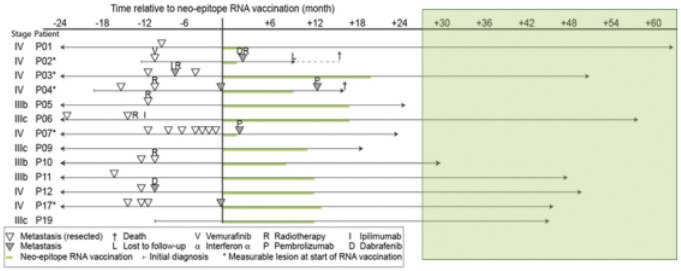
No severe adverse drug reactions were reported in the study. Common adverse events included flu-like symptoms.



Immune responses documented in our prior BNT121 study. Patients showed immune responses, including both CD4+ and CD8+ responses, against multiple neoantigens. Source: Nature 547, 222-226 (13 July 2017)**.**

In addition, metastases resected from two patients following treatment with BNT121 demonstrated evidence of BNT121-induced infiltration with neoantigenspecific T cells and neoantigenspecific killing of tumor cells. The cumulative rate of metastatic events was significantly reduced after the start of treatment, resulting in a sustained progression-free survival. Of the 13 patients entering the trial, eight patients that had no radiologically detectable lesions at start of neoantigen treatment were relapse free and remained recurrence-free for the whole follow-up period (12 to 23 months). Five patients experienced melanoma relapses shortly after inclusion in the trial and despite initiation of standard treatment had progressing metastases at start of their BNT121 treatment. Of these, two patients developed BNT121-treatment-related objective clinical responses. One of these patients exhibited a complete response and remained relapse-free for 26 months. The second patient had an immunotherapy-related partial response. This patient had a late relapse owing to outgrowth of ß2-microglobulin-deficient melanoma cells as an acquired resistance mechanism. A third patient developed a complete response to treatment in combination with PD-1 blockade therapy.

As of October 2019, nine out of 13 patients had remained recurrence free through follow-up of up to 60 months post-vaccination.



Metastatic relapses before and after treatment with BNT121. The chart above shows the 27 metastatic relapses of patients before and 3 after treatment with BNT121. Each horizontal line represents the time course of a single patient. The vertical line indicates the treatment start of BNT121. Source: Nature 547, 222-226 (October 2019).

c) Intratumoral Immunotherapy

We, in collaboration with Sanofi, are developing intratumoral immunotherapies utilizing our proprietary mRNA technology. These immunotherapies are designed to be administered directly into the tumor in order to alter the tumor microenvironment and enhance the immune system's ability to recognize and fight cancer cells within the tumor (proximal) as well as in other non-injected tumor sites (distal).

i. SAR441000 (BNT131): Our Initial Intratumoral Immunotherapy for the Treatment of Solid Tumors

In a collaboration with Sanofi, we are developing SAR441000 (BNT131) as a novel intratumoral immunotherapy for the treatment of solid tumors. SAR441000 (BNT131) consists of modified mRNAs encoding for immunomodulatory cytokines and is directly injected into the tumor sites. In the tumor, the cytokine encoding mRNAs are expected to be taken up by tumor and other resident cells and translated into functional cytokine proteins which are expected to be capable to modulate the tumor microenvironment. SAR441000 (BNT131) is being studied in a Sanofi-sponsored Phase 1 clinical trial as monotherapy and in combination with an anti-PD-1 checkpoint inhibitor in patients with advanced solid tumors.

Our SAR441000 (BNT131) Targets

SAR441000 (BNT131) comprises four mRNAs encoding the cytokines IL-12sc, IL-15sushi, IFN-α and GM-CSF, that we have identified as mediators of tumor regression across different murine tumor models. By expressing these cytokines in the tumor microenvironment, the immune system may more easily recognize and fight cancer cells. Combining the cytokine encoding mRNAs with checkpoint inhibitors enhanced antitumor responses in both injected and non-injected tumors, thereby improving survival and tumor regression in mice.

Our SAR441000 (BNT131) Clinical Trials

Ongoing Phase 1 Clinical Trial

Sanofi, in collaboration with us, commenced a first-in-human, multi-center, open-label, Phase 1, dose escalation and expansion trial to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of SAR441000 (BNT131) administered intratumorally as monotherapy and in combination with cemiplimab. In this trial, up to 231 patients with certain advanced solid tumors may be enrolled.

In this trial, eligible patients are treated with weekly intratumoral administration of SAR441000 (BNT131) in the monotherapy arm or in combination with a fixed dose of 350 mg cemiplimab q3wks in the combination arm. Blood samples and tumor biopsies are collected to characterize the pharmacokinetic/pharmacodynamic profile of SAR441000 (BNT131), immune cell tumor infiltration and the presence of tumor proinflammatory signatures.

Interim data presented at SITC 2020

As of July 2020, 17 patients across various solid tumor types had received SAR441000 (BNT131) as a monotherapy at varying dose levels. Six patients received SAR441000 (BNT131) in combination therapy. No dose limited toxicities were observed, and no grade three, four, or five adverse events related to study treatment were reported. Adverse events related to study treatment in two or more patients in both treatment groups combined were nonserious CTCAE grade 1 or 2 fatigue, vomiting, nausea, local injection site reaction, chills, diarrhea, and rash. In some patients, increases in plasma IP10 and IFN gamma and CD8+ T cell infiltration were observed in tumor biopsies.

d) RiboMabs

Our RiboMab product candidates, BNT141 and BNT142, encode cancer cell targeting antibodies. These product candidates leverage our proprietary optimized mRNA technology combining nucleoside modifications to minimize immunogenicity and modifications in the mRNA backbone to maximize protein expression. RiboMab product candidates are formulated using liver-targeting LNPs for intravenous delivery. RiboMabs potentially address the limitations of recombinant antibodies, including costly manufacturing processes and unfavorable pharmacokinetics, such as short plasma half-life.

i. BNT141: Our Initial RiboMab for the Treatment of Solid Tumors

BNT141 is our RiboMab product candidate for the treatment of solid tumors. BNT141 encodes an IgG antibody which upon injection is secreted into the bloodstream.

Our BNT141 Targets

BNT141 is designed to target Claudin-18.2, an antigen found in multiple epithelial solid tumors, including gastric and pancreatic cancers.

Our BNT141 Clinical Trial

Ongoing Phase 1 trial

We dosed the first patient in January 2022 in an open-label, multi-site, Phase 1/2 dose escalation, safety, and pharmacokinetic trial of BNT141 followed by expansion cohorts in patients with CLDN18.2-positive tumors.

The trial design consists of three parts. The first part will perform dose escalation as monotherapy in patients with unresectable or metastatic Claudin 18.2-positive gastric cancer, gastroesophageal junction (GEJ) and esophageal cancer of the adenocarcinoma subtype, colorectal cancer, pancreatic cancer, biliary tract cancers, and mucinous ovarian cancer, for which there is no available standard therapy likely to confer clinical benefit. Part 1B is a dose escalation in combination with standard of care (SOC) nab-paclitaxel and gemcitabine in patients with advanced unresectable or metastatic CLDN18.2-positive pancreatic adenocarcinoma or cholangiocarcinoma who are eligible for treatment with SOC nab-paclitaxel and gemcitabine. Part 1B intends to define the MTD and/or RP2D of the combination. Part 2 (expansion) consists of the following pre-defined expansion cohorts: (1) CLDN18.2-positive unresectable locally advanced or metastatic pancreatic adenocarcinoma eligible for treatment with SOC nab-paclitaxel and gemcitabine; and (2) CLDN18.2-positive unresectable locally advanced or metastatic cholangiocarcinoma eligible for treatment with SOC nab-paclitaxel and gemcitabine. Part 2 will be further defined via an amendment after careful evaluation of all available safety, PK and PD, and efficacy data generated in Parts 1A and 1B by the Safety Review Committee (SRC).

ii. BNT142: Our Second RiboMab for the Treatment of Solid Tumors

BNT142 is our RiboMab product candidate for the treatment of solid tumors. BNT142 is designed to encode a secreted bispecific antibody that targets CD3 and CLDN6.

Our BNT142 Targets

BNT142 is designed to encode bispecific antibodies that target CD3, a T cell receptor component that plays a key role in the activation of T cells, and CLDN6, a highly specific oncofetal cell surface antigen that is found in solid tumors, but not in normal cells.

Planned BNT142 Clinical Trial

We expect to start a first-in-human Phase 1 clinical trial for BNT142 in the first half of 2022.

e) RiboCytokines

Our RiboCytokine product candidates BNT151 and BNT152+BNT153 are nucleoside-modified mRNAs encoding human cytokines fused to human serum albumin. The modified mRNA is formulated with liver-targeting LNP for intravenous delivery

Our RiboCytokine product candidates are designed to address the limitations of recombinantly expressed cytokines, including limited serum half-life and production costs. We are developing RiboCytokines to be used primarily in combination with other drugs, including our other pipeline candidates.

i. BNT151: Our Initial RiboCytokine for the Treatment of Solid Tumors

We are developing BNT151, our RiboCytokine designed to encode a modified version of the human interleukin-2, or optimized IL-2, cytokine for the treatment of solid tumors. BNT151 is designed to stimulate T cells without triggering immunosuppression in the tumor microenvironment.

Our BNT151 Target

BNT151 comprises our nucleoside-modified mRNA that encodes mRNA for a function-modified IL-2. IL-2 is a key cytokine in T cell immunity, supporting the differentiation, proliferation, survival and effector functions of T cells.

Recombinant IL-2, aldesleukin, was the first approved cancer immunotherapy, and has been marketed globally for the treatment of late stage melanoma and renal cell cancer for decades. Most patients with complete responses after IL-2 treatment remain regression free for more than 25 years after initial treatment, but overall response rates are low due in part to the limitations of recombinant cytokines. Recombinant IL-2 has a very short half-life, requiring high and frequent dosing and a partially unfavorable activity profile, which leads to increased side effects, thus limiting its utility as a cancer treatment.

Our BNT151 Clinical Trials

Ongoing Phase 1/2 trial

We dosed the first patient in February 2021 in an open-label, multicenter Phase 1/2 trial. The trial evaluates dose escalation, safety, pharmacokinetics and pharmacodynamics of BNT151 with expansion cohorts in multiple solid tumor indications, including head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma (HCC), renal cell cancer (RCC), non-small cell lung cancer (NSCLC), and triple-negative breast cancer (TNBC). The monotherapy dose escalation will enroll patients with tumors that are metastatic or unresectable with no available standard therapy likely to confer clinical benefit. The trial also plans to implement a biomarker expansion cohort with longitudinal biopsies with the goal to identify ideal drug combination partners

In the combined treatment dose escalation, patients with different solid tumors will be enrolled and treated with BNT151 and the respective standard of care. Part 2B is the expansion phase where a predefined number of patients in each indication cohort will be treated with the confirmed recommended Phase 2 dose of BNT151 in combination with respective standard of care treatment.

ii. BNT152+BNT153: Our Second RiboCytokine for the Treatment of Solid Tumors

We are developing our RiboCytokine product candidate BNT152+BNT153 for the treatment of solid tumors. BNT152 encodes IL-7 and BNT153 encodes IL-2.

Our BNT152+BNT153 Clinical Trials

Ongoing Phase 1 Trial of BNT152+153

In June 2021 we dosed the first patient in an open-label, multisite Phase 1 dose escalation trial, which will evaluate the safety, pharmacokinetics and pharmacodynamics, and preliminary anti-tumor activity of BNT152+BNT153. The clinical trial will enroll approximately 72 patients with various solid tumors that are metastatic or unresectable for whom there is no available standard therapy likely to confer clinical benefit, or patients who are not candidates for such available therapy.

The trial consists of 2 parts with adaptive design elements. Part 1 consists of Groups A and B.

- Group A is a BNT153 monotherapy dose escalation in patients with advanced solid malignancies until the maximal tolerated dose (MTD) is defined.
- Group B is a BNT152 monotherapy dose escalation in patients with advanced solid malignancies until the MTD or optimal biological dose (OBD) is defined, whichever occurs earlier.

This trial also plans to implement biomarker expansion cohorts after BNT153 and/or BNT152 dose escalation is completed. The objective of the cohorts is to observe pharmacodynamics activity and drug induced changes in the blood and tumor. Up to 20 patients will be enrolled in each cohort.

Part 2 will start once Part 1 is completed, *i.e.*, when dose escalations for both BNT152 and BNT153 monotherapy are completed, and will evaluate the combination treatment of BNT152 and BNT153.

2. Oncology Cell Therapy Product Candidates

a) CAR-T

We are advancing multiple CAR-T product candidates, the most advanced of which, BNT211, is targeting the novel and highly specific target CLDN6+ in solid tumors. We plan to use our initial CAR-T cell product candidates in combination with a FixVac immunotherapy, a CAR-T cell-Amplifying RNA Vaccine, in short: CARVac, that encodes the antigen CLDN6 the CAR-T cells are targeting. The RNA vaccine selectively targets dendritic cells, which leads to uptake, antigen expression and maturation of the dendritic cells. The co-stimulation provided by dendritic cell maturation has been shown in preclinical studies to amplify and expand CAR-T cells *in vivo*, leading to increased persistence of the CAR-T.

i. BNT211: Our CAR-T Cell Therapy for the Treatment of CLDN6+ Solid Tumors

BNT211 is our CAR-T cell therapy for the treatment of CLDN6+ solid tumors. BNT211 targets CLDN6+ solid tumors in combination with a CAR-T cell-Amplifying RNA Vaccine, or CARVac, encoding the antigen CLDN6. Claudin-6 CAR-T cells are equipped with a second-generation chimeric antigen receptor of high sensitivity and specificity for the tumor-specific carcino-embryonal antigen Claudin-6. CARVac drives in vivo expansion of transferred CAR-T cells, increasing their persistence and efficacy. BNT211 is designed to overcome CAR-T cell therapy limitations in patients with solid tumors.

Our BNT211 Target

BNT211 targets Claudin 6, or CLDN6, a highly specific oncofetal cell surface antigen that is found in multiple cancers, including ovarian, testicular and lung cancers, but not in normal cells.

Ongoing Phase 1/2 Clinical Trial

We started a Phase 1/2 open-label, multi-center dose escalation and dose expansion basket trial of BNT211 with or without a CLDN6 CARVac immunotherapy with first patient dosed with BNT211 in February 2021. We are enrolling patients with CLDN6-positive relapsed or refractory advanced solid tumors, including ovarian and testicular cancers. The trial assesses CLDN6 CAR-T cell immunotherapy in combination with a CLDN6 RNA vaccine for improved expansion and persistence of CAR-T cells (CARVac). The primary outcome measure of the trial will be safety, with secondary efficacy outcome measures to include objective response rate, disease control rate and duration of response. Part 1 is the dose escalation with CLDN6 CAR-T cell therapy after lymphodepletion, followed by part 2 dose escalation that combines CLDN6 CAR-T cell therapy plus CLDN6 RNA-LPX vaccination. Within the Phase 1 trial, we will introduce a change to the manufacturing process providing for a high degree of automation.

We expect a data update in the second half of 2022.

December 2021 Data update from BNT211 Phase 1/2 Trial

At ESMO-IO 2021, we presented a data update from the Phase 1/2 trial. As of November 18, 2021, 15 patients have been treated, including patients with testicular, ovarian, endometrial, fallopian tube cancers and sarcoma. 9 received CAR-T cell monotherapy and 5 CAR-T cells plus CARVac vaccine combination therapy. Overall, the safety profile for Claudin-6 CAR-T cells as monotherapy or combined with CARVac continued to be tolerable at the dose levels evaluated. Only one dose-limiting toxicity (DLT) occurred. The observed DLT was prolonged pancytopenia after lymphodepletion. To avoid pancytopenia in patients with history of high-dose chemotherapy a cohort without lymphodepletion chemotherapy has been opened. 13 patients had adverse events of grade three or higher which were suspected to be related to treatment and which were mainly caused by lymphodepletion or were asymptomatic enzyme elevations. Cytokine release syndrome (CRS) was observed in four patients in the monotherapy treatment arm and three patients in the combination treatment arm. CRS cases were all grade one or grade two, accompanied by IL-6 elevation, and manageable with tocilizumab if needed. Patients receiving CARVac in the combination therapy arm had transient flu-like symptoms that resolved within 24 hours. Robust engraftment of CAR-T cells resulting in a total amount of around 10^9 CAR-T cells was achieved in most patients and suggests the potential for clinical activity. 9 of 10 patients evaluable for efficacy assessment showed initial disease control including 4 partial responses and 5 stable disease cases, of which four showed signs of clinical activity with shrinkage of target lesions.

ESMO-IO 2021/BNT211 Phase 1/2: CAR-T Engraftment and Tolerable Safety Profile with CLDN6 CAR-T without (Part 1) and with (Part 2) CARVac

Cohort/Patient Characteristics	Part 1 DL1 (n=3)	Part 2 DL1 (n=3)	Part 1 DL2 (n=6)	Part 2 DL2 w/ LD (n=2)	Part 2 DL2 w/o LD (n=1)	All patients (n=15)
Median (range) age, years	33 (26-68)	41 (27-68)	56 (26-68)	52.5 (48-57)	58	54 (26-68)
Cancer type, n						
Testicular	1	3	2	0	1	7
Ovarian	1	0	1	2	0	4
Endometrial	0	0	1	0	0	1
Fallopian tube	0	0	1	0	0	1
Sarcoma	1	0	0	0	0	1
Gastric	0	0	1	0	0	1
Median (range) CLDN6 IHC+ cells, %	60 (60-80)	90 (90-95)	82.5 (50-80)	90 (90-100)	85	85 (50-100)
Median (range) of prior treatment lines	4 (3-5)	4 (3-4)	5 (2-11)	5 (5-7)	4	4 (2-11)

Safety
- CLDN6 CAR-T cells alone or combined with CARVac well tolerated at the dose levels evaluated to date with only 1 DLT observed
- CRS was seen in 1 patient at DL1 + CARVac and 6 patients at DL2, and was manageable by administration of tocilizumab

Efficacy
- Robust engraftment of CAR-T cells resulting in a total amount of around 10^9 achieved in most patients and seems predictive for clinical activity
- 9 of 10 patients evaluable for efficacy assessment showed initial disease control including 4 PRs (3 in testicular cancer patients with recent relapse after HDCT/ASCT)

b) Neoantigen-Targeting T Cells.

Our neoantigen-targeting T cell stimulation platform can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies. Our lead product candidate under this platform is our individualized neoantigen-targeting T cell therapy, BNT221.

We are also developing NEO-STC-01 (BNT222), targeting shared RAS neoantigens prevalent across many solid tumor types.

i. BNT221 (NEO-PTC-01): Our Individualized Neoantigen-targeting T Cell Therapy for the Treatment of Cancer

BNT221 (NEO-PTC-01) is our individualized neoantigen-targeting T cell therapy for the treatment of cancer. BNT221 (NEO-PTC-01) targets selected sets of individualized neoantigens.

Our BNT221 (NEO-PTC-01) Target

BNT221 (NEO-PTC-01) is a personal neoantigen-targeted T cell therapy candidate derived from patients' peripheral blood cells. The product consists of multiple CD8+ and CD4+ T cell populations targeting multiple selected neoantigens from each patient`s tumor.

The proprietary stimulation process allows for the induction of T cells from the naïve, as well as expansion of T cells from the memory compartment. Other product characteristics are i. cells with high specificity profile towards the mutant epitope; ii. cells exhibiting multiple effector functions; iii. a product that contains both central and effector memory T cells; iv. cells that have cytotoxic response towards endogenously processed and presented antigens as well as recognition of autologous tumor.

The neoantigens are selected using our proprietary RECON bioinformatics engine.

Ongoing Phase 1 Clinical Trial

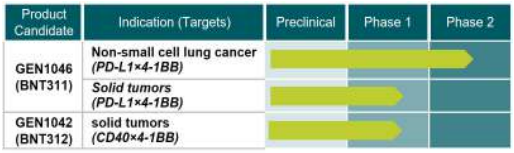
In April 2021, the first patient was dosed in a first-in-human Phase 1 dose escalation trial evaluating BNT221 (NEO-PTC-01) in patients with checkpoint inhibitor unresponsive or refractory metastatic melanoma. Part 1 of the trial consists of a monotherapy dose escalation of BNT221 (NEO-PTC-01). In Part 2, BNT221 (NEO-PTC-01) will be dosed in combination with anti-PD-1 therapy after first-line treatment. Major objectives of this study include evaluation of the safety and feasibility of administering BNT221 (NEO-PTC-01), as well as evaluations of immunogenicity and preliminary efficacy.

Based on data from the first in human trial, we will decide how to best proceed with further clinical development of BNT221 (NEO-PTC-01), including expanding to other tumor types and potential development in the United States.

3. Antibody Product Candidates in Oncology

a) Next-Generation Checkpoint Immunomodulators

In our 50:50 collaboration program with Genmab, we are currently studying two bispecific antibody checkpoint immunomodulators. Our Next Generation Immunomodulators are designed to prime and activate anti-tumor T-cell and Natural Killer cell function.



i. GEN1046 (BNT311): Our Jointly Owned DuoBody® PD-L1x4-1BB Bispecific Antibody for the Treatment of Solid Tumors

GEN1046 (BNT311), our jointly owned PD-L1x4-1BB product candidate, is a potential first-in-class bispecific antibody combining PD-L1 checkpoint inhibition with 4-1BB checkpoint activation. A Phase 1/2 trial of GEN1046 (BNT311) for the treatment of malignant solid tumors is ongoing. In December 2021 we dosed the first patient in a randomized Phase 2 trial of BNT311 as monotherapy and in combination with pembrolizumab in patients with recurrent/refractory metastatic non-small cell lung cancer.

Our GEN1046 (BNT311) Targets

GEN1046 (BNT311) is a PD-L1x4-1BB bispecific antibody that induces activation of T cells through conditional 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis, even in the absence of 4-1BB binding. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane

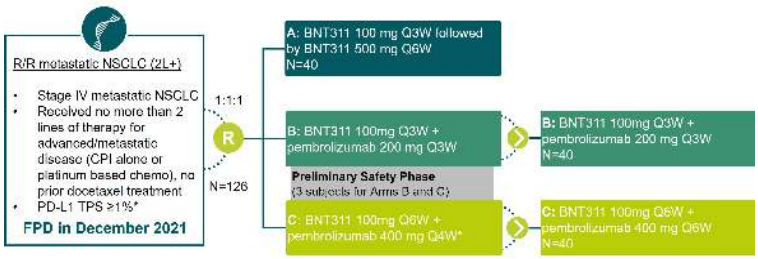
receptor belonging to the TNF super-family and is expressed predominantly on activated T cells. DuoBody® is a registered trademark of Genmab.

GEN1046 (BNT311) Trials

Ongoing Phase 2 Trial in metastatic NSCLC

In December 2021 the first patient was dosed in a Phase 2, multicenter, randomized, open-label trial of GEN1046 (BNT311) as monotherapy and in combination with anti-cancer therapy in subjects with relapsed/refractory metastatic Non-Small Cell Lung Cancer after treatment with Standard of Care therapy with an immune checkpoint inhibitor. This three-arm trial is expected to enroll up to 132 patients with histologically or cytologically confirmed diagnosis of Stage 4 Non-Small Cell Lung Cancer with at least 1 prior line of systemic therapy containing an anti-PD-1/PD-L1 monoclonal antibody and that has progressed. Another inclusion criterion is tumor PD-L1 expression of tumor proportion score (TPS) ≥1%. The primary endpoint is objective response rate (ORR) according to RECIST v1.1. Secondary endpoints include duration of response (DOR), time to response, progression free survival (PFS), overall survival (OS), and safety.

Lung cancer is the 2nd most common cancer and leading cause of cancer death, with an estimated nearly 2.1 million new cases diagnosed in 2018, resulting in an estimated 1.8 million deaths worldwide (Bray et al., 2018). Non-Small Cell Lung Cancer (NSCLC) represents approximately 85% of lung cancers and includes adenocarcinomas (50%), squamous cell carcinomas (20%) and large cell carcinomas (10%). Refractory/Relapsed NSCLC after treatment with checkpoint inhibitors has a particularly poor prognosis with an estimated PFS of less than 6 months and OS of less than 1 year. Despite the success of CPIs in NSCLC, the majority of patients eventually fails to respond to CPI therapy due to evolution of primary or secondary resistance.



Trial design of BNT311 Phase 2 trial in R/R metastatic NSCLC

Ongoing Phase 1/2 Clinical Trial

The ongoing Phase 1/2, open-label, single-arm GEN1046 (BNT311) trial with multiple expansion cohorts, conducted in collaboration with Genmab, is expected to enroll approximately 192 patients with malignant solid tumors. The trial consists of a dose escalation part and an expansion part. The dose escalation part will determine the safety profile of GEN1046 (BNT311) in patients with certain relapsed or refractory, advanced and/or metastatic malignant solid tumors who are no longer candidates for standard therapy. The expansion part will be initiated once the recommended expansion dose has been established. In the expansion part, GEN1046 (BNT311) will be administered intravenously once every 21 days. The primary endpoints of the trial are dose-limiting toxicities, adverse events and safety laboratory parameters, including hematology, biochemistry, coagulation and endocrinology.

Dose escalation has been finalized and ten expansion cohorts are currently ongoing, including patients with NSCLC, TNBC, urothelial cancer, SCCHN and cervical cancer. The expansion phase 2 dose is 100 mg Q3W. .

Interim data from the Phase 1/2 trial of GEN1046 (BNT311) (DuoBody-PD-L1x4-1BB) in 61 heavily pretreated patients with advanced solid tumors was presented at SITC 2020. In the dose escalation phase, GEN1046 (BNT311) demonstrated a manageable safety profile and encouraging early single-agent clinical activity. Most adverse events were mild to moderate and treatment-related Grade 3 transaminase elevations resolved with corticosteroids. No treatment-related

bilirubin increases or Grade 4 transaminase elevations were observed. Clinical benefit was observed across tumor types and dose levels, including in patients resistant to prior immunotherapy and with tumor types less sensitive to immune checkpoint inhibitors. Disease control was achieved in 65.6% of patients in the dose escalation portion, including partial responses in one TNBC patient, one ovarian cancer patient and two immune checkpoint inhibitor pre-treated NSCLC patients. In the expansion cohort, which includes patients with PD-L1 relapsed/refractory NSCLC, two of 12 patients that could be objectively assessed achieved confirmed single-agent partial responses. One patient had an unconfirmed partial response and four patients demonstrated stable disease. The data were published in the journal Cancer Discovery.

November 2021 Data update from BNT311 Phase 1/2 Trial

At SITC 2021, we presented updated data from the ongoing Phase 1/2 trial. As of September 21, 2021, 80 patients were included in the analysis. BNT311 elicited pharmacodynamic effects consistent with its proposed mechanism of action. The data demonstrated induction of IFN-γ and expansion of CD8+ effector memory T cells & activated NK. In addition, relationships between disease control and PD-L1 tumoral expression, as well as time from last prior anti-PD-1 therapy were observed. Patients with tumor reduction had mainly PD-L1 positive tumors. A tumor reduction was observed in seven of eleven patients with PD-L1 positive tumors.

ii. GEN1042 (BNT312): Our Jointly Owned DuoBody® CD40x4-1BB Bispecific Antibody for the Treatment of Solid Tumors

GEN1042 (BNT312), our jointly owned CD40x4-1BB antibody product candidate, is a potential first-in-class bispecific antibody designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells.

GEN1042 (BNT312) Targets

GEN1042 (BNT312) is a bispecific antibody designed to enhance an anti-tumor immune response by crosslinking CD-40 on antigen presenting cells with 4-1BB+ T cells to induce conditional stimulation and co-stimulatory activity in both types of cells. It has demonstrated increased tumor infiltrating lymphocyte expansion in human tumor tissue cultures *ex vivo*, and induces activation of B cells in the presence of 4-1BB+ cells. Both 4-1BB and CD40 are members of the tumor necrosis factor receptor superfamily.

GEN1042 (BNT312) Trials

Ongoing Phase 1/2 Clinical Trial

A Phase 1/2 dose-escalation trial with expansion cohorts evaluating safety and anti-tumor activity of GEN1042 (BNT312) in patients with solid tumors is ongoing. A monotherapy expansion cohort is recruiting patients with advanced or metastatic melanoma after treatment with standard of care. GEN1042 (BNT312) is also being explored in combination with other anti-cancer therapies in subjects with advanced or metastatic melanoma, non-small cell lung cancer, head and neck cancer, and pancreatic cancer with no prior systemic therapy. Expansion cohorts in melanoma, NSCLC, pancreatic and head and neck carcinoma are actively recruiting.

November 2021 Data update from GEN1042 (BNT312) Phase 1/2 Trial

At SITC 2021, we presented data from the dose escalation part of the ongoing Phase 1/2 trial. As of August 27, 2021, 50 patients have received GEN1042 (BNT312) monotherapy in the dose-escalation part. Overall, the data demonstrated a favorable safety profile in patients with advanced solid tumors, as well as biologic and early antitumor activity. The maximum tolerated dose was not reached, and treatment-related adverse events were mostly mild-to-moderate. Increases in peripheral monocyte and dendritic cell cytokines and also increased levels of CD8+ and effector memory T cells were observed, suggesting biological activity that is consistent with the proposed mechanism of action for GEN1042 (BNT312). Disease control was achieved in 25 of 50 (50%) patients, including two confirmed partial responses per RECIST1.1 in melanoma and neuroendocrine lung cancer.

b) Targeted Cancer Antibodies

i. BNT321 (MVT-5873): Our Targeted Cancer Antibody for the Treatment of Pancreatic Cancer

In 2019, we acquired certain antibody assets from MabVax Therapeutics Holding, Inc., including MVT-5873 (BNT321), a clinical-stage targeted cancer antibody.

Our MVT-5873 (BNT321) Target

BNT321 (MVT-5873) is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLea), an epitope on CA19-9 that is expressed in pancreatic and other gastrointestinal cancers that plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

Ongoing BNT321 (MVT-5873) Trial

BNT321 (MVT-5873) is being investigated in an open-label, multi-center, non-randomized dose escalation/expansion trial evaluating the safety and recommended Phase 2 dose of BNT321 (MVT-5873) for a Q2 and Q4 week schedule in approximately 108 patients with pancreatic and other CA19-9+ malignancies. Secondary objectives include evaluating tumor response rate by RECIST 1.1, duration of response, and determining pharmacokinetics. This study utilizes a conventional 3+3 design to identify the recommended Phase 2 dose.

4. Oncology Small Molecule Immunomodulator Product Candidates

i. BNT411: Our Small Molecule TLR7 Agonist for the Treatment of Solid Tumors, Including Small Cell Lung Cancer

BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is designed to activate both the adaptive and innate immune system through the TLR7 pathway. We are developing BNT411 to be used both as a monotherapy and in combination with chemotherapy and checkpoint inhibitors.

Our BNT411 Target

BNT411 is a TLR7 agonist that is designed to activate both the adaptive and innate immune system through the TLR7 pathway. This activity and the release of cytokines and chemokines are designed to result in the potent stimulation of antigen-specific CD8+ T cells, B cells and innate immune cells such as NK cells and macrophages.

Ongoing Phase 1/2 Trial

A phase 1/2, first-in-human, open-label, dose-escalation trial with expansion cohorts evaluates safety, PK, PD, and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve ES-SCLC is ongoing. *November 2021 Data update from BNT411 Phase 1/2 Trial*

At SITC 2021, we presented data from the monotherapy arm of the dose escalation part. As of August 26, 2021, BNT411 demonstrated an acceptable safety profile at all doses tested as a monotherapy and in combination with atezolizumab, carboplatin and etoposide. No dose-limiting toxicities were observed and the only drug-related adverse events reported were non-serious pyrexia, chills, and mild-to-moderate anemia. As of August 26, 2021, 18 heavily pretreated patients have received BNT411 monotherapy. Pharmacodynamic signals were encouraging and showed a strong induction of type 1 interferon-dominated cytokines in line with the proposed mechanism-of-action. BNT411 showed early signal of prolonging stable disease even in heavily pre-treated patients including post-anti-PD-1. Both pharmacodynamics and anti-tumor responses warrant further expansion in various indications either as a monotherapy or in combination with other standard-of-care treatments.

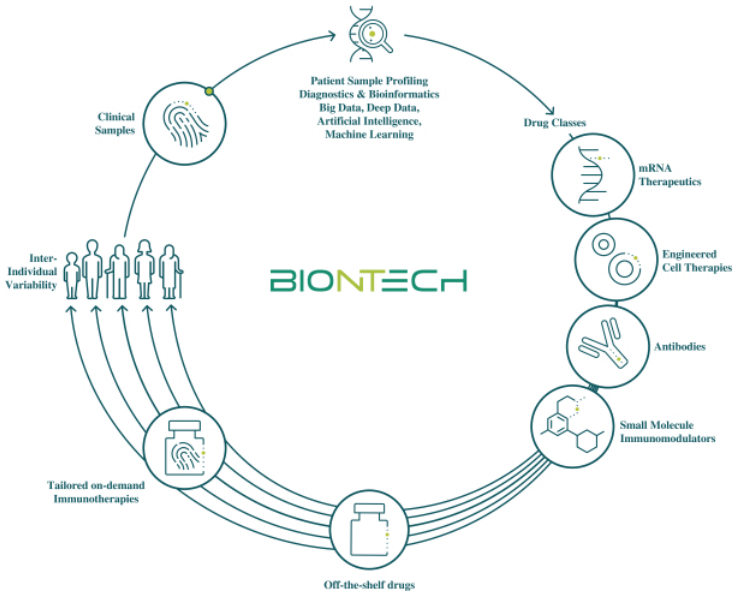
C. Rare Disease Protein Replacement mRNA Product Candidates

We are collaborating with Genevant, in order to combine our mRNA technology with Genevant's LNP delivery technology, to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. The first product candidate under the Genevant collaboration, BNT171, is being developed for Ornithine Transcarbamylase (OTC) Deficiency. Our mRNA replacement product candidate is associated with a favorable tolerability profile and good protein expression (in mice) and demonstrated phenotype rescue in a mouse disease model. Currently, we have put the programs under review in order to focus on other disease areas.

VI. Oncology approach

A. Patient-Centric Approach

Our patient-centric approach starts with profiling and diagnostics by utilizing a target identification engine. This engine combines next generation sequencing, genomics, bioinformatics, machine learning and artificial intelligence to (a) identify gene targets of interest, (b) characterize the functional relevance of these targets (*i.e.* the ability to raise an immune response to or through a target) and (c) demonstrate their drugability. From our very beginning onwards, we have been developing the novel technologies needed to match the identified targets to the optimal individualized treatment approach.



Our patient-centric approach. Utilizing patient profiling, diagnostics and bioinformatics, we select from our suite of drug classes to provide optimal individualized treatment. Our treatments include off-the-shelf drugs as well as highly tailored immunotherapies that are produced on-demand for the individual patient.

Utilizing this approach:

1. We develop and leverage our competencies in target discovery, biomarker science and computational medicine to thoroughly profile a patient's tumor sample and immune cells for the selection of suitable targets and treatments, and use this data to develop next-generation product candidates.

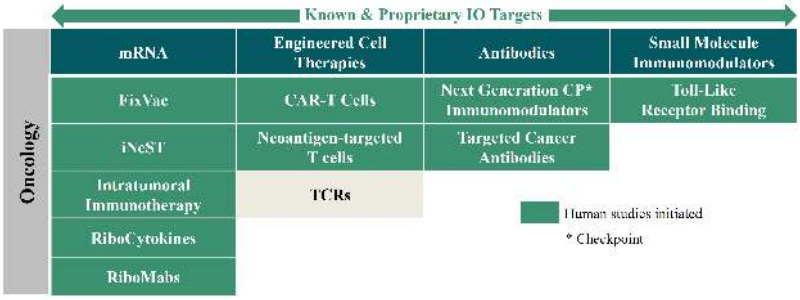
2. Each of our therapeutic platforms bundles innovations designed to deliver a distinct mode of action with high-precision targeting, high potency and efficacy. Each platform is being developed to provide a pipeline of drug candidates with complementary and potentially synergistic modes of action.

3. Our drug platforms are highly versatile and support the fast development of scalable manufacturing processes. We develop and establish highly digitalized and automated manufacturing technologies and quality controlled

processes enabling fast delivery of customized therapies comprising off-the-shelf drugs, on-demand immunotherapies, and combinations thereof.

Broad and Potentially Synergistic Suite of Platforms

We believe the depth and breadth of our understanding of immune system and cancer biology allows us to create an extensive pipeline of specific and potentially efficacious product candidates. We are exploiting a comprehensive repertoire of known and proprietary therapeutically relevant immuno-oncology targets and are developing a diverse spectrum of immunotherapeutic approaches, as shown in the chart below.



We believe that harnessing complementary, potentially synergistic modes of action increases the likelihood of therapeutic success, reduces the risk of emergence of secondary resistance mechanisms, and also unlocks a larger potential market. Critically, this approach allows us to pursue a technology agnostic approach, providing the most appropriate therapeutic platform or a combination thereof for the intended patient and purpose.

For example, we believe our neoantigen immunotherapies are particularly well-suited to treat high mutation load cancers in the adjuvant setting to prevent the tumor from spreading or recurring following initial treatment, such as surgery. In this setting, tumor volumes tend to be low and there remains the potential for strong T cell responses since the patient's immune system has not been weakened by prior lines of treatment, and checkpoint inhibition alone often offers a poor risk-benefit profile or low response rate. Similarly, we believe our FixVac, CAR-T, neoantigen-targeted T cell and next-generation checkpoint immunomodulator platforms may have especially strong potential in lower mutation burden tumors such as ovarian or prostate cancers, which comprise a significant proportion of tumors and often also have a poor response to checkpoint inhibition. Likewise, we believe that monoclonal targeted cancer antibodies and CAR-T cell therapies are particularly well-suited for tumors that have defects in their antigen-presentation machinery.

We believe our breadth of our technology positions us to combine modes of action in a coordinated way to treat cancer in a more efficacious manner than current existing therapies. We further believe that our patient-centric approach

and our broad, potentially synergistic portfolio of drug platforms place us at the forefront of the paradigm shift toward individualized immunotherapies.

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	• ***mRNA Neoantigen Immunotherapy*** *(iNeST)*
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	• ***Shared Antigens*** *(FixVac, CAR-T cells, Antibodies)*
"Immune desert" cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME[1]	• ***mRNA Immunotherapy*** • ***Immunostimulatory Compounds*** *(intratumoral, RiboCytokines)*
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	• ***Antibodies*** • ***CAR-Ts***
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	• ***Engineered Cell Therapies*** • ***Combination Therapies***

[1]Tumor microenvironment

Diversity of cancer patient populations, challenges and our therapeutic strategies. We believe our diversified portfolio allows us to potentially address a large share of cancer patients. Abbreviations: B2M, beta-2 microglobulin, a component of MHC.

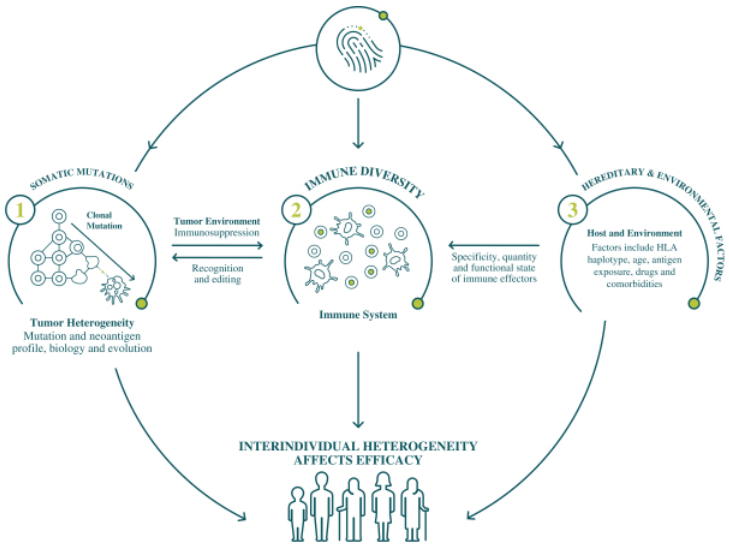
B. Challenges and Opportunities of Cancer Therapies

Cancer results from an accumulation of abnormalities, known as somatic mutations, in the genome of cells over time leading to malignant transformation, combined with a failure by the immune system to detect and eradicate such transformed cells. Due to their random nature, the vast majority of these aberrations are unique to the individual patient.

As a consequence, heterogeneity is an intrinsic hallmark of cancer, posing a key challenge for cancer therapy:

- **Interindividual tumor heterogeneity.** Tumors, even within the same cancer type, differ at the molecular level. For example, two patients with the same type of cancer usually share less than five percent of their mutations. As a result, patients often respond very differently to the same drug.
- **Intratumor heterogeneity.** Within the same patient, cancer also evolves over time so that different tumor cell clones co-exist, in a manner known as clonal evolution. As a result, a patient's cancer may be intra-tumorally as well as inter-tumorally heterogeneous. Therapies might target only a subfraction of tumor cell clones. This can lead to immune escape and therapy failure.
- **Cancer evolution and immune escapes**. Cancer cells can adapt to therapeutic pressure, which results in treatment resistance. During immunotherapy, tumor cell clones may evolve that no longer express T cell recognized antigens or have defects in their antigen presentation machinery.
- **Tumor microenvironment**. Tumors induce various forms of immunosuppressive microenvironments that prevent T cells from proliferating and executing their anti-tumor effector function.
- **Host, environment and immune system**. The functional state of each patient's immune system is dependent on the patient's age, genetic makeup and environmental exposures. For example, the HLA haplotype, or the genetic makeup that encodes the major histocompatibility complex, is highly individual and decisive for which epitopes of an antigen are presented to T cells. Whereas a given tumor antigen might be a good target in one patient, a second patient might not be able to respond to it at all.

The graphic below depicts the interaction between three key factors influencing the patient unique tumor profile:



Interindividual heterogeneity of patients. The interaction between cancer and immune system is shaped by various host, tumor and environmental factors. The complex interplay of these sources of interpatient heterogeneity affects both the course of disease and the efficacy of immunotherapy.

Together, these factors make cancer an extremely complex and heterogeneous disease. As a consequence, in the majority of cancer types, many treated individuals do not benefit from highly potent approved therapies, and responses are often not durable. While these hallmarks of cancer are a challenge for cancer therapy, they also present opportunities for immunotherapy. These interconnected layers of complexity and variability require a deep understanding of an individual cancer and call for a patient-centric approach in order to find an optimal treatment.

C. Selection of Therapeutic Targets and Therapies

Immunotherapy targets can be categorized as *antigens* for targeted immunotherapy with antibody- or T cell-based effector mechanisms and *immunomodulatory targets* to be exploited to improve the anti-tumoral function of immune cells.

1. Targeting Cancer Antigens

In order to address the broadest possible number of patients, our therapeutically targeted cancer antigen library comprises tumor associated antigens, viral neoantigens and mutant neoantigens:

a. Tumor Associated Antigens

Tumor associated antigens, or TAAs, are cancer selective targets that typically have a highly restricted expression pattern in normal tissues but are frequently expressed in a wide range of human cancers. Over the last 15 years, we have built up a database of approximately 200 cancer-selective antigens, including proprietary disease targets that could be used as targets for immunotherapy-based approaches.

- Cancer-Germline and Cancer-Embryo-Fetal Antigens, which are normally expressed during embryonal development and silenced after birth or restricted to germline cells. These antigens are aberrantly expressed in a variety of human malignancies and are generally not expressed in healthy tissue, making them particularly suitable for our FixVac-, antibody- and CAR-T cell-based therapeutic approaches.
- Differentiation antigens, which are normally expressed in a highly tissue-specific manner in normal tissues (*e.g.*, on melanocytes or on prostate cells) but are also present in a high proportion of tumors derived from these tissues, are well-suited for therapeutic targeting with FixVac and antibody approaches.
- Tumor-associated carbohydrate antigens are carbohydrate-based cell surface tumor antigens generated by cancer cell-specific aberrant glycosylation that enable the development of antibody and CAR-T cell therapies.

b. Viral Neoantigens

Viral oncoproteins, or viral neoantigens, are virus-derived proteins that drive the oncogenic transformation of infected cells by viruses that can cause cancer. Examples are the E6 and E7 oncoproteins from human papilloma virus, or HPV. Viral oncoproteins are commonly acknowledged as safe and promising targets for immunotherapy as they are (i) absent from any non-infected tissue, (ii) highly immunogenic since they are not prone to central tolerance mechanisms and (iii) not subject to immune escape by gene silencing as they are crucial to maintaining the transformed state of the tumor cells. We leverage viral neoantigens as targets for our BNT113 FixVac program in HPV16+ head and neck cancer.

c. Mutant Neoantigens

Somatic mutations, or mutations of non-germline cells, are a hallmark of cancer. Driver mutations promote the oncogenic process, whereas passenger mutations are considered as functionally irrelevant. Both types of mutations, however, can alter the sequence of proteins and create new epitopes which are processed and presented on specialized major histocompatibility complex, or MHC, molecules. Mutated epitopes that are recognized by T cells are called neoepitopes and the sequence-altered proteins they are derived from are neoantigens. They are promising targets for cancer immunotherapy as (i) activation of the immune system against such antigens is highly specific (they are only expressed on cancer cells) and (ii) mutant neoantigens are exempt from central tolerance and thus T cell affinity for neoantigens may be significantly superior. We utilize individualized mutant neoantigens as targets for our iNeST product candidates.

2. Immunomodulatory Targets

The activity of immune cells can be controlled or manipulated by the targeting of receptors that control key biological processes in these cells, known as immunomodulation. Immunomodulatory targeting strategies include:

a. Checkpoint Inhibition

Checkpoint inhibition is a therapeutic approach by which T cell function is stimulated with mAbs that block their inhibitory receptors, which can be exploited by cancer cells to shut down T cell activity. Examples of checkpoint targets are PD-1, PD-L1, CTLA-4, TIGIT, LAG3 and many others. The concept is known as “releasing the brakes” and has been shown to be therapeutically effective in tumors with strong pre-existing immune cell infiltration. Our GEN1046 (BNT311) product candidate is a next-generation bispecific checkpoint immunomodulator, with one arm targeting PD-L1.

b. Immunostimulation

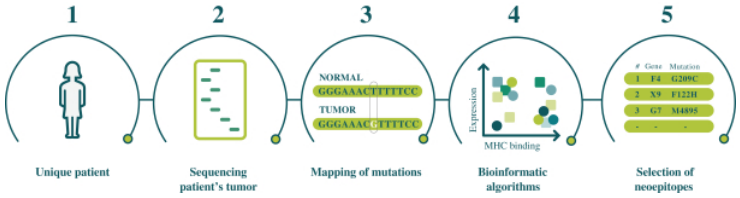
Immunostimulatory approaches are directed against receptors known to directly activate immune cells. Examples of these targets include co-stimulatory molecules such as CD40 and 4-1BB or cytokine receptors such as IL-2R, IL-7R and IL-12R. Immunostimulatory approaches provide a powerful opportunity to enhance immune activation, even in types of cancer that are not responsive to checkpoint inhibition due to lack of immune cell infiltration. However, this approach is often limited by a narrow therapeutic window associated with dose-limiting toxicity.

We believe that both concepts can be combined in a potentially synergistic and safe fashion by developing precisely engineered molecules, such as our BNT151 RiboCytokine program or GEN1042 (BNT312), our next-generation bispecific checkpoint immunomodulator targeting both CD40 and 4-1BB.

3. Computational Approach to Individualized Immunotherapy

Bioinformatics are critical in the production of individualized therapies. We have accumulated a high level of experience in bioinformatic approaches to mutation detection, cancer genomics and immunotherapy through our ongoing research and preclinical studies and clinical trials.

Our validated patient-centric bioinformatic process, as illustrated below, allows the application of complex algorithms to the patient's data in the context of drug manufacturing. Our bioinformatics processes are robust and scalable, incorporating our experience handling genomic data in a high-throughput environment, as we target making on-demand production of individualized immunotherapies commercially viable.



From Patient to Analysis. Our bioinformatic process for the selection of neoepitopes.

a. Sequencing

We sequence the patient's tumor and healthy tissue samples using NGS technology. Comparison of the patient's sequenced tumor and healthy samples provides us with the data from which we can identify targets for the design of individualized cancer immunotherapies. This is a multi-step process in which mutation detection and neoantigen prediction are particularly important.

b. Mutation Detection

Mutation detection, which defines which tumor-specific mutations are present in any cancer, is the starting point for defining targets for individualized immunotherapy. Determining mutations from NGS data with high precision and sensitivity is challenging because numerous factors can lead to false positives, which can mask mutations. Despite advances in the field, commonly used mutation detection algorithms still exhibit high false positive mutation detections.

c. Neoepitope Selection

Only a portion of mutated peptides (neoepitopes) are suitable for raising an immune response *in vivo*. Our approach focuses on evoking responses involving both CD8+ T cells and CD4+ T cells. We do this by discerning the likelihood of presentation of the neoepitope to the T cell receptor as an MHC peptide complex using data from mRNA expression levels and MHC binding affinity predictions, among other factors. For example, in our first individualized neoepitope immunotherapy clinical study, all 13 stage III and IV melanoma patients selected for treatment developed a CD4+ and/or CD8+ T cell response, achieving an overall 60% immune response rate to predicted neoepitopes.

Presentation of a neoepitope on an MHC molecule does not, however, guarantee recognition by T cells, and an integrated view combining several properties impacting immunogenicity is necessary. Our algorithms are continuously being improved and extended with data collections from various sources such as our past and current clinical studies as well as HLA data. By using machine learning approaches applied to these large datasets we aim to further improve prediction of overall presentation of neoepitopes tailored to patients' specific HLA types. With our acquisition of Neon Therapeutics, Inc., or Neon, we further bolstered our neoepitope selection capabilities with the addition of Neon's RECON bioinformatics engine. RECON uses a number of inputs from each patient, including DNA sequences from samples of tumor and normal tissue, RNA sequences from tumor samples, and the patient's specific MHC allele profile. RECON processes data from these inputs using a proprietary combination of algorithms in order to produce a prioritized list of neoantigen-targeting peptides that can be manufactured for use in our product candidates.

VII. mRNA Drug Class

At a glance: mRNA as a Therapeutic Drug Class

- Natural molecule found universally within cells, with well-characterized properties.
- Suitable to encode for antibodies, antigens, cytokines and any other type of protein.
- Transient, with adaptable activity and half-life. Avoids genomic integration problems sometimes seen in gene therapy, potentially resulting in a better safety profile.
- Can be designed and optimized pharmacologically and immunologically, making it suitable for a broad range of applications.
- Fast manufacturability, making it a cost-effective and flexible therapeutic to produce.
- Our mRNA portfolio includes BNT162b2, our mRNA-based COVID-19 vaccine, which has received emergency or temporary use authorization or approval or been granted conditional marketing approval in over 100 countries

In the last decade mRNA has progressed into a promising new class of medicine, with the potential to treat a wide variety of diseases with high unmet medical needs. mRNA is a long, polymeric molecule, composed of four different building blocks called nucleotides. In mRNA, hundreds or thousands of these nucleotides are linked in a unique order to convey genetic information to cells, where it is used to express proteins with biological effects.

Considering that all mRNA is generated with four different building blocks, but with unique sequence order, all therapeutic mRNAs have highly similar compositions, while having the capacity to encode a variety of different proteins. These characteristics allow for rapid development of mRNA therapeutics that are broadly applicable for treatment of many diseases, including cancer, infectious diseases and rare diseases. Our mRNA pipeline addresses all of these therapeutic areas.

A. General Principles of mRNA Pharmacology

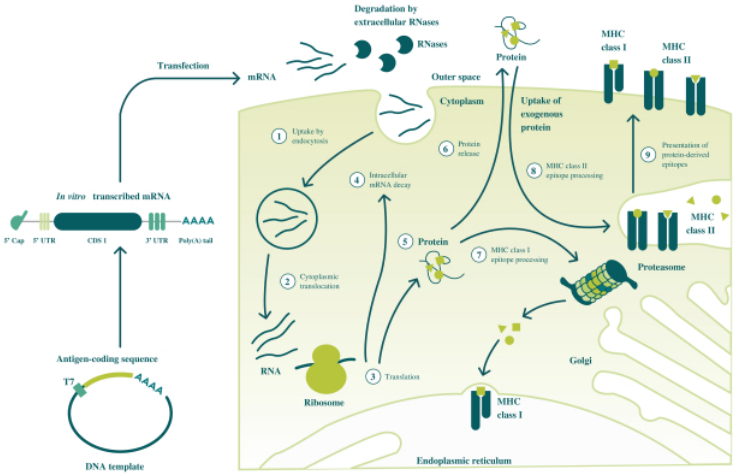
As a drug, manufactured mRNA provides instructions to a target cell to produce a desired therapeutic protein. An mRNA drug will temporarily change the status of the target cell where these instructions are translated into proteins. Based on the information encoded by the mRNA, the proteins will be either secreted or remain intracellular. The mRNA drug will eventually be degraded and eliminated from the body.

Our mRNA drugs are synthesized from a DNA template. With the exception of the 5’ cap, the template determines all structural elements of the mRNA. The mRNA molecule comprises:

- an open reading frame, or ORF, which encodes for the protein of interest;
- untranslated regions, or UTRs, which flank the ORF; and
- the cap and the poly(A) tail, which are the two terminal structures of the linear mRNA, and are responsible for increased stability and translational efficiency of mRNA.

The mRNA drug needs to be appropriately formulated in order to protect it from breakdown by extracellular RNAses. The formulation is selected based on the intended application and route of delivery. After uptake into the target cell, the mRNA molecules are loaded into ribosomes, where translation into protein takes place. Subsequently, the mRNA is degraded by cellular mechanisms. In case of an immunotherapy application, the protein is degraded into immunogenic epitopes. These are loaded onto specialized molecules, namely MHC I or MHC II. These molecules present the epitopes to

immune cells to provoke the desired immune response. In the case of other mRNA applications, the mRNA encodes proteins that are secreted from the cells, such as antibodies, and function extracellularly.

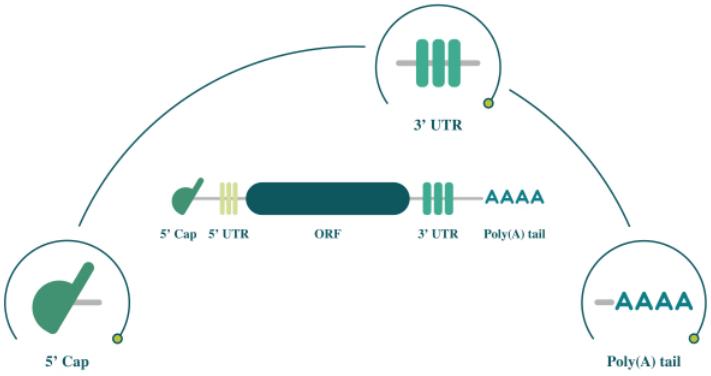


General principles of mRNA pharmacology. Step 1: mRNA is either delivered in a buffered solution as naked molecules or formulated as nano-particles to protect degradation by extracellular enzymes and is taken up by cells. Step 2: Subsequently, mRNA is released from endosomes into the cytoplasm. Step 3: mRNA is translated by the protein synthesis machinery of host cells. Step 4: Termination of translation
by degradation of mRNA. Step 5: The translated protein product acts in the cell in which it has been generated. Step 6: Alternatively, the protein product is secreted and may act via autocrine, paracrine or systemic, body-wide mechanisms. Steps 7 and 8: For vaccine activity, mRNA encoded antigens are degraded into shorter fragments and loaded onto MHC class I and class II molecules. Step 9: Protein-derived epitopes can then be presented on the cell surface by both MHC class I and MHC class II molecules, enabling stimulation of CD8+ and CD4+ T cells.

The structural elements of the mRNA have an impact on its performance. This includes potential immunogenicity, efficacy of translation and stability of the molecule. We leverage our extensive experience to design, synthesize, manufacture and formulate our therapeutic mRNA, and adapt its composition to suit the desired application.

B. mRNA Backbone Concepts and Technologies

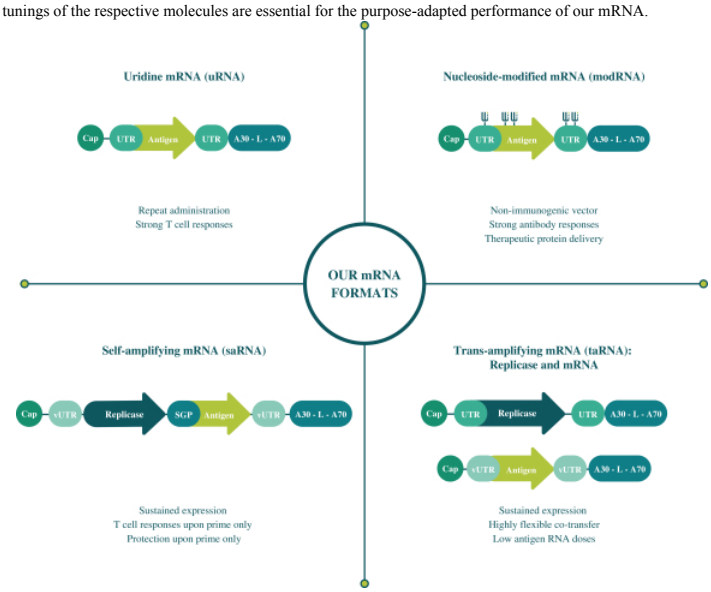
Our mRNAs all contain basic structural elements, including the 5' cap, the untranslated regions and the poly(A) tail, in addition to a coding sequence, that are all encoded by our DNA template.



- The cap is added to the 5' end of the mRNA during its synthesis. Our studies have demonstrated that incorporation of a unique cap analogue into the mRNA helps to achieve superior translational performance by stabilizing the mRNA molecule and directing the immune response. This unique cap analogue is extremely useful for our immunotherapy approaches.
- The composition and structure of the 5' and 3' untranslated regions of the mRNA molecule are important determinants of the intracellular stability of mRNA. As a result of rigorous screening of different mRNA sequences, we identified specific UTRs that promote increased protein translation for long duration.
- We have performed extensive research on the structure of the poly(A) tail and the translational performance of mRNA and customized our template design accordingly.

The translational performance of mRNA can be increased by removing contaminating double-stranded RNA from the mRNA. We have extensive expertise in different mRNA purification procedures. We have also invented a novel mRNA purification method that greatly impacts translatability of our mRNA. Depending on the protein characteristics needed for treatment of a disease, we optimize the DNA template through a proprietary codon optimization process, changing the nucleotide sequence of the template without altering the amino acid composition of the encoded protein. We make further

adjustments during mRNA production. We believe these fine tunings of the respective molecules are essential for the purpose-adapted performance of our mRNA.



Our mRNA formats. As shown above, we have developed four mRNA formats, each optimized for different therapeutic applications. Abbreviations: y, 1-methylpseudouridine; UTR, untranslated region.

Our mRNA formats include:

1. Optimized Uridine mRNA (uRNA)

The nucleotide sequence of mRNA determines the amino acid sequence of the protein. In addition, the nature of nucleosides used for production of mRNA drugs can also influence recognition of the molecule by the immune system. Presence of naturally occurring uridine (U) in our optimized uridine mRNA makes it immunogenic by activating immune sensors. We have further optimized our uridine mRNA for immunogenicity (augmented antigen presentation on MHC I and MHC II) and pharmacological activity (enhanced stability and translational efficiency). Immunogenicity of the mRNA is an added benefit when mRNA is used for immunotherapy applications, by acting as an immunotherapy adjuvant. This makes our therapeutics for iNeST and FixVac even more potent.

2. Nucleoside-modified mRNA (modRNA)

Immunogenic reaction against mRNA drugs needs to be avoided in applications where therapeutic proteins are produced, such as in our RiboMab and RiboCytokine platforms. We have profound expertise in incorporating naturally-occurring modified nucleosides into our therapeutic mRNAs. We have demonstrated that the presence of a variety of modified nucleosides in the manufactured mRNA suppresses its intrinsic immune activation, while leading to superior protein production for long duration. Deimmunizing mRNA by incorporating modified nucleosides helps to avoid production of anti-drug antibodies and broaden the therapeutic application of these types of mRNA drugs. We believe this customization has resulted in therapeutic mRNA that is both potent and well tolerated.

3. Self-amplifying mRNA (saRNA)

Our self-amplifying mRNA, or saRNA, drugs use the concept of viral replication, while not being an infectious, disease-causing agent itself. saRNA resembles conventional mRNA encoding the protein of interest, but also encoding a polymerase, called replicase, that multiplies part of the mRNA within the target cell. During self-amplification inside the cell, a double-stranded RNA intermediate is generated, which is recognized by intracellular immune sensors. This makes saRNA a very potent activator of the immune system and therefore an excellent category of immunotherapy. As we have demonstrated, our saRNA ensures high levels of sustained antigen production with a small amount of initial mRNA input. Our scientific team has designed this mRNA technology to act as a potent tool for prophylactic vaccination, with the potential application in infectious diseases with high medical needs.

4. Trans-amplifying mRNA (taRNA)

We have also expanded on our self-amplifying mRNA capabilities, developing a novel mRNA amplification technology by separating the target mRNA to be amplified and the replicase encoding mRNA. This advancement broadens the spectrum of applications by making the development of therapeutic mRNAs even more flexible, as the replicase can amplify mRNA encoding of not only one protein, but several different ones. In the case of vaccines, this allows us to produce the replicase in advance for use with different vaccines. Our trans-amplifying mRNA is a proprietary mRNA format that is particularly well-suited for prophylactic vaccines to prevent infectious diseases.

C. mRNA Delivery Formulation Technologies

We have deep and broad expertise in the targeted delivery of mRNA therapeutics. We are convinced that our development of suitable delivery formulations in conjunction with our own therapeutic mRNAs is a key competitive advantage.

We employ multiple mRNA delivery formulations, each designed for different functions and optimized for therapeutic product needs:

- **Lipoplex:** Our lipoplex formulation, or LPX, embeds the mRNA between a lipid bilayer, which is used for our FixVac and iNeST platforms. We use a proprietary size- and charge-based non-viral mRNA lipoplex that was developed to deliver mRNA to dendritic cells in lymphoid compartments such as the spleen for optimal antigen presentation and immune response activation.
- **LNPs:** For other applications, we encapsulate our mRNA in lipid nanoparticles, or LNPs. These formulations are suitable for our RiboMab, RiboCytokine and rare disease protein replacement platforms. Our LNP formulations can be adjusted according to our needs for delivery to particular target tissues, such as the liver in the case of our rare disease protein replacement platform.
- **Polyplexes:** Our portfolio also comprises polyplexes, which are being utilized in certain of our discovery programs, in which the mRNA is bound to a polymer and then forms nanoparticles.

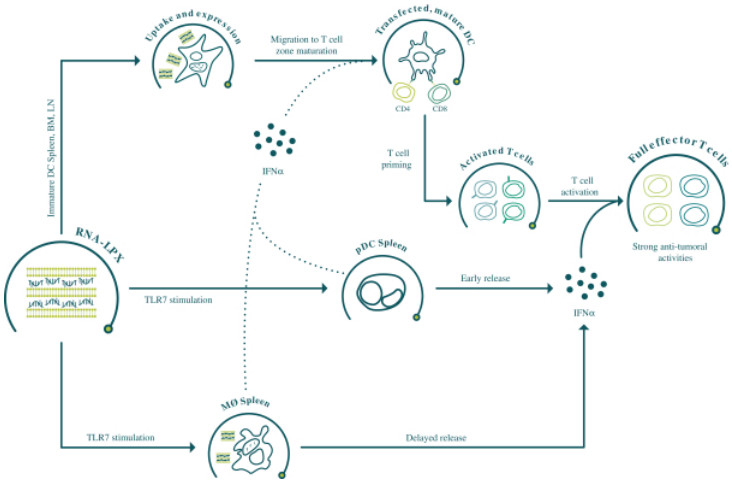
RNA-LPX Technology

At a glance: RNA-LPX Cancer Immunotherapy Technology

- Potential first-in-class clinical intravenous nano-particulate mRNA immunotherapy, allowing systemic delivery.
- Strong potency by systemic targeting to dendritic cells in lymphoid tissues.
- Universally applicable for all cancer antigens.
- Opportunity to deliver multiple antigens in parallel, enabling the induction of poly-specific T cell responses.
- Synchronized adjuvant effect mediated by toll-like receptor 7 (TLR7)-triggering and type-I interferon-driven innate and adaptive immune stimulation.
- Preclinical anti-tumoral activity demonstrated against multiple tumors.
- Unprecedented clinical immune responses against shared TAAs.
- Beneficial clinical activity demonstrated in advanced melanoma patients.

To advance from local to systemic dendritic cell, or DC, targeting, we developed an innovative liposome-based RNA-lipoplex formulation, RNA-LPX, that allows for intravenous administration of our mRNA cancer immunotherapies. We

have demonstrated in the clinic that systemic DC targeting by mRNA cancer immunotherapies can result in potent activity at very low doses. Consequently, less material is required for treating high patient numbers, making manufacturing more cost-effective.



Our RNA-LPX technology. Our proprietary RNA-LPX formulation is designed to deliver vaccine mRNA precisely into DCs and macrophages in the spleen and other lymphoid compartments. The RNA-LPX has an inherent adjuvant function stimulating the release of cytokines such as IFN-a thereby promoting the activation of DCs and the induction of strong T cell responses. Abbreviations: BM, bone marrow; LN, lymph node; DC, dendritic cell; pDC, plasmacytoid dendritic cell; Mø, macrophage; IFN-a, interferon alpha.

RNA-LPX protects mRNA from degradation outside of the cell and mediates its efficient uptake and expression of encoded antigens in various dendritic cell populations. Our RNA-LPX technology is designed to target a wide variety of antigens and address cancer patients with all possible HLA haplotypes. Utilizing RNA-LPX, we can target fixed groups of known shared antigens with our FixVac platform and a whole new class of patient-specific neoantigen targets with our iNeST platform.

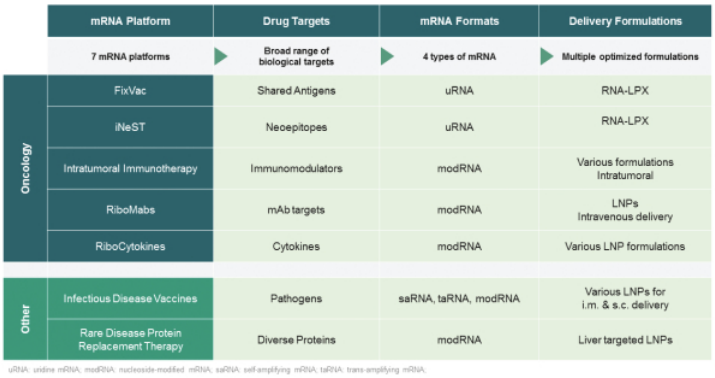
RNA-Lipid Nanoparticle Formulation for infectious disease vaccines

Our COVID-19 Vaccine BNT162b2 is based on an RNA-LNP platform of nucleoside modified RNA, which has blunted innate immune sensor activating capacity and thus augmented antigen expression. BNT162b2 encodes a P2 mutant S (P2 S) and is formulated in LNPs. Encapsulation into LNPs enables transfection of the RNA into host cells after intramuscular injection. These LNPs are composed of four different lipids in a defined ratio. During mixing of the RNA and the dissolved lipids, the lipids form the nanoparticles encapsulating the RNA. After injection, the LNPs are taken up by the cells, and the RNA is released into the cytosol. In the cytosol, the RNA is translated to the encoded viral protein.

D. mRNA Platforms

We are developing multiple mRNA-based therapeutic platforms. These include FixVac, iNeST, mRNA-based intratumoral immunotherapy, RiboMabs and RiboCytokines in the oncology space. In addition, we have implemented mRNA platforms for the development of infectious disease vaccines and protein replacement therapies for rare diseases.

Importantly, each of these platforms enables the development of multiple pharmaceutical product candidates or programs.



Our mRNA Platforms. We have multiple mRNA-based platforms utilizing different mRNA formats and delivery formulations, directed at a range of biological targets in oncology and infectious and rare diseases.

1. Cancer Immunotherapies

Our goal is to develop safe, potent, efficacious and cost-effective cancer immunotherapies which stimulate and potently expand tumor cell specific CD4+ and CD8+ T cells in cancer patients. Our cancer immunotherapy development integrates our competencies in mRNA backbone optimization, formulation development and immunological research.

a) FixVac

At a glance: Our FixVac Platform

- **Concept:** Cancer immunotherapies targeting shared antigens that we have identified to be frequently expressed across patients with a specific cancer type.
- **mRNA Format:** Optimized uridine mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting dendritic cells (DCs).
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT111 for metastatic melanoma.

Our FixVac approach involves off-the-shelf mRNA immunotherapies targeting cancer cell-specific shared tumor associated antigens, or TAAs, for selected patient populations. Our FixVac product candidates target TAAs which are commonly expressed by a significant portion of patients in a given cancer type. We have developed a sophisticated target selection process which enables us to produce poly-specific FixVac immunotherapies that cover up to 95% of patients with a given cancer type. The use of off-the-shelf FixVac immunotherapies allows for large-batch manufacturing and prompt supply to patients with ready-to-use medication, ensuring a straight-forward cost- and time-efficient manufacturing process with favorable logistics.

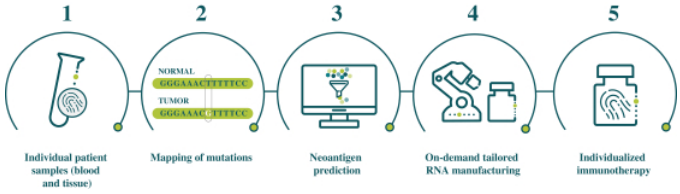
Besides targeting commonly expressed TAAs, our target selection strategy facilitates the identification of suitable viral oncoproteins for the treatment of virus-induced cancers like HPV+ head and neck cancer. Patient stratification, if needed, can easily be performed at the clinical site or a central lab using standard biotechnological methods, thereby reducing treatment costs. As the viral genome is comparatively small, encoding only for a few proteins, we believe our FixVac approach is ideally suited for the treatment of virus-induced cancers.

b) Individualized Neoantigen Specific Immunotherapy (iNeST)

At a glance: Our iNeST Platform

- **Concept:** Individualized cancer immunotherapy targeting neoantigens identified on a patient by patient basis and selected for immunogenicity.
- **mRNA Format:** Optimized uridine mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting DCs.
- **Development Approach:** 50:50 cost share with Genentech.
- **Lead Candidate:** autogene cevumeran (BNT122) as a first-line melanoma therapy in combination with pembrolizumab.

We are a pioneer and global leader in developing fully individualized cancer immunotherapies. We have developed a first of its kind, on-demand manufacturing process to treat each individual patient based on the mutation profile of the patient's tumor. We are investigating this treatment approach in the clinic in collaboration with Genentech.



Our iNeST process. The figure above depicts our iNeST process for the on-demand production of individualized mRNA cancer immunotherapies.

Our iNeST process is summarized below:

- A blood sample and tumor biopsy is taken from the patient to obtain healthy cells and tumor tissue. We extract healthy cells from the patient's blood sample and tumor cells from the tumor sample. We use NGS to analyze genetic material (DNA and RNA) of these cells to identify which mutations are present in the cancer cells compared to healthy cells.
- We apply proprietary bioinformatic algorithms to identify tumor-specific mutations. The mutations within a cancer cell differ widely from patient to patient and form a unique signature for each tumor. This genomic information can be further utilized to analyze tumor heterogeneity and microenvironment as well as individual aspects of the immune system like the HLA type.
- Based on these bioinformatic algorithms, we then select mutations that are the most promising therapeutic targets. The specific traits of the patient's immune system, including HLA type, are key to the selection of the most appropriate targets. Picking multiple mutations increases the chance to induce potent T cell responses and reduces the risk that the tumor evades T cell attack over time. We account for heterogeneity of each tumor by preferentially selecting mutations that are expressed on all tumor cells. Importantly, the selected mutations are intended to ensure both CD4+ and CD8+ T cell induction.
- Following mutation selection, we design the structure for the iNeST product. The chosen mutations have to be arranged in a certain order and the DNA sequence of the mutations has to be optimized. This is important to ensure a robust production of the starting material, or DNA matrix, for the GMP manufacturing of the iNeST product.
- Next we produce the patient-specific iNeST product under GMP conditions and the iNeST product undergoes numerous different quality control tests.
- The iNeST product is transferred to the hospital and injected into the same patient by the physician.
- This process has been designed for the on-demand delivery of our iNeST products, and currently takes approximately six weeks.

We are currently developing iNeST therapeutics for the treatment of metastatic melanoma and multiple solid tumors.

c) Intratumoral mRNA Immunotherapy

At a glance: Our Intratumoral mRNA Platform

- **Concept:** Immunomodulator-encoding mRNA injected directly into the tumor in order to avoid off-target toxicities.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- **mRNA Delivery Formulation:** Various formulations, delivered by intratumoral injection.
- **Development Approach:** Co-development and co-commercialization, at our option, in collaboration with Sanofi.
- **Lead Candidate:** SAR441000 (BNT131) for advanced solid tumors as a monotherapy and in combination with cemiplimab.

In collaboration with Sanofi, we are leveraging our mRNA technology to develop intratumoral immunotherapies for the treatment of solid tumors. Intratumoral immunotherapy is designed to promote innate and adaptive immune responses against tumors, without toxicities related to systemic administration. Our intratumoral immunotherapy involves injection of cytokine-encoding mRNA directly into a tumor in order to alter the tumor microenvironment and promote greater T cell activity. This approach has been found in preclinical studies to boost cancer-specific immune responses locally, while also producing tumor responses in remote parts of the body due to the circulation of properly activated anti-tumor immune cells, known as an abscopal effect.

The first intratumoral immunotherapy product candidate arising from our collaboration, SAR441000 (BNT131), includes modified mRNA that encodes for the IL-15sushi, IL-12sc, GM-CSF and IFN-α cytokines. We and Sanofi published data from our Phase 1 trial of SAR441000 (BNT131) as a monotherapy and in combination with cemiplimab in advanced solid tumors in July 2020, in which no patient experienced a dose limiting toxicity and no grade 3, 4, or 5 adverse events related to study treatment were reported.

2. Infectious Disease Vaccines

At a glance: Our Infectious Disease Vaccine Platform

- **Concept:** mRNA-based vaccines targeting infectious disease pathogens.
- **mRNA Format:** Multiple.
- **mRNA Delivery Formulation:** LNPs.
- **Development Approach:** Collaborations with Pfizer and Fosun Pharma and exclusive option arrangement with Penn.
- **Commercial Product:** COVID-19 vaccine (COMIRNATY in the EUand other locations where we have received marketing approval).
- **Lead Candidates:** Influenza vaccine candidate BNT161 and other vaccine candidate variants in our BNT162 development program.

Expanding beyond our research in oncology, we are leveraging our mRNA technologies to direct the immune system more effectively against infectious diseases. Our infectious disease vaccine candidates contain self-replicating or trans-replicating, modified mRNA-encoding antigens specific to a target pathogen, delivered in various LNP formulations in order to activate and direct T cells and B cells to fight the pathogen.

BNT162b2 COVID-19 vaccine and Other COVID-19 Vaccine Candidates

Our COVID-19 vaccine, referred to as COMIRNATY in the European Union and other locations where we have received marketing approval, has received emergency or temporary use authorization or approval in over 100 countries.

Our BNT162 mRNA Formats

The overall development program initially included multiple vaccine candidate variants, some of which target the entire two-point -mutated full spike protein antigen and others which target the more specific receptor binding domain subunit of the antigen protein. The Phase 1 clinical studies were conducted with several different candidates, however to-date we have only advanced further development on BNT162b2.

Coronavirus Spike Glycoprotein as vaccine target

Coronaviruses are a family of (+) ssRNA enveloped viruses that encode four structural proteins. Among these structural proteins, S is a key target of neutralizing antibodies and therefore an important antigen for vaccine development. The spike protein is an important vaccine target or antigen, as it mediates first the specific binding of the virus to the angiotensin-converting enzyme 2 (ACE2) host cell receptor and then the fusion of the viral envelope with a host cell membrane. By these actions, the virus can enter human cells where it replicates, often causing illness, and potentially spreading to other people. Data available from other coronaviruses such as SARS and MERS had established that antibodies to the S protein can block the binding of the virus to cells and prevent viral infection. BNT162b2 encodes a membrane-anchored, full-length S protein with two-point mutations to proline within the central helix domain to lock S protein in an antigenically preferred prefusion conformation.

Influenza Vaccine

We are collaborating with Pfizer to develop an influenza vaccine using our mRNA-based immunotherapy technology. Current influenza vaccines consist of antigens from inactivated influenza viruses, recombinant influenza haemagglutinin, or HA, proteins or live attenuated influenza viruses and are available as trivalent (containing two influenza A strains and one influenza B strain) or quadrivalent (containing two influenza A strains and two influenza B strains) vaccines. Currently available influenza vaccines are produced in chicken eggs or cell culture and take about five to six months to produce. This requires the composition of the coming season's vaccine to be selected by the World Health Organization, or WHO, far in advance for the vaccine to be available on time, which reduces the reliability of that prediction.

We anticipate that our mRNA-based vaccines can be manufactured within three months from the time the recommendation is published, including cloning and production and therefore the WHO's review of the vaccine components can occur closer to the influenza season to obtain a more reliable prediction. In addition, the mRNA manufacturing process is designed to produce an HA vaccine antigen that matches the HA of circulating influenza strains, in contrast to egg- or cell-based processes which can introduce mutations in the HA amino acid sequence. The flexibility of the mRNA vaccine platform could allow for generation of vaccines against genetically drifted seasonal viruses or pandemic strains.

3. mRNA-based Protein Replacement Platform for Rare Diseases

At a glance: Our Protein Replacement Platform for Rare Diseases

- **Concept:** Therapeutic proteins encoded by mRNA and produced in the patient as an alternative to recombinant protein replacement.
- **mRNA Format:** Nucleoside-modified mRNA, deimmunized to avoid immune activation in order to allow for translation of the therapeutic protein in the cells.
- **mRNA Delivery Formulation:** Liver-targeting LNPs.
- **Development Approach:** 50:50 cost and profit share with Genevant.

By incorporating modified nucleosides into our mRNA, we are able to reduce the immunogenicity of our product candidates, thereby allowing their use for therapeutic protein production. In addition, we utilize advanced mRNA delivery methods to protect the mRNA cargo *en route* to its target and promote its uptake into liver cells. Current protein-based replacement therapies were developed to treat rare diseases by administering recombinant proteins. Such therapies are limited to diseases where the missing protein function is extracellular. However, mRNA-based protein replacement therapy also has the potential to treat illnesses with intracellular protein defects, as long as the mRNA can be delivered into the affected cells.

Our mRNA-based protein replacement therapy features:

- **Nucleoside-modified mRNA.** Replacing uridines in mRNA with modified analogues is important to avoid immune activation that can provoke anti-drug antibody production and would limit efficacy of the treatment.
- **Liver targeted expression.** mRNA encoding therapeutic proteins are formulated into LNPs using in-licensed clinically-validated LNP delivery technology owned by Genevant. The mRNA-loaded LNPs are less than 100nm in size. When injected intravenously, these particles are selectively taken up by hepatocytes, the major cell component of the liver.

Our protein replacement technology is designed for the treatment of:

- Genetic disorders that manifest due to a missing or defective protein, where mRNA would need to be administered regularly for a lifetime.
- Acute diseases caused by transient depletion of a protein, such as a hormone, where treatment of such diseases with a single or a few doses of the encoding mRNA could be curative.

Therapeutic proteins encoded by the mRNA can either act intracellularly or be secreted and act extracellularly, in order to produce the desired therapeutic effect.

mRNA-based protein replacement technology has several advantages over recombinant proteins:

- **No need to develop a procedure for protein purification.** The development of recombinant proteins is a laborious and expensive procedure due to the requirement for a unique purification protocol for each protein. During mRNA-based protein replacement the protein is produced by the patient, which we believe avoids the need for purification and also accelerates drug development.
- **The protein has proper post-translational modification.** To function properly, most recombinant proteins need to be modified after synthesis. Proteins produced in patients from mRNA are more likely to obtain the correct modifications than recombinant proteins produced in cultured bacterial or mammalian cells.
- **Continuous *in vivo* supply of encoded protein.** Recombinant proteins, especially those with short half-lives, can be cleared from the body very quickly, thereby limiting therapeutic effect. During mRNA-based therapy, the encoded therapeutic protein is produced for a longer duration (*e.g.*, 10-14 days).
- **Production of intracellular proteins.** Recombinant proteins have limited intracellular therapeutic effects. In contrast, proteins encoded by mRNA can reach any cellular compartment and potentially help to cure diseases where the therapeutic protein needs to function in different subcellular locations, including the mitochondria, nucleus or cell membrane.

4. RiboMabs

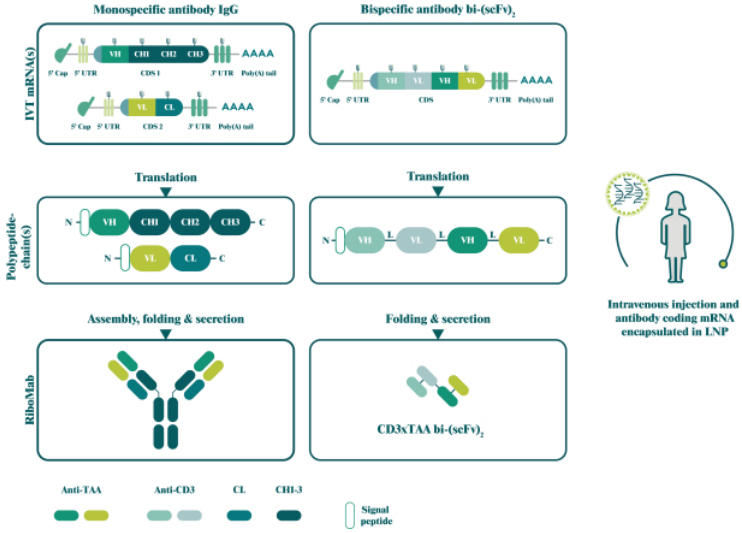
At a glance: Our RiboMab Platform

- **Concept:** Antibodies encoded by mRNA and produced in the patient as an alternative to recombinant antibodies.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded antibodies to occur within the cells.
- **mRNA Delivery Formulation:** Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the antibody *in vivo*.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT141 in multiple solid tumors.

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. We believe our RiboMab technology represents the next generation of antibody-based drugs. Antibody drugs are a leading class of biologics for the treatment of various diseases, but have a number of limitations. The development of antibodies is currently challenged by demanding and costly procedures of production, purification and formulation of a recombinant protein, which we believe hampers the rapid development and clinical testing of new drugs in this class. Recombinant protein antibodies require development of a cell line, establishment and adaptation of processes for production, purification and analytical testing. The whole process typically takes 18 to 30 months to optimize, scale-up and

produce first clinical batches. Some of these antibodies are produced in low yields making them unsuitable for therapeutic application.

By contrast, mRNA not only involves a simpler and less expensive manufacturing process, but also is effective in much lower volumes than are required to produce similar effects using recombinant proteins. RiboMabs provide an antibody's mRNA sequence, and the body does the production work itself. This simplicity is designed to allow for both shorter development times and a greater diversity of druggable targets. For efficient RiboMab production, the encoding mRNA is encapsulated in LNPs that deliver the mRNA to the liver cells. For cancer treatment, we focus on tumor-associated antigens to keep adverse effects for the patients as low as possible. We believe we can integrate any antibody sequence in our RiboMab-encoding mRNA. We have demonstrated the feasibility of our RiboMab technology for a variety of antibody formats, such as full immunoglobulins (Ig), primarily IgG, or different bispecific antibody variants, all of which engage the patient's own immune cells to eradicate antigen-positive tumor cells.



Our RiboMab technology. The figure above depicts the structure of *in vitro* transcribed (IVT) IgG and bi-(scFv)2 RiboMabs. IVT-mRNA encoding the therapeutic antibody is encapsulated in LNPs and injected intravenously into patients. The mRNA is delivered to the liver where it is translated into antibodies and secreted into the blood stream. Abbreviations: A100, poly adenosine tail; bi-(scFv)2, bispecific single chain variable fragment; C, C-terminus; CH, constant heavy domain; CL, constant light domain; IgG, immunoglobulin G; IVT, *in vitro* transcribed; L, linker; LNP, lipid nanoparticles; m1y, 1-methylpseudouridine; N, N-terminus; TAA, tumor-associated antigen; VH, variable heavy domain; VL, variable light domain; UTR, untranslated region.

We believe our broad portfolio of antibody formats will enable us to produce mRNAs encoding the appropriate antibody format for the individual patient's medical need and the desired treatment regimen (*e.g.,* monotherapy or combination therapy).

5. RiboCytokines

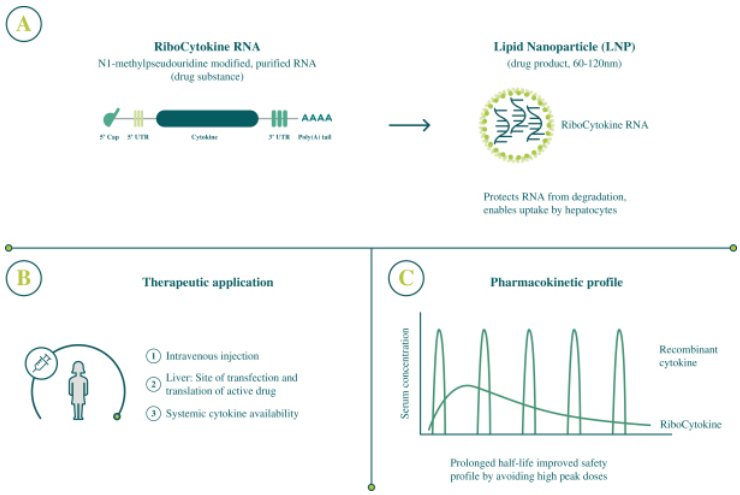
At a glance: Our RiboCytokine Platform

- **Concept:** Cytokines encoded by mRNA and produced in the patient as an alternative to recombinant cytokines.

- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- **mRNA Delivery Formulation:** Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the cytokine *in vivo*.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT151 in multiple advanced malignancies.

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. Cytokines represent a large group of relatively small proteins (<30 kDa) that regulate a variety of biological functions as they elicit signaling for immune and non-immune cells. In particular, cytokines play a pivotal role in orchestrating the initiation, execution and extinction of innate and adaptive immunity against pathogens as well as malignant cells. Due to their natural role as immunomodulators, recombinant cytokines are currently used for the treatment of a number of infectious, inflammatory, autoimmune and malignant diseases. One of the major challenges associated with the therapeutic use of cytokines relates to their short serum half-life and low bioavailability. This impedes therapeutic efficacy as it necessitates high and frequent dosing, which often results in dose-limiting toxicities.

We have developed a wholly owned, novel mRNA-based platform technology called RiboCytokines, designed to address the limitations of recombinantly expressed cytokines.



Concept of our RiboCytokine technology. The graphic above depicts our RiboCytokine technology, including mRNA formulated in LNPs and administered by injection, having a beneficial pharmacokinetic profile.

Our RiboCytokine platform allows for sustained delivery of the encoded cytokines with prolonged half-life, including through:

- **Usage of N1-methylpseudouridine modified mRNA.** N1-methylpseudouridine as a nucleoside analogue prevents the recognition of mRNA by TLRs, avoiding immune attack against the RiboCytokines.
- **Liver targeted expression.** RiboCytokines are formulated using clinically validated LNP delivery technology owned by Genevant. LNPs selectively target the liver resulting in high-level expression.

We believe that apart from a beneficial pharmacokinetic profile, our mRNA-based RiboCytokine technology has a number of additional advantages over other types of cytokine therapies:

- **Less immunogenic than recombinant cytokines.** Expression of self and foreign antigens in the liver is associated with immune tolerance due to a unique anti-inflammatory microenvironment. We expect RiboCytokines to be less likely to trigger an immune response when compared to their recombinant counterparts.
- **Shorter development times and greater diversity.** The development of recombinant cytokines is a challenge due to demanding and costly CMC procedures of production, purification and formulation. The simplicity of our mRNA manufacturing allows for both shorter development times and a greater diversity of druggable targets.

We believe that our RiboCytokine technology is particularly well-suited to identify candidates for combination treatment with our proprietary CAR-T cell and cancer immunotherapies platforms.

VIII. Cell Therapies Drug Class

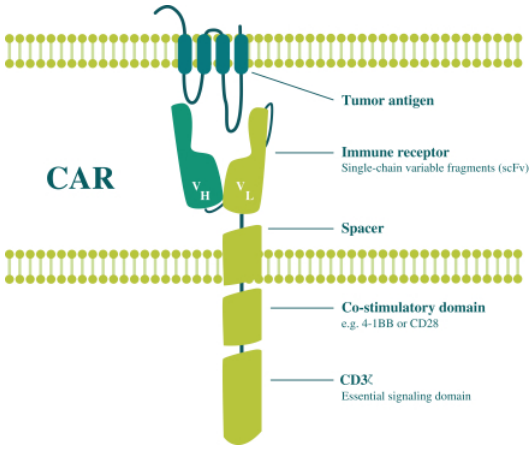
The tailored reprogramming of autologous T cells from cancer patients to recognize and attack their tumors has become a disruptive medical innovation. Retargeting of T cells can be achieved via introduction of tumor-specific receptors into patient-derived T cells. For that purpose, T cells are mostly engineered by retroviral gene transfer to express either T cell receptors, or TCRs, or chimeric antigen receptors, or CARs. Recently, CAR expressing T cells, or CAR-T cells, became the first engineered T cell therapy to obtain FDA approval for some B cell derived hematological malignancies. Additionally, with our Neon acquisition we recently acquired an adoptive T cell platform targeting patient-specific and shared neoantigens. This platform utilizes a proprietary *ex vivo* co-culture process, NEO-STIM, to prime, activate and expand autologous neoantigen-specific T cells specific either for a personal set of neoantigens for each patient or for a set of selected shared neoantigens.

A. CAR-T Cells

At a glance: Our CAR-T Platform

- **Concept:** Second-generation CAR-T therapy designed to overcome the shortcomings of CAR-T therapy in solid tumors.
- **Mechanism:** T cells with CARs engineered to target cancer-specific antigens, including novel antigens selected from our proprietary antigen library and administered with an mRNA-based immune booster, which we refer to as CARVac, to enhance CAR-T cell expansion and persistence.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT211 for multiple solid tumors.

CARs are artificial receptors that consist of an antigen recognition domain derived from a tumor-specific antibody linked to intracellular T cell signaling domains. CARs redirect T cells to eradicate tumors through specific recognition of native surface proteins expressed on tumor cells in a non-MHC-restricted manner. Therefore, CAR-T cells can be used for the treatment of all individuals whose tumor expresses the respective target, independent of the individual's HLA genotype. CARs can be used for redirection of both CD4+ and CD8+ T cells.



Second-generation CAR. The figure above illustrates the basic structure of a second-generation CAR, such as those included in our BNT211 and BNT212 product candidates.

While CAR-T therapy has shown potent anti-tumor responses in patients with B cell malignancies, clinical efficacy in solid tumors so far is limited. The main hurdles for application of CAR-T therapies in solid tumors are:

- Lack of highly tumor-selective targets, which are needed for safe and effective tumor targeting; and
- Low anti-tumoral activity due to insufficient expansion of engineered T cells.

We are developing the next generation of engineered T cell therapies that:

- target novel and known tumor-specific antigens, including mutant neoantigens, and a broad spectrum of tumor-associated antigens expressed in a wide range of cancers; and
- leverage our proprietary CARVac technology for controlled *in vivo* stimulation, activation and expansion of engineered T cells.

The powerful characteristics of CAR-T cells, including their potential to eradicate targeted tumor cells in combination with their potentially life-long persistence in the host, require careful target selection. We believe the essential features of an ideal antigen for T cell-based immunotherapy are:

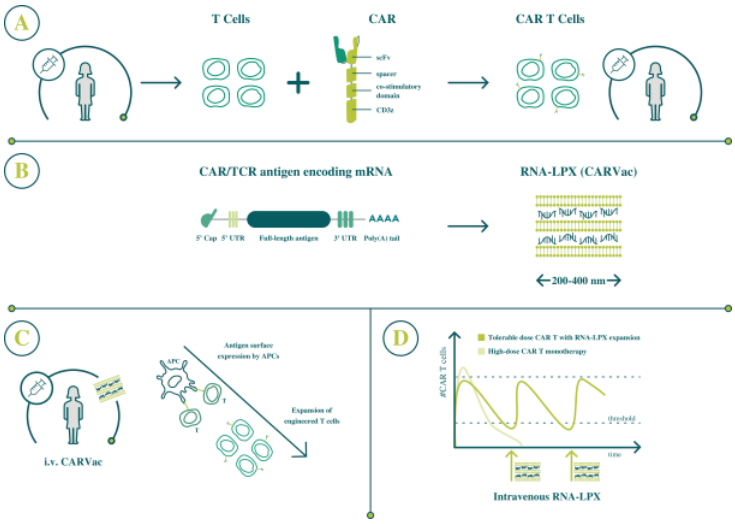
- Absence of expression from any toxicity-relevant non-malignant tissue, to prevent off-tumor/on-target toxicity; and
- Expression on the cell surface of tumor cells at sufficient levels to allow for recognition and lysis by CAR-T cells.

We are developing CAR-T programs targeting two different members of the Claudin family, namely CLDN6 and CLDN18.2. Claudins, or CLDNs, are central components of tight junctions that regulate epithelial-cell barrier function and polarity. Most of the CLDNs are broadly expressed, while CLDN6 and CLDN18.2 are exclusively expressed in different high medical need cancers. Disturbance and dysregulation of tight junction molecules is a frequent hallmark of cancer cells and often associated with malignant transformation and metastasis and, hence, disease progression.

In-vivo *expansion of engineered T cells using liposomally formulated mRNA*

Besides targeting an ideal tumor-specific antigen, the frequency and the persistence of CAR-T cells in the respective patient is a critical factor determining antitumor efficacy. A positive correlation between clinical outcome and CAR-T cell engraftment and persistence has been shown in several CD19-targeting CAR-T trials. Both tend to be much more limited in the solid tumor setting, likely due to the lack of circulating antigen-presenting cells, or APCs, such as dendritic cells expressing the target CAR antigen.

To address this critical factor, we developed an approach for *in vivo* stimulation of CAR-T cells that relies on our proprietary FixVac technology for systemic mRNA delivery in combination with our CAR-T product candidates. Intravenous administration of a FixVac encoding for the tumor antigen induces expression of the desired target on antigen-presenting cells in secondary lymphoid tissues. FixVac treatment facilitates *in vivo* expansion of CAR-T cells in a dose-dependent manner. Moreover, repetitive administration of FixVac results in an improved CAR-T cell persistence as well as increased anti-tumor activity.



Our CAR-T cell immunotherapies combined with CARVac-mediated *in vivo* expansion. (A) Autologous T cells engineered to express a CAR are adoptively transferred into the patient. (B) Full-length CAR target-encoding mRNA is complexed with liposomes to form RNA-LPX lipoplexes (CARVac). (C) Intravenously administered CARVac selectively targets APCs in secondary lymphoid organs facilitating uptake, antigen expression and maturation of APCs. Exposure of CAR-T cells to their target results in CAR-T cell *in vivo* expansion. (D) CARVac can be administered repetitively to achieve controlled expansion and persistence of CAR-T cells within the therapeutic window.

B. Neoantigen-targeting T Cells

At a glance: Our Neoantigen-targeting T Cell Platform

- **Concept:** Adoptive T cell therapies targeting personal or shared sets of cancer neoantigens.
- **Mechanism:** Autologous, neoantigen-specific T cells primed, activated and expanded utilizing a proprietary antigen-specific T cell induction protocol, NEO-STIM, to target either a personal set of neoantigens for each patient or a set of selected shared neoantigens.
- **Development Approach:** Worldwide rights.

- **Lead Candidate:** BNT221 for metastatic melanoma and other potential cancer indications.

Through our acquisition of Neon in 2020, we obtained a neoantigen-targeting T cell platform. This platform can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies using two distinct approaches:

- An individualized approach enabling neoantigen-targeted therapies that are tailored for the individual profile of each patient's tumor.
- A shared neoantigen approach enabling neoantigen therapies that target prevalent neoantigens that are shared across subsets of patients or tumor types.

Our RECON bioinformatics engine is designed to predict the most therapeutically-relevant neoantigen targets associated with each patient's tumor. Effective prediction is critical because, although many mutations within a patient's tumor will lead to the production of a mutated protein, not all mutated proteins lead to suitable therapeutic neoantigen targets. RECON uses a number of inputs from each patient, including DNA sequences from samples of tumor and normal tissue, RNA sequences from tumor samples, and the patient's specific MHC allele profile. RECON processes data from these inputs using a proprietary combination of algorithms in order to produce a prioritized list of neoantigen-targeting peptides that can be manufactured for use in product candidates. After selection of the target neoantigens, our proprietary method for *ex vivo* T cell stimulation, which we call NEO-STIM, allows us to directly prime, activate and expand antigen-specific T cells.

C. TCRs

The T cell receptor, or TCR, is part of a complex signaling machinery, which includes the TCR a and ß chains that are responsible for antigen recognition, the co-receptor CD4+ or CD8+ and the CD3 signal transduction complex. TCRs recognize antigens presented on the cell surface as small peptides loaded on the patients' HLA molecules. Those peptides are derived from proteins after intracellular degradation. In contrast to CARs that recognize solely native membrane proteins, the repertoire of suitable TCR target antigens include TAAs and mutant neoantigens.

Our TCR Discovery and Validation Platform

We have developed an integrated technology platform for the systematic identification of functional, fully human TCRs from single antigen-reactive T cells. This technology consists of a proprietary high-throughput approach for the fast retrieval, cloning and rapid validation of novel paired T cell receptor sequences. Our approach facilitates the isolation of tumor cell specific TCRs against multiple antigens and various HLA class I and II alleles.

We believe our TCR discovery technology has the potential to unlock an array of patient- and tumor-specific TCRs suitable for clinical use. We believe this technology has potential utility for:

- therapeutic TCR products encompassing single TCRs to target a specific antigen;
- a therapeutic TCR warehouse encompassing multiple TCRs to target one or more tumor antigens; or
- individualized T cell therapy involving on-demand identification and timely manufacturing of customized, engineered T cells with autologous TCRs against neoepitopes for adoptive transfer.

IX. Antibodies Drug Class

In the past decades, monoclonal antibodies, or mAbs, have transformed from scientific tools to powerful human therapeutics. As one of the fastest growing classes of drugs, to date, dozens of mAbs have been approved to treat a variety of diseases including cancer, inflammation, autoimmune diseases and others. In addition, identified antigen-binding domains are also fundamental elements for the construction of novel therapeutic formats and formulations, such as CAR-T cells, bispecific therapeutics and targeted nanoparticles.

We have developed and integrated multiple complementary antibody and antibody-mimetic protein technologies into our overall portfolio of treatment approaches.

A. Our Next-generation Checkpoint Immunomodulators

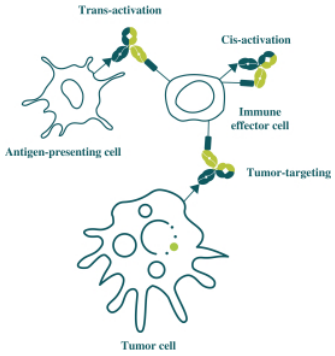
At a glance: Our Next-generation Checkpoint Immunomodulators

- **Concept:** Bispecific antibodies for dual immunomodulation, initially targeting 4-1BB, an immune checkpoint that is expressed on T cells and NK cells and can enhance immune cell proliferation and activation, in combination with simultaneous checkpoint inhibition.
- **Mechanism:** Conditional activation of 4-1BB checkpoint only upon simultaneous binding of PD-L1 or CD40 (in the case of our initial candidates), potentially avoiding toxicities seen in prior attempts at 4-1BB agonism by localizing 4-1BB activation to the tumor environment.
- **Development Approach:** 50:50 cost and profit share with Genmab, combining our and Genmab's immunostimulatory antibodies and extensive immunology expertise with Genmab's DuoBody® bispecific antibody platform.
- **Lead Candidate:** GEN1046 (BNT311), our PD-L1x4-1BB product candidate for multiple solid tumors.

Following the success of immune checkpoint-blocking antibodies targeting CTLA-4, PD-1 or PD-L1 in cancer treatment, bispecific antibody approaches represent the next generation of emerging immunotherapies with the potential to further improve clinical efficacy. In addition to bispecific T cell engager formats, which redirect T-cell cytotoxicity to malignant cells, bispecific antibodies can be formatted as tumor-targeted immunomodulators and dual immunomodulators. Tumor-targeted immunomodulators direct potent immune costimulation to the tumor-infiltrating immune cells, whereas dual immunomodulators simultaneously address two immunomodulating targets, resulting in blockade of inhibitory targets, depletion of suppressive cells or activation of immune effector cells.

We are developing, in collaboration with Genmab, bispecific antibodies that function as tumor-targeted and dual immunomodulators, applying Genmab's proprietary DuoBody® technology in combination with our joint target identification and product concept expertise. These next-generation checkpoint immunomodulators are thought to induce beneficial co-stimulation, promoting specific T cell activation, survival, proliferation and T cell effector functions. Our collaboration encompasses three potential classes of immunotherapeutic bispecific antibodies:

- Tumor-targeted DuoBody® molecules are bispecific antibodies targeting a tumor-specific antigen expressed by the malignant cell, and an immunomodulatory receptor expressed by tumor-infiltrating immune cells. This is expected to induce powerful activation of tumor-specific effector immune cells with reduced risk of immune-related adverse events.
- Cis-activating DuoBody® molecules are bispecific antibodies that bind two distinct immunomodulating targets presented on the same cell. These targets are specifically expressed on activated immune cells with the rationale to boost existing immune responses by additive or synergistic effects of dual immunomodulation.
- Trans-activating DuoBody® molecules are bispecific antibodies that bind two distinct immunomodulating targets expressed on two separate cell subsets. By simultaneously targeting, for example, effector immune cells and antigen-presenting cells, these compounds are thought to amplify the immune cell priming process and augment subsequent effector responses.



Next-generation checkpoint immunomodulators. Our collaboration with Genmab potentially includes bispecific antibodies from three different classes: trans-activating, cis-activating and tumor-targeting antibodies.

X. Small Molecule Immunomodulator Drug Class

At a glance: Small Molecule Immunomodulators

- **Concept:** Small molecule therapies, with a specific focus on TLRs, that can be used synergistically with other cancer therapeutics, including other product candidates in our portfolio.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT411, our TLR7 agonist product candidate intended as a monotherapy or in combination with chemotherapy and/or checkpoint inhibitors.

Small molecule cancer therapeutics can be used to regulate cancer growth, halt blood vessel formation in tumors, deliver toxins to cancer cells and mark cancer cells for destruction by the immune system. Unlike larger antibody-based cancer therapies, small molecule compounds are often developed for targets located within cells since they can enter the cells more easily as a result of their physical properties and low molecular weight. Small molecules also often have other intrinsic benefits including relative ease and cost of production compared to larger compounds, as well as more frequently having the potential for oral administration to patients. They can also often be used synergistically in combination with other therapeutics such as mRNA, checkpoint inhibitors, radiation therapy and chemotherapy.

Our immunomodulatory small molecule product class focuses on a range of endosomal and intracellular targets that are known to stimulate the activity of a wide range of immune cells. We have a particular emphasis on TLRs, a family of pattern recognition receptors that function as primary sensors of the innate immune system to recognize pathogens. We believe TLRs represent a promising target class for cancer immunotherapy, particularly for inflammatory re-programming of the tumor microenvironment. In many cancers, tumors are protected by an anti-inflammatory environment, which reduces the ability of the immune system to attack the cancer cells. TLR7 agonists are able to initiate a direct cellular immune response, for example, by activating immature dendritic cells, cytotoxic T cells and NK cells, as well as stimulating the release of signal molecules such as cytokines and chemokines including IFN-a and IP-10, which can be directed against tumor cells. The activation of the innate and adaptive immune system and the release of cytokines and chemokines, for instance by our small molecule TLR7 agonist, results in the potent stimulation of antigen-specific T cells, B cells and innate immune cells such as NK cells and macrophages.

Our initial focus is on small molecule product candidates that activate the innate and adaptive immune system via TLR7 and are designed to be used in combination with chemotherapeutics as well as checkpoint inhibitors.

XI. Sales, Marketing and Distribution

Our commercial organization focuses on supporting sales of our COVID-19 vaccine in Germany and certain markets where approved or authorized. Our sales and marketing organizations are responsible for promoting our products to health care providers and providing information to stakeholders, including governmental organizations, in the countries where we have authorization to sell the vaccine. Our commercial organization is also responsible for preparing and obtaining reimbursement from third-party payors, including governmental organizations, for our COVID-19 vaccine and will have the same responsibilities for our clinical-stage oncology product candidates, if approved.

Our German commercial team is comprised of a small number of individuals to support commercialization of our COVID-19 vaccine. We focus our marketing and sales efforts in Germany on all physicians and health care professionals involved in the vaccination efforts against COVID-19.

The commercialization models in the countries where we have the rights to commercialize are adjusted based on the respective commercialization agreements with our collaborators as well as the nature of the supply agreements with the governments for our COVID-19 vaccine.

XII. Manufacturing

We are building a fully integrated biotechnology company, with operations spanning from research through clinical development, and manufacturing through sales and marketing. We operate four GMP-certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers, including a state-of-the art, multi-platform, GMP-certified manufacturing facility located in a life science industrial park in Marburg, Germany, which we acquired in October 2020 from Novartis AG to increase manufacturing capacity of our COVID-19 vaccine for commercial supply commencing in 2021. We also operate a fifth facility in Germany where we manufacture custom peptides to support our extensive immunomonitoring activities within our development programs. Our subsidiary BioNTech Innovative Manufacturing Services GmbH, or BioNTech IMFS, has been manufacturing GMP-certified cellular products since 1999. It was granted its first GMP license for manufacturing mRNA in 2011 and has been manufacturing individualized mRNA products since 2014.

We have expanded our capability to produce and supply drug products to support clinical development of our, and our collaborators', product candidates. To date, we have manufactured about 1,000 drug substance batches in our manufacturing facilities.

Our approach has been to proactively build capacity in anticipation of demand from internal research and development, as well as from our collaborators. We have done so by continuing to make significant investments in manufacturing infrastructure and increasingly expanding our capacity to manufacture mRNA, viral vectors, cellular products and peptides. We believe the development and optimization of our manufacturing processes in parallel to drug development is crucial to our success. We have also collaborated with Siemens to develop a process for a fully-automated, on-demand production of mRNA therapies.

A. **Manufacturing Operations**

COVID-19 Vaccine. Our recently acquired manufacturing site in Marburg was approved by the EMA for manufacturing of the COVID-19 drug product in March 2021. This approval makes it one of the largest mRNA manufacturing sites worldwide alongside two of our existing GMP facilities, which currently produce the COVID-19 vaccine candidates for clinical trials. Marburg has reached an annual capacity of more than 1 billion doses mRNA drug substance in 2021. For 2022 we plan to expand the capacity to up to 3bn doses mRNA drug substance. The first vaccines manufactured at the Marburg site were delivered in April 2021. We rely on a network of sub-contractors to provide drug substance, drug conjugate, drug product, and fill and finish services to enable production. As of mid March 2022, we have signed orders for 2.4 billion doses of the vaccine for 2022 and already more than 500 million doses contracted for 2023, based on existing supply agreements with governments worldwide. Discussions for additional dose commitments are ongoing. As of the end of 2021, we and Pfizer have supplied more than 2.6 billion doses of our COVID-19 vaccine, including more than 1 billion doses to low- and middle-income countries, to more than 165 countries and regions worldwide. This estimate is based on the six BioNTech and Pfizer manufacturing sites producing the vaccine, the updated label permitting six doses per vial and continuous process improvements and expansion at our current facilities. It is further contingent upon us contracting with more suppliers and external contract manufacturers to expand LNP and fill and finish capacity.

The Marburg site contains approximately 100,000 square feet of laboratory and office space, including 50,000 square feet of GMP facilities and currently employs more than 400 people. We plan to manufacture additional therapeutic and vaccine drug candidates at the plant, such as other mRNA vaccine and antibody product candidates to support the development of our product pipeline. The site is also fully equipped to hold cell culture labs and produce viral vectors, with further potential for long-term growth and expansion.

mRNA. We believe scaling up manufacturing for mRNA can best be executed as part of a proprietary manufacturing approach, not as part of an outsourcing strategy. We believe this approach allows us to maintain control of our proprietary processes and gives us the flexibility we need for scheduling batch production for our drug substances to match our development plans as they evolve. Our mRNA manufacturing is currently conducted at our in-house BioNTech IMFS facility, our BioNTech East Wing facility, and at our Marburg facility. The East Wing facility is dedicated to iNeST (finished product) and bulk mRNA manufacturing. Our mRNA manufacturing process involves standardized production of all mRNA constructs and minimal restrictions in construct length. We have the capacity to undertake sterile filtration and final filling in up to 1,200 vials of various sizes in the EastWing and about 7000 vials at IMfS. Batch sizes range from a few milligrams for individualized applications (*i.e.*, iNeST) to 10g for standard mRNA applications (*i.e.*, FixVac, intratumoral immunotherapies and infectious diseases), and up to 360g batches for COVID-19. In 2022 we will further increase the batch size.

To date, we have produced more than 1000 batches of mRNA drug substance to support our studies. We currently have infrastructure capable of producing more than 100 batches of mRNA drug substance and formulated drug product per month with a turnaround time of about 30 to 40 days from sequence identification to released product. We believe we currently have the capacity to supply needs of our product candidates in clinical trials up to registration.

In recent years, we have successfully decreased the time required to deliver individualized immunotherapy to patients. In 2014, it took us over three months to manually manufacture and deliver individualized immunotherapies to patients. Since December 2017, with the implementation of semiautomatic GMP manufacturing in collaboration with Siemens, we have been consistently manufacturing and delivering individualized immunotherapies in under six weeks. This advancement represents significant progress toward our target commercial manufacturing turnaround time of less than 28 days and we have already demonstrated <30 days in 2021. We plan to continue to develop additional process improvements, which we expect will further reduce our turnaround times as we progress through clinical development.

Cell Therapy Products. We have end-to-end capabilities and over 20 years of experience in cell therapy manufacturing. Our manufacturing process for cellular products involves the isolation of primary human cells and subpopulations, including CD34+ and CD3+ cells. We engage in the culturing, expansion and genetic modification of primary human cells as well as mammalian cell lines. Our processes include vector production for transfection of cells with CARs, cell banking and cryopreservation.

We have set up a broad range of quality control assays for the characterization of cell therapy products that allow us to certify the manufactured drug products in a short time. We are a leader in the production of gamma retroviral vectors. To date, we have produced more than 50 different cell therapy products.

Peptides. Our custom peptide synthesis business has developed unique technologies to produce several million peptides during the past three years to support our growing clinical pipeline. These include fast small-scale manufacturing of peptides for target and epitope discovery as well as for neoepitope characterization and production of high content arrays. It is important to synthesize highly purified peptides in order to avoid false positives in immunomonitoring in our mRNA immunotherapy trials. We also use these peptides as starting material in our engineered cell therapies. We have developed know-how to produce highly complex and purified peptide pools that consist of overlapping peptides spanning entire antigens or neoepitopes. We plan to establish a new production facility, which will roughly double our current capacity.

B. Manufacturing Facilities

In addition to our Marburg site, we operate four other manufacturing and packaging facilities in Germany. In these facilities, we manufacture and package individualized mRNA, bulk mRNA, retroviral vectors, cellular products and peptides. In Mainz, we are currently constructing another facility for iNeST manufacturing at a commercial scale, which is planned to get qualified in 2023 and will supply markets mainly in Europe and the United States.

BioNTech IMFS. Our manufacturing operations for retroviral vectors, cell therapy products and mRNA are housed in our wholly owned subsidiary, BioNTech IMFS. Founded in 1997, BioNTech IMFS specializes in services for innovative therapeutic approaches. In 2009, BioNTech IMFS became our wholly owned subsidiary, giving us access to synergistic platforms and complementary expertise for development, testing and manufacturing services. BioNTech IMFS and its predecessors have had GMP-certified cell and gene therapy manufacturing capabilities since 1999, and obtained GMP manufacturing authorization for mRNA production in 2011. In 2017, BioNTech IMFS began automated manufacturing of the iNeST product candidate and entered into its first commercial supply contract for retroviral vectors. Located near Mainz, the BioNTech IMFS facility occupies over 30,000 square feet. More than 220 staff members are employed at this facility, with collective expertise in molecular biology, cell biology and virology.

BioNTech iNeST Clinical Manufacturing (East Wing). We dedicate our GMP-certified manufacturing facility at our headquarters in Mainz, Germany to the production of iNeST immunotherapies. In 2015, our wholly owned subsidiary, BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, and Siemens announced a collaboration for developing an automated, paperless and digitalized production site for individualized mRNA. We obtained our GMP manufacturing authorization for iNeST production at our East Wing facility in June 2018 and released our first drug product there the following month.

This facility contains approximately 17,000 square feet of laboratory and office space, including 4,300 square feet of GMP facilities. About 200 staff members are employed at this facility and operate it seven days per week. In its first year of operation the facility manufactured and released more than 250 batches of mRNA and has, since inception, manufactured and released more than 1000 batches of mRNA.

BioNTech Clinical Manufacturing. Our GMP-certified manufacturing facility in Kupferbergterrasse, Mainz, Germany is authorized to conduct secondary packing, labeling, storage and batch release of primary packed investigational medicinal products. This facility contains approximately 11,500 square feet of laboratory and office space, including 1,250 square feet of GMP facilities.

JPT. JPT, our peptide manufacturing facility, was established in 2004 and became a wholly owned subsidiary of BioNTech in 2008. JPT is located in Berlin, Germany and occupies over 16,000 square feet of clean rooms, laboratory and office space.

Gaithersburg Clinical Manufacturing facility. In August 2021 we acquired the solid tumor neoantigen T cell receptor R&D platform and clinical manufacturing facility's assets and leases in Gaithersburg, MD, from Kite, a Gilead Sciences, Inc. company. The acquisition strengthens BioNTech's cell therapy pipeline by accelerating the individualized solid tumor Neoantigen TCR cell therapy research and development program. It also expands the Company's cell therapy capabilities and manufacturing footprint in North America, building on its acquisition of Neon Therapeutics in 2020.

We and Pfizer are also expanding our global manufacturing capabilities with regional solutions in Africa and Latin America. This includes the letter of intent we signed with Eurofarma Laboratorios in Brazil to manufacture our COVID-19 vaccine. Per the agreement, Eurofarma will obtain drug product from facilities in the United States, and manufacturing of finished doses are expected to commence in 2022. At full operational capacity, the annual production is expected to exceed 100 million finished doses annually. BioVac (South Africa) is to start manufacturing (fill & finish) of up to 100 million doses annually in 2022.

Additionally, in 2021, we signed a memorandum of understanding with the Rwandan Government and the Institut Pasteur de Dakar and announced plans to start the construction in mid-2022 of the first state-of-the-art modular manufacturing site for mRNA-based vaccines in the African Union. We believe this facility can become a node in a decentralized and robust African end-to-end manufacturing network to provide sustainable vaccine supply on the African continent. Establishment of this regional network is expected to enable annual manufacturing capacity of several hundreds of million mRNA vaccine doses.

In February 2022, BioNTech announced its turnkey manufacturing solution, named "BioNTainer, which is designed to enable scalable mRNA prophylactic vaccine production in bulk. The novel approach utilizes a modular manufacturing unit made up of state-of-the-art manufacturing containers. BioNTainers will be equipped to manufacture a range of mRNA-based prophylactic vaccines, which can be targeted to local infectious disease needs. The establishment of the first modular

mRNA manufacturing facility in the African Union is expected to start in mid-2022 with the first BioNTainer expected to arrive in Africa in the second half of 2022.

C. Other Certifications

BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System to allow production of European CE marked companion diagnostics.

D. Quality Assurance

We have implemented and maintain several Quality Assurance systems. BioNTech IMFS, BioNTech Clinical Manufacturing and BioNTech iNeST Clinical Manufacturing have implemented GMP-certified quality assurance systems. BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System.

XIII. Third-Party Collaborations

We have forged productive collaborations with pharmaceutical companies and academic research institutions with area expertise and resources in an effort to advance and accelerate our discovery and development programs in oncology, and also to leverage our drug classes into additional disease indications while minimizing our incremental costs.

Our collaborations include:

- Pfizer for our COVID-19 and influenza, which leverage technology from our infectious disease mRNA-based platform;
- Fosun Pharma for our COVID-19 vaccine program;
- Genentech for our iNeST platform in our mRNA drug class;
- Sanofi for our intratumoral therapy platform in our mRNA drug class; and
- Genmab for our next-generation checkpoint immunomodulator platform in our antibodies drug class.

We either wholly own or retain significant rights to all of our clinical stage programs, either in the form of a global share of profit and co-commercialization rights with our collaborators in certain markets or significant royalties and milestones. We plan to continue to identify potential collaborators who can contribute meaningful resources and insights to our programs and allow us to more rapidly expand our impact to broader patient populations.

A. Pfizer-COVID-19 Collaboration

On April 9, 2020, effective as of March 17, 2020, we entered into a Collaboration Agreement with Pfizer for the research and development of immunogenic compositions comprising RNA encoding a SARS-CoV-2 polypeptide or fragment thereof for prophylaxis against SARS-CoV-2 in humans, which we refer to as the Pfizer Corona Field. On January 29, 2021, effective as of March 17, 2020, we entered into an amended and restated Collaboration Agreement with Pfizer for the research, development and commercialization of immunogenic compositions comprising RNA in the Pfizer Corona Field, which we refer to as the Pfizer Agreement.

We and Pfizer agreed to collaborate on research, development and commercialization in the Pfizer Corona Field worldwide (excluding the Fosun Collaboration Territory), which we refer to as the Pfizer Collaboration Territory. The details of such activities are set forth in a research and development plan that is governed by a joint steering committee. Each party bears its own personnel and capital expenditures costs, but the parties will share the costs of all other agreed development activities (including the costs of manufacturing material for use in clinical trials) evenly. Each party will, in good faith, seek funding from government funds, non-governmental organizations and other third-party organizations to support their research and development activities. Under the Pfizer Agreement, Pfizer is leading clinical development of and is seeking regulatory approval for any candidates or products in the United States and we are leading clinical development of and are seeking regulatory approval for any candidates or products in the European Union, and we will agree on a strategy for all other countries in the Pfizer Collaboration Territory on an ongoing basis through the joint steering committees.

BioNTech can solely commercialize the vaccine in Germany and Turkey (collectively referred to as the BioNTech Commercialization Territory, which is a subset of the Pfizer-Collaboration Territory). We have the option to opt-out of commercializing the vaccine in Germany and/or Turkey, whereupon such countries will become part of the Pfizer Commercialization Territory of the Pfizer Collaboration Territory.

Pfizer has the right to commercialize any approved COVID-19 vaccine in the rest of the Pfizer Collaboration Territory. On a country-by-country basis in relation to the United Arab Emirates, Southeast Asia, and certain developing countries, if we obtain funding from a third-party organization that obligates us to commercialize an approved vaccine in such country, we are obligated to request from Pfizer in writing a decision as to whether Pfizer wishes to commercialize or distribute such vaccine in such country in accordance with the requirements agreed with the third-party funder. If Pfizer elects not to commercialize the vaccine in such country, then such country shall become a part of the BioNTech Commercialization Territory.

If our Collaboration Agreement with Fosun expires or is otherwise terminated for any reason, as between us and any international pharmaceutical group headquartered outside of China, we granted Pfizer a right of first negotiation to expand the Pfizer Commercialization Territory to include the Fosun Territory. See "Fosun-COVID-19 Collaboration" below for more information on the Fosun Agreement.

We and Pfizer will share responsibilities for manufacturing and supplying an approved COVID-19 vaccine. If there is insufficient supply to satisfy the entire demand for a vaccine in the Pfizer Collaboration Territory, we and Pfizer have agreed to determine by mutual consent the allocation of supplies on a fair and equitable basis, subject also to any applicable law, export controls, and taking into account any government supply obligations, or supply obligations included in any agreement reached with a third-party funding organization.

Under the Pfizer Agreement, we granted Pfizer an exclusive, sublicensable license in the Pfizer Collaboration Territory under certain of our intellectual property, including our patents and know-how, relating to uridine RNA, modified RNA and replicons in the Pfizer Corona Field as well as certain intellectual property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Agreement. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the Pfizer Agreement and not to modify or amend any such license in a manner that would adversely affect any of the rights granted to Pfizer under the Pfizer Agreement. We are obligated to notify Pfizer of any breach of our current licenses and may be obligated to take steps to maintain Pfizer's access to any intellectual property licensed under such licenses. Under the Pfizer Agreement, we are obligated to indemnify Pfizer with respect to certain patent infringement claims that Pfizer elects to control.

During the term of the Pfizer Agreement and a certain period thereafter, we and Pfizer have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions comprising RNA in the Pfizer Corona Field, or exploit vaccine candidates or products developed under the agreement for any use, other than pursuant to the Pfizer Agreement, provided, however, that Pfizer shall have the right to work as a contract manufacturer for a third party and Pfizer shall not be precluded from acquiring a third party, or being acquired by a third party, that at the time of acquisition is active in the development or commercialization of an immunogenic composition comprising mRNA in the Pfizer Corona Field.

On April 9, 2020, Pfizer also subscribed for $113 million of our ordinary shares under a separate investment agreement. In addition, under the Pfizer Agreement, Pfizer made an upfront payment of $72 million and agreed to make potential payments of up to $563 million upon the achievement of specified regulatory and commercial milestones. We and Pfizer agreed to share development costs equally. We and Pfizer will share the gross profits from commercializing a vaccine evenly, as well as the costs for shipping. The Pfizer Agreement continues for so long as either at least a vaccine is being developed for use in the Pfizer Collaboration Territory or a vaccine is being commercialized anywhere in the Pfizer Collaboration Territory. In addition to termination rights granted to each party in the case of the other party's uncured material breach, Pfizer may terminate the agreement (i) upon our insolvency or (ii) on a country-by-country basis or in its entirety for convenience upon one (1) year's prior written notice provided that any such termination shall not become effective less than two (2) years from the first commercial sale of an approved vaccine.

B. Fosun-COVID-19 Collaboration

On March 13, 2020, we entered into a Development and License Agreement with Shanghai Fosun Pharmaceutical Industrial Development, Co., Ltd, or Fosun Pharma, for the development and commercialization in mainland China, Hong Kong special administrative region, or SAR, Macau SAR and in the region of Taiwan, or collectively the Fosun Collaboration Territory, of immunogenic compositions generated by BioNTech and comprising uridine RNA, modified RNA and/or replicon technology for prophylaxis against SARS-CoV-2 in humans. We refer to this agreement as the Fosun Agreement.

The details of the development activities to be undertaken by Fosun Pharma are to be set forth in a development plan that is being overseen by a joint steering committee. Fosun Pharma's development activities are to be undertaken at its own cost and expense. Fosun Pharma has the sole responsibility to prepare, obtain and maintain regulatory approvals for the vaccine candidates in the Fosun Territory. We agreed to give Fosun Pharma reasonable assistance with the regulatory aspects of these activities.

Fosun Pharma has the sole responsibility, authority and control of the commercialization of a vaccine candidate in the Fosun Collaboration Territory, but must use commercially reasonable efforts to do so in accordance with an agreed commercialization plan, including by launching a vaccine product in the Fosun Collaboration Territory within three months after receiving marketing approval for it, provided sufficient quantities of the vaccine have been delivered.

We retain the sole right to manufacture (or have manufactured) and supply any vaccine candidates and products for development purposes and commercial sale in the Fosun Territory. We agreed to manufacture and supply all quantities of vaccine from a GMP-certified RNA manufacturing facility. As compensation for supply of the vaccine Fosun Pharma will reimburse us our manufacturing costs plus an administrative fee that is between 10 and 19 percent.

Under the Fosun Agreement, we granted Fosun Pharma an exclusive license under certain of our owned or in-licensed intellectual property, including our patents relating to replicons, uridine RNA and modified RNA and other mRNA technology or a vaccine to use, develop, commercialize and otherwise exploit the vaccine candidates in the Fosun Territory. In the event of any failure of the development of a vaccine, we agreed to grant Fosun Pharma a right of first negotiation on a separate competent vaccine for the prophylaxis of COVID-19 in the Fosun Collaboration Territory.

In consideration of the rights granted to Fosun Pharma under the Fosun Agreement, Fosun Pharma subscribed for $50 million of our ordinary shares under a separate investment agreement. In addition, under the Fosun Agreement, Fosun Pharma made an upfront payment of $1 million and agreed to potential payments of up to $14 million upon the achievement of specified development and regulatory milestones and up to $70 million upon the achievement of specified sales milestones. Fosun Pharma further agreed to pay us a royalty rate that is between 30 and 50 percent of its profits on net sales of a vaccine product, if approved, for a period of 15 years from launch of that vaccine in the Fosun Territory.

The Fosun Agreement ends upon expiration of the royalty term. Fosun Pharma may elect to continue to pay royalties and extend the agreement and its rights thereunder. In addition to termination rights granted to each party in the case of the other party's uncured material breach or insolvency, Fosun Pharma may terminate the agreement, in whole, for convenience and with or without reason at any time upon 180 days' prior written notice. If the agreement is terminated by Fosun Pharma for cause, the licenses to Fosun Pharma survive, we will manufacture and deliver the vaccine candidate or product for one year and we will grant a non-exclusive license to a reasonably acceptable contract manufacturing organization for manufacturing of the vaccine candidate or product thereafter for development and commercialization by Fosun Pharma in the Fosun Collaboration Territory.

During the term of the Fosun Agreement, we have committed not to, and not to license the licensed intellectual property to any third party to, develop or commercialize the same vaccine candidate or vaccine in the Fosun Collaboration Territory.

C. Genentech-iNeST Collaboration

Collaboration Agreement

On September 20, 2016, we and BioNTech RNA entered into a Collaboration Agreement with Genentech and F. Hoffman-La Roche Ltd, which, as amended on June 1, 2018 and December 6, 2019, we refer to as the Genentech Collaboration Agreement, to jointly research, develop, manufacture and commercialize certain pharmaceutical products that comprise neoepitope RNAs, or the Genentech Collaboration Products, which include our iNeST development candidates,

for any use worldwide. Under the Genentech Collaboration Agreement, we and Genentech agreed to perform joint research under a research plan to further improve our technology platform for the manufacturing of Genentech Collaboration Products. Under the terms of the Genentech Collaboration Agreement, Genentech paid us $310 million in upfront and near-term milestone payments.

We and Genentech must use commercially reasonable efforts to jointly develop one or more Genentech Collaboration Products in accordance with an agreed global development plan, with the costs of such development to be shared equally. We will continue certain clinical studies that were initiated prior to the execution of the Genentech Collaboration Agreement at our sole expense, and any future material changes in the operation of such clinical studies require Genentech's approval. Genentech may access and use any data generated in these ongoing clinical studies.

In addition to the clinical studies included in the global development plan, we may propose certain additional clinical studies for indications not included in the global development plan, and if the joint development committee formed by the parties does not elect to include the proposed studies in the global development plan, then we may conduct the study at our sole expense under certain conditions, and subject to certain restrictions. Genentech has the option to select any candidate in such studies for potential further joint development and/or commercialization by Genentech as a Genentech Collaboration Product. In the case that Genentech wishes to pursue the clinical development of a Genentech Collaboration Product in an indication that we are not interested in pursuing, then under certain conditions, we may opt out of the co-funding of such development and Genentech may continue do so at its own costs, except that we are obligated to repay Genentech's development costs in the event that such product subsequently receives regulatory approval.

Genentech has the sole right to commercialize the Genentech Collaboration Products on a worldwide basis, with all profits and losses from such commercialization to be split equally with us. If we exercise our right to opt out of sharing equally in future development costs for any Genentech Collaboration Products, then we will no longer split all such profits and losses for such Genentech Collaboration Products equally with Genentech and will instead receive a royalty on annual worldwide net sales of such Genentech Collaboration Products that are covered by a valid claim included in certain of our patents and certain joint patents that arise out of the collaboration. Furthermore, for certain Genentech Collaboration Products for which we share co-promotion rights with Genentech, we have the option to assume a percentage to be determined of the total sales force in the United States and certain other countries, including Germany and other major European markets. In addition, under certain regulatory and other circumstances, we have the right to independently commercialize Genentech Collaboration Products in indications that the joint development committee declines to pursue and that Genentech does not subsequently elect to commercialize, provided that we market such Genentech Collaboration Products under a separate brand and trademark that is approved by the joint commercialization committee established by the parties as not confusingly similar to the Genentech Collaboration Products being commercialized by Genentech. Our ability to research, develop, co-promote and/or independently commercialize Genentech Collaboration Products may be terminated or limited in the event we undergo a change of control.

We granted to Genentech an exclusive license under certain of our intellectual property, and our interest in any jointly-owned intellectual property developed under this agreement, to research, develop, make, sell and import any pharmaceutical products that comprise neoepitope RNA. Genentech granted to us an exclusive, non-transferable, sublicensable licenses under certain Genentech intellectual property, our intellectual property exclusively licensed to Genentech, and their interest in any jointly-owned intellectual property developed under this agreement for the performance of our ongoing clinical studies and the exercise of our rights and obligations under the Genentech Collaboration Agreement.

Until the first marketing approval for a Genentech Collaboration Product, we have granted Genentech the first right to negotiate an exclusive license to develop, manufacture and commercialize combination therapies involving pharmaceutical products based on neoepitope RNA and pharmaceutical products based on non-neoepitope RNA for the treatment of cancer in humans.

The Genentech Collaboration Agreement will remain in effect so as long as Genentech Collaboration Products are in development or commercialization, or until the date of the expiration of the last royalty term if BioNTech has exercised its option to opt-out of joint development of Genentech Collaboration Products. If the agreement expires, the licenses granted to Genentech become fully-paid up, royalty-free and irrevocable. Genentech may terminate the Collaboration Agreement if we fail to achieve certain milestone targets or at any time for convenience with or without reason upon 60 days' prior written notice. In the event of any such termination, all rights to the development and commercialization of Genentech Collaboration Products developed under the collaboration would revert to us and Genentech would grant us licenses under

its intellectual property to further develop and commercialize Genentech Collaboration Products. We would be required to pay certain royalties to Genentech for such license(s). In addition, either party may terminate the agreement upon the other party's uncured material breach or insolvency.

Manufacturing Development and Supply Agreement

Concurrent with the Genentech Collaboration Agreement, we entered into a Manufacturing Development and Supply Agreement with Genentech and F. Hoffman-La Roche Ltd, or the Genentech Manufacturing Agreement, which governs the manufacturing, related manufacturing development activities and supply of Genentech Collaboration Products. Pursuant to the Genentech Manufacturing Agreement, we are responsible for clinical manufacturing and supply, for developing and implementing manufacturing processes (including pursuant to specified target turnaround times), and for constructing, commissioning, qualifying and obtaining permits for the clinical facilities. We are permitted to subcontract certain steps in the clinical manufacturing process to our affiliate, BioNTech IMFS.

In addition, we are responsible for developing the commercial manufacturing process, which requires more stringent turnaround times than the clinical manufacturing process. Genentech will generally be responsible for conducting commercial manufacturing. We are obligated to use commercially reasonable efforts to achieve certain predetermined clinical manufacturing capacity commitments.

Under the Genentech Manufacturing Agreement, we and Genentech will jointly develop a manufacturing network plan detailing the location, capacity, scale-out, associated timing and other appropriate details of the commercial manufacturing facilities. We may participate in commercial manufacturing through our right to include as part of the commercial manufacturing network one of our own facilities in the European Union or the United States and one of our own facilities in another region to be agreed upon with Genentech (provided that in each region our facility is not the first facility to be included in the commercial manufacturing network).

D. Sanofi-Intratumoral Therapy Collaboration

On November 2, 2015, BioNTech RNA entered into a Collaboration and License Agreement with Sanofi, which we refer to as the Sanofi Agreement. Pursuant to the Sanofi Agreement, we and Sanofi will collaborate on intratumorally administered mRNA-based therapeutics for the treatment of solid tumors in humans.

The Sanofi Agreement contemplates: (i) research, (ii) development and commercialization and (iii) possible co-development and co-commercialization activities with us.

During the research phase, the parties sought to identify, characterize and validate up to five "mixtures" of two or more mRNAs encoding different proteins administered together in the same solution. Sanofi at its sole discretion was able to select up to five mixtures created under the research plan for further development and commercialization, which we refer to as Sanofi Collaboration Products.

After selection of a Sanofi Collaboration Product, Sanofi was responsible for all development and commercialization activities involving that product. We have the option, by payment of an exercise fee, to co-develop and co-commercialize up to two Sanofi Collaboration Products primarily in the United States and in some European countries, including the United Kingdom, France, Germany, Italy and Spain. If we exercise such an option, the costs for co-development and co-commercialization of the chosen Sanofi Collaboration Products would be allocated between the parties. In turn, Sanofi has an option to co-develop and co-commercialize certain mixtures developed by us or with third parties that contain a certain amount of the mRNAs of a Sanofi Collaboration Product.

In March 2018, Sanofi selected the first Sanofi Collaboration Product for further development and commercialization and we exercised our option for co-development and co-commercialization of the Sanofi Collaboration Product. Effective as of March 2018, the parties entered into a separate development agreement for the co-development of this Sanofi Collaboration Product.

Under the Sanofi Agreement, Sanofi has paid upfront and near-term milestone payments of approximately €60 million. We are entitled to receive up to approximately €260 million per product upon achievement of certain development, regulatory and commercial milestones. If commercialized successfully, we would also be eligible for mid-single digit to very low double-digit tiered royalties on net sales on a country-by-country and product-by-product basis until the later of (i)

expiration of the last relevant patent covering such product in such country, (ii) 10 years following first commercial sale of such product in such country, (iii) expiration of regulatory data exclusivity for such product in such country or (iv) the market entry of a generic biological product with a certain market share in relation to such product in such country.

The Sanofi Agreement will remain effective until the last-to-expire royalty term (or, when a co-development option has been exercised, the completion of all co-development and co-commercialization activities). The parties may terminate the Sanofi Agreement in its entirety or terminate certain co-development activities for convenience, with or without cause.

The Sanofi Agreement provides that we may not engage in certain research and development activities relating to the intratumoral injection of mRNAs.

In July 2021, the parties entered into an Amendment to the Collaboration and License Agreement to wind down the research phase. By this termination of the research phase, Sanofi's option to select any further mixture created under the research plan has ceased.

E. Genmab-Next-generation Immunomodulator Collaboration

On May 19, 2015, we entered into a License and Collaboration Agreement with Genmab (together with all amendments and side letters thereto, collectively referred to as the Genmab Agreement) to jointly research, develop and commercialize polypeptide-based bispecific antibodies against certain target combinations for the treatment of cancer worldwide, or the Genmab Agreement Field, using certain Genmab technology. In connection with our entry into the Genmab Agreement, Genmab paid us an upfront fee of $10 million.

Under the Genmab Agreement, we and Genmab must use commercially reasonable efforts to research and develop clinical candidates, including our next-generation checkpoint immunomodulators, with costs split equally during the research and evaluation phase. Our joint activities in this phase are governed by a research plan, which is subject to annual review and updates, and which specifies the clinical candidates to be developed. This research and evaluation phase is currently set to expire on May 19, 2022, but has in the past been extended.

During the research and evaluation phase, we and Genmab may propose clinical candidates for consideration by a joint research committee for further preclinical and clinical development. If a party, through the joint research committee, indicates that it is not interested in further development and commercialization of any clinical candidate, the other party may continue development and commercialization of such products on a unilateral basis, at its sole expense. The party that continues such development and commercialization is obligated to pay the other party certain development, regulatory and sales milestone payments and royalties on net sales of the applicable Unilateral Products. During either party's development and commercialization of a Unilateral Product, the other party must not develop or commercialize any bispecific antibody targeting the same target combination of such Genmab Unilateral Product if such bispecific antibody was generated as part of the collaboration under this agreement.

We and Genmab must use commercially reasonable efforts to develop candidates selected by the joint research committee, or the Genmab Collaboration Products, through preclinical and clinical development. In addition, the joint research committee may select an additional candidate, or the Genmab Back-up Candidate, as a back-up for each Genmab Collaboration Product and may decide at any time to replace the Genmab Collaboration Product with its Genmab Back-up Candidate. The preclinical and clinical development of the Genmab Collaboration Products would be performed pursuant to a development plan to be agreed upon by us and Genmab, with costs to be split equally. The joint steering committee may designate a third party as a manufacturer of a Genmab Collaboration Product or of any of its components.

We and Genmab must use commercially reasonable efforts to jointly commercialize all Genmab Collaboration Products and share equally all expenses and profits arising from such commercialization. We and Genmab, on a product-by-product basis and at least 12 months prior to the anticipated start of a pivotal clinical trial for a Genmab Collaboration Product, will jointly designate between the two of us a lead party responsible for establishing the distribution and marketing operations in each geographical region. Each party would be entitled to equally co-promote the products pursuant to a separately negotiated global commercialization agreement that the parties agree to negotiate.

Unless otherwise agreed by the joint steering committee established under the agreement, Genmab is responsible for all regulatory actions and shall own all regulatory approvals obtained for the Genmab Collaboration Products. Genmab is obligated to provides regular updates to us on regulatory activities.

Each party grants to the other party a worldwide, co-exclusive, sublicensable, royalty-free license under certain of such first party's intellectual property, including certain patents and know-how, to perform the research under this agreement and to research, develop, make, import, use and sell Genmab Collaboration Products in the Genmab Agreement Field pursuant to the terms of the Genmab Agreement. These licenses shall continue on a country-by-country and product-by-product basis for as long as development or commercialization activities are contemplated under the Genmab Agreement.

During the research and evaluation phase prior to the selection of a Genmab Collaboration Product, neither we nor Genmab may engage in any research and development activity in the Genmab Agreement Field relating to the development of any bispecific antibody which targets any combination that is the subject of our joint research plan. During the preclinical and clinical development phase for any Genmab Collaboration Product, engagement in research and development activities in the Genmab Agreement Field unilaterally by a party relating to a Genmab Collaboration Product or its Genmab Back-up Candidate or any bispecific antibody which targets the same target combination for which such Genmab Collaboration Product or Genmab Back-up Candidate has been developed would require the other party's prior written consent.

Each party has the right to discontinue its participation in the further development and commercialization of a Genmab Collaboration Product at two points: (i) when an IND submission package has been agreed upon by the parties and (ii) when the draft clinical trial report from the first Phase 1/2 clinical trial becomes available. The party that wishes to opt out of such further development and commercialization may choose to permit the other party to continue the development and commercialization of the Genmab Collaboration Product or divest its interest in such Genmab Collaboration Product. If the opt-out party permits continued development and commercialization, the other party may elect to pursue development and commercialization of such Genmab Collaboration Product alone as a Unilateral Product, at its sole cost and subject to pre-defined milestone and royalty payments and certain additional pre-defined terms. If the other party wishes to not pursue such continued development and commercialization on such pre-defined payment and additional terms, then the parties will jointly divest their interest in such Genmab Collaboration Product to a third party, and if such divestiture fails, the parties will cease all development and commercialization of such Genmab Collaboration Product. Alternatively, if the opt-out party seeks to unilaterally divest its interest in the applicable Genmab Collaboration Product, the other party has the right of first exclusive negotiation to obtain exclusive, worldwide rights to develop and commercialize such Genmab Collaboration Product. If such unilateral divestiture fails after the other party's exercise of its right of first exclusive negotiation, the opt-out party may either continue development and commercialization of such Genmab Collaboration Product or offer the other party to continue such development and commercialization on such pre-defined payment and additional terms as set forth above.

The Genmab Agreement will remain in effect until the later of (i) the expiration of the last-to-expire royalty term for any Unilateral Product or (ii) the time when no Genmab Collaboration Products are being developed or commercialized under this agreement. Either party may terminate the agreement in its entirety or on a product-by-product basis with immediate effect upon the other party's uncured material breach or insolvency.

F. Pfizer-Influenza Collaboration

On July 20, 2018, we and BioNTech RNA entered into a Research Collaboration and License Agreement with Pfizer, or the Pfizer Influenza Agreement, for the research, development and Pfizer's commercialization of immunogenic compositions comprising modified RNA and/or replicon technology for prophylaxis against influenza in humans, which we refer to as the Pfizer Influenza Agreement Field.

We and Pfizer agreed to collaborate on the research in the Pfizer Influenza Agreement Field for an initial period of three years. The details of such research were set forth in a research plan that is governed by a joint steering committee, with Pfizer holding the final decision-making right. Each party will bear its own costs under the research plan. The research term will be extended automatically by a reasonable amount of time if the activities or deliverables under the research plan are delayed due to our material breach of our research obligations under the research plan. In addition, Pfizer may unilaterally extend the research term by up to a year by making an additional payment to us.

After the research term expires, Pfizer has the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products. Pfizer undertakes to use commercially reasonable efforts to seek regulatory approval for one product in the United States and in two countries out of France, Germany, Italy,

Spain, the United Kingdom and Japan, and to commercialize such product in such countries where such product has received regulatory approval.

Under the Pfizer Influenza Agreement, we grant to Pfizer an exclusive, worldwide, sublicensable license under certain of our intellectual property, including our patents and know-how, relating to replicons and modified RNA in the Pfizer Influenza Agreement Field as well as certain intellectual property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Influenza Agreement. We also grant to Pfizer a non-exclusive, royalty-free, sublicensable license under all intellectual property controlled by us or our affiliates to use, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Influenza Agreement in the Pfizer Influenza Agreement Field. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the agreement and to not modify or amend any such license in a manner that would adversely affect any of the rights granted to Pfizer under the Pfizer Influenza Agreement. We are obligated to notify Pfizer of any breach of our current licenses and may be obligated to take steps to maintain Pfizer's access to any intellectual property licensed under such licenses.

We also granted Pfizer a right of first negotiation to acquire an exclusive worldwide license under certain intellectual property controlled by us for Pfizer to develop, manufacture and commercialize immunogenic products comprising RNA for prophylaxis against respiratory syncytial virus or human cytomegalovirus. The right of first negotiation may be exercised until the end of the research term.

In consideration of the rights granted to Pfizer under the agreement, Pfizer subscribed to shares in BioNTech AG under a separate investment agreement. In addition, under the Pfizer Influenza Agreement, Pfizer made an upfront payment of $50 million and agreed to potential payments of up to $325 million upon the achievement of specified development, regulatory and commercial milestones. Pfizer further agreed to a mid-single digit to very low double-digit tiered royalty on net sales if a product is commercialized. Royalties are subject to stacking provisions. The obligation of Pfizer to pay royalties ends, on a country-by-country and a product-by-product, basis upon the later of (i) the expiration of the last valid licensed patent right covering such product category in such country, (ii) 10 years after the first commercial sale of a product of such product category in such country and (iii) the lapse of regulatory data exclusivity for the first product in such product category in such country. There are only two product categories: one for modified RNA and a second for replicon products.

During the term of the Pfizer Influenza Agreement, we have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions compromising RNA in the Pfizer Influenza Agreement Field other than pursuant to the Pfizer Influenza Agreement.

The Pfizer Influenza Agreement ends on a country-by-country basis upon expiration of the last royalty term for any product in that country. Thereafter, the licenses granted to Pfizer with respect to such product in such country will convert into a perpetual, exclusive, fully paid-up and royalty-free license. In addition to termination rights granted to each party in the case of the other party's uncured material breach, Pfizer may terminate the agreement, in whole or in part, for convenience and with or without reason at any time upon 60 days' prior written notice. In addition, Pfizer is entitled to terminate the agreement and initiate a technology transfer of certain intellectual property if one of its key competitors acquires control over us.

XIV. Government Regulation

Government authorities in the United States, at the federal, state and local levels, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, record-keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other requirements of regulatory authorities, require the expenditure of substantial time and financial resources.

A. Regulation and Procedures Governing Approval of Drug and Biological Products in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Both drugs and biologics are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject a sponsor to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

A sponsor seeking approval to market and distribute a new drug or biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by the IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance applicable regulations, including with GCP, regulations;
- preparation and submission to the FDA of a NDA for a drug product, or a BLA for a biological product requesting marketing approval for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development, evidence of safety, purity and potency from preclinical testing and clinical trials, and proposed labeling;
- review of the product by an FDA advisory committee, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current GMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and to conduct any post-approval studies required by the FDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates and any future product candidates will be granted on a timely basis, or at all.

Preclinical Studies and Investigational New Drug Application

Before testing any drug or biological product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical

trial, including concerns that patients will be exposed to unreasonable health risks, and places the trial on a clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or not be conducted on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. A clinical hold issued by the FDA may therefore delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. This could cause significant difficulties in completing planned clinical trials in a timely manner.

The FDA may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human Clinical Trials in Support of an NDA or a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified principal investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all patients provide their informed consent for their participation. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, dosing procedures and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the NDA or BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of patients. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials (or Phase 1) are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as in the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.
- Phase 2 clinical trials (or Phase 2) are generally conducted in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials. When a drug is intended to treat life-threatening or severely debilitating illnesses, the FDA may accept well-controlled Phase 2 clinical trials

as adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, in which case Phase 3 clinical trials would not be required.

- Phase 3 clinical trials (or Phase 3) proceed if the Phase 2 clinical trials demonstrate that a certain dose or dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population, often at geographically dispersed clinical trial sites, to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the product and to provide an adequate basis for product labeling.

In some cases, the FDA may approve an NDA or a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials (or Phase 4). These studies may be used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its DSMB may suspend a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the new drug candidate or biological product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Compliance with GMP Requirements

Before approving an NDA or a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug or biological product does not undergo unacceptable deterioration over its shelf life. In particular, the PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of drugs and biological products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process.

The manufacturing facilities may be subject to periodic unannounced inspections by government authorities to ensure compliance with GMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of an NDA or a BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of an NDA or a BLA requesting a license to market the product. These applications must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling. The FDA adjusts the Prescription Drug User Fee Act, or PDUFA, user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the NDA or BLA is sufficient to accept for filing based on the agency's threshold determination that it is substantially complete so as to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of a standard application and respond to the sponsor within ten months of the 60-day filing date, and for a priority review application within six months. The FDA does not always meet its PDUFA goal dates for standard and priority NDA or BLA applications, and its review goals are subject to change from time to time. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also be extended by three months if the FDA requests or if the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

The FDA reviews NDA and BLA applications to determine, among other things, whether the proposed product is safe and potent, and/or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter, denial letter or complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the FDCA, the FDA may approve an NDA if it determines that the product is safe and effective for its intended use, the benefits of the drug outweigh any risks, and the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. If a complete response letter is issued, the sponsor may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Sponsors that receive a complete response letter who elect to address the deficiencies may submit to the FDA information that represents a complete response to the issues identified by the FDA in the response letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2, based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on a Class 1 resubmission with two months of receipt and, with respect to a Class 2 resubmission, within six months of receipt. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an Advisory Committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an Advisory Committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product, or limit the approval to specific dosages. It may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including risk evaluation and mitigation strategies, or REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA may designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or the FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to facilitate the design of clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application to six months (compared to 10 months under standard review).

Fast track designation, priority review and breakthrough therapy designation may expedite the development or approval process, but do not change the standards for approval.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has stated that although it has limited experience with accelerated approvals based on intermediate clinical endpoints, such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may lead the FDA to withdraw the product from the market. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Accelerated approval pathways are available for regenerative medicine therapies that meet certain conditions. Regenerative medicine therapies include cell therapies (both allogenic and autologous), therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except those regulated under section 361 of the PHSA. Human gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues, may also meet the definition of a regenerative medicine therapy, as may xenogeneic cell products.

Regenerative medicine therapies designed to treat, modify, reverse or cure serious conditions are eligible for FDA's expedited programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, if they meet the criteria for such programs. They may also be eligible for Regenerative Medicine Advanced Therapy Designation, or RMAT designation.

An investigational drug is eligible for RMAT designation if it meets the definition of regenerative medicine therapy, it is intended to treat, modify, reverse or cure a serious condition, and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy.

RMAT designation confers all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with the FDA. The FDA reviews each application on a case-by-case basis to determine whether the clinical evidence is sufficient to support RMAT designation, considering factors such as the rigor of data collection, the consistency and persuasiveness of the outcomes, the number of patients, and the severity, rarity or prevalence of the

condition, among other factors. The FDA may decline to grant RMAT designation if it finds the clinical evidence insufficient.

RMAT designation may expedite the development or approval process, but it does not change the standards for approval.

Emergency Use Authorizations

The Secretary of Health and Human Services has the authority to authorize unapproved medical products, including vaccines, to be marketed in the context of an actual or potential emergency that has been designated by government officials. The COVID-19 pandemic has been designated such a national emergency. After an emergency has been announced, the Secretary of Health and Human Services may authorize the issuance of, and the FDA Commissioner may issue, Emergency Use Authorizations, or EUAs, for the use of specific products based on criteria established by statute, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA is subject to additional conditions and restrictions and is product-specific. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, so it is not possible to predict how long an EUA may remain in place.

Post-Approval Regulation

If regulatory approval for marketing of a product or for a new indication for an existing product is obtained, the sponsor will be required to comply with rigorous and extensive post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed on the particular product as part of the approval process. The sponsor will be required, among other things, to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including GMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the BLA holder and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with GMP regulations and other regulatory requirements. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market study requirements or clinical trial requirements to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- adverse publicity;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions, fines, debarment, disgorgement of profits or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the

approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain financial incentives, including tax advantages and, if the product receives the first FDA approval for the indication for which it has orphan designation, market exclusivity for seven years following the date of the product's marketing approval. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Once a product receives orphan drug designation from the Office of Orphan Products Development at the FDA, the product must then go through the review and approval process like any other product.

In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, the manufacturer makes a showing of clinical superiority over the product with orphan exclusivity, or the sponsor is unable to provide sufficient quantities.

Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors who are planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit pediatric study plans prior to the assessment data, and no later than 60 calendar days following an end-of-Phase 2 meeting with the FDA or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. Pediatric study plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or a BLA sponsor

submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

B. Regulation of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- A product comprised of two or more regulated components that are physically, chemically or otherwise combined or mixed and produced as a single entity;
- Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- A drug, or device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, *e.g.*, to reflect a change in intended use, dosage form, strength, route of administration or significant change in dose; or

- Any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biological product, the FDA center responsible for premarket review of the biological product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market and sell the product in those countries or jurisdictions.

C. Regulation and Procedures Governing Approval of Medicinal Products in the European Union

The process governing approval of medicinal products, including biological medicinal products and advanced therapy medicinal products, or ATMPs, which comprise gene therapy products, somatic cell therapy products and tissue-engineered products, in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical and clinical studies to establish the safety and efficacy of the medicinal product for each proposed indication. Moreover, an applicant must also demonstrate the ability to manufacture the product to a suitable quality.

Clinical Trial Approval

Until recently, pursuant to the Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, a sponsor must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the sponsor may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which took effect on January 31, 2022 and replaces the current Clinical Trials Directive 2001/20/EC. Commission Implementing Regulation (EU) 2017/556 replaces the GCP Directive 2005/28/EC. The Regulation overhauls the current system of approvals for clinical trials in the European Union. Specifically, the Regulation, which is directly applicable in all member states, aims to simplify and streamline the approval of clinical trials in the European Union. For instance, it provides for a streamlined application procedure using a single entry point and strictly defined deadlines for the assessment of clinical trial applications. This means that one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

Pursuant to transitional provisions under the Regulation, trials for which a request for approval was submitted prior to January 31, 2022 may continue under the national implementations of the Directives for a period of up to three years. In addition, for a period of 18 months from January 31, 2022, sponsors elect which process to follow.

Under either regime, clinical trials must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCP. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of ATMPs. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative.

The clinical trial application must be accompanied by a copy of the trial protocol and an investigational medicinal product dossier with supporting information prescribed by applicable legislation as further detailed in applicable guidance documents. Moreover, the sponsor must take out a clinical trial insurance policy, and in most European Union countries the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The sponsor of a clinical trial must register the clinical trial in advance, and information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase 1 trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the European Medicines Agency, or EMA, and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union member states (decentralized procedure, national procedure or mutual recognition procedure).

All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical and clinical trial information. There is an increasing trend in the European Union toward greater transparency and, while the manufacturing or quality information is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the nonclinical and clinical information in marketing authorization dossiers, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. In October 2014, the EMA adopted a policy under which clinical study reports would be posted on the agency's website following the grant, denial or withdrawal of a MAA, subject to procedures for limited redactions and protection against unfair commercial use. The operation of this policy has been suspended in recent years. However, it continues to apply the policy to COVID-19 vaccines and therapeutics. A similar transparency requirement is contained in the new Clinical Trials Regulation (date of application: January 31, 2022).

A marketing authorization may be granted only to a sponsor established in the European Union. Regulation (EC) No. 1901/2006 on medicinal products for pediatric use provides that prior to obtaining a marketing authorization in the European Union in the centralized procedure, a sponsor must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or deferral for one or more of the measures included in the Pediatric Investigation Plan.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines (including vaccines) produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions from the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional

cases, when a medicinal product is of major interest from the point of view of public health determined by three cumulative criteria: (i) the seriousness of the disease (*e.g.*, heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit.

If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment. The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines, which are not legally binding, provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, inter alia, the preclinical studies required to characterize ATMPs, the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances." Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital, and in the case of a radio-pharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual re-assessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of the marketing authorization of a medicinal product under exceptional circumstances follows the same rules as a "normal" marketing authorization. After five years, the marketing authorization will then be renewed under exceptional circumstances for an unlimited period, unless the EMA decides, on justified grounds, to proceed with one additional five-year renewal.

The European Commission may also grant a so-called "conditional marketing authorization" prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products and vaccines) if the CHMP finds that all the following requirements are met:

- the benefit-risk balance of the product is positive;
- it is likely that the applicant will be able to provide comprehensive data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the medicinal product's immediate availability on the market outweighs the risks due to need for further data.

A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. Once comprehensive data on the medicinal product have been obtained, the marketing authorization may be converted into a standard marketing authorization which is no longer subject to specific obligations. Initially, this is valid for five years, but can be renewed for unlimited validity.

For COVID-19 vaccines to date, the EMA has followed a so-called 'rolling review' process, an *ad hoc* procedure by which data is assessed as it becomes available with the aim of granting a conditional marketing authorization.

The European Union medicines rules expressly permit the member states to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal products containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State within three years after authorization ceases to be valid.

Emergency Use Authorizations

The European Union medicines rules, as implemented into the national laws of the EU member states, permit national authorities to authorize temporarily the distribution of an unapproved medicinal product in certain emergency situations, including suspected or confirmed spread of pathogenic agents. Such an Emergency Use Authorization (EUA) would apply for the duration of the emergency only and would be limited to the member state in which it has been issued. When considering whether to grant an EUA, the relevant member state decides, which data it requires for the grant of the EUA. For COVID-19 vaccines to date, the EU member states have not relied on EUAs. Rather products have followed the centralized procedure combined with a rolling review of data with a view to granting conditional marketing authorizations. Member states have relied on EUAs to permit the distribution and use of certain unapproved medicines for in unapproved indications to assist in the treatment of COVID-19 patients.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in the manufacturing, processing

and packing of products to assure their safety and identity. Specifically, medicinal products may only be manufactured in the European Union, or imported into the European Union from another country, by the holder of a manufacturing/import authorization from the competent national authority. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with European Union standards of good manufacturing practice, or GMP, before releasing the product for commercial distribution in the European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the European Union. In principle, all advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines (including vaccines) is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under Directive 2001/83/EC, as amended, the details are governed by regulations in each member state and can differ from one country to another.

Human Cells and Tissues

Human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. However, there are European Union rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are ATMPs. These rules also cover the processing, preservation and distribution of human cell and tissues that are not ATMPs. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

Named Patient Supplies

The European Union medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the European Union and imported to treat specific patients or small groups of patients.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the product has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

European Data Collection and Data Protection Laws

We are required to comply with strict data protection and privacy legislation in the jurisdictions in which we operate, including the General Data Protection Regulation (EU) 2016/679, or GDPR. The GDPR governs our collection and use of personal data in the European Union relating to individuals (*e.g.*, patients). The GDPR imposes several requirements on organizations that process such data, including: to observe core data processing principles; to comply with various accountability measures; to provide more detailed information to individuals about data processing activities; to establish a legal basis to process personal data (including enhanced consent requirements); to maintain the integrity, security and confidentiality of personal data; and to report personal data breaches. The GDPR also restricts the transfer of personal data outside of the European Economic Area (*e.g.*, to the United States and other countries that are not deemed to provide adequate protection under their domestic laws). The GDPR may impose additional responsibility and liability in relation to personal data that we process, and require us to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the requirements of the GDPR and related national data protection laws of European Union member states may result in a variety of enforcement measures, including significant fines and other administrative measures. The GDPR has introduced substantial fines for breaches of the data protection rules, increased powers for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress. We may be subject to claims by third parties, such as patients or regulatory bodies, that we or our employees or independent contractors inadvertently or otherwise breached GDPR and related data protection rules. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial fines and/or damages and could suffer significant reputational harm. Even if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

D. Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. In the United States, the member states of the European Union and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Reimbursement rules and levels are not harmonized in the European Union and therefore differ from member state to member state. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacoeconomic studies are conducted, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that such coverage will continue or that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit a company's ability to generate revenue.

The containment of healthcare costs also has become a priority of federal, state and foreign governments as well as other third-party payors such as statutory health insurance funds, and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented or coverage may be ended in the future.

Outside the United States, we will face challenges in ensuring and obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries, including in particular the member states of the European Union. Pricing negotiations with governmental authorities or other third-party payors such as statutory health insurance funds can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. The European Union recently adopted Regulation (EU) 2021/2282 on health technology assessment, which provides a framework for member states to cooperate on health technology assessments at the EU level. The Regulation is directly applicable in all EU member states and will apply from January 12, 2025. Moreover, at the national level, European Union member states may restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any product. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

For COVID-19 vaccine candidates in the European Union, no pricing and reimbursement or health technology assessments discussions have taken place with the respective health insurances and competent bodies at a national member state level. Currently, COVID-19 vaccine candidates are supplied in the European Union based on vaccine supply agreements with the European Commission that is acting on behalf and in the name of the member states of the European Union.

E. Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, in a national referendum, a majority of the electorate voted in favour of the United Kingdom leaving the European Union (commonly referred to as "Brexit"). On March 29, 2017, the United Kingdom Government formally notified the European Union of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on the European Union. The United Kingdom formally left the European Union on January 31, 2020. Pursuant to the terms of the Withdrawal Agreement between the European Union and the United Kingdom, a transitional period ran between

February 1, 2020 and December 31, 2020, during which all applicable EU law, including the regulation of medicinal products, applied to and in the United Kingdom. This transitional period has now expired. On December 24, 2020, the United Kingdom and the European Union announced that they have reached agreement on the terms of their future relationship as set out in the Trade and Cooperation Agreement ("TCA"). The European Union and the United Kingdom had agreed to provisionally apply the terms of the TCA, while the formal execution was still ongoing. The TCA formally entered into force on May 1, 2021. While the TCA governs tariff and quota free trade between the United Kingdom and the European Union markets, it does not provide for regulatory alignment. The regulatory framework for medicinal products in the United Kingdom is predominantly derived from European Union law. Currently, domestic United Kingdom law provides that all existing European Union law is transposed into national law, subject to certain revisions that have become necessary as a result of Brexit. Thus, at least initially, the United Kingdom and the European Union laws are aligned. However, Brexit could have a material impact on the regulatory regime in the United Kingdom, as the country is free to deviate from the European Union regime. One example of such deviation is the approval of COVID-19 vaccines. While in the European Union vaccines have been granted conditional marketing authorizations, in the United Kingdom, vaccine candidates were granted emergency use authorizations.

F. Rest of the World Regulation

The requirements governing the conduct of clinical trials, product (including vaccine) licensing, pricing, and reimbursement vary from country to country in markets outside the EU and the United States. In many markets, clinical trials must be conducted in accordance with Good Clinical Practice and applicable regulatory requirements. Ethical standards typically follow the Declaration of Helsinki principles. In response to the COVID-19 pandemic, some markets have granted or are considering the grant of emergency use authorizations for vaccine candidates instead of the otherwise available regulatory approval pathways. Supply of the COVID-19 vaccine to a number of countries outside of the US and the EU is similarly governed by vaccine supply agreements with local governments.

Failure to adhere to regulatory requirements may lead to, among others, fines, suspension or withdrawal of regulatory authorizations or approvals, product recalls, seizure of products, restrictions or suspensions of operations, or criminal prosecution.

G. Greater China

a.) Mainland China

Similar to the United States and the European Union, Mainland China has rules governing the approval for development and commercialization of drugs, including specialized rules for vaccines. China's drug law and regulations require that the National Medical Products Administration's, or NMPA's, Center for Drug Evaluation, or CDE, approve a clinical trial application prior to initiating a study to support the safety and effectiveness of a drug. This clinical trial application and the testing procedure that may precede it can be expedited if there is a pressing declared health emergency, as was the case with COVID-19.

Once approved, vaccine clinical trials must be conducted at sites that are qualified disease prevention and control, or CDC, institutions and grade III hospitals, and the implementation of the trial must be in accordance with China's vaccine good clinical practice regulations and related guidelines. Furthermore, prior to the commencement of the clinical trial in China each site's ethics committees must approve the trial, and the Office of Human Genetic Resources Administration must approve the use of samples and related data. The human genetic resources, or HGR, approval requires a joint approval or record-filing application by the Chinese and foreign parties, setting forth the parties that will handle data and samples, the type and amount of samples that will be utilized during the study, the tests/analysis run, and the plans for storage or destruction, and the intellectual property sharing arrangement among the parties, among other items. Once approved, the HGR approval/filing may require updates and amendments and additional procedures to transfer data to certain foreign parties. Once a clinical trial in China is complete and/or foreign data is assembled, a company may submit an application for a marketing authorization, or MA, of the vaccine. This procedure will include submission of clinical data, manufacturing information and test results, among other items, and may include an onsite pre-market verification by the NMPA. This application may be considered more quickly if the applicant qualifies for admission to various expedited programs, including "special approval" procedures for drugs needed to control a public health emergency and/or conditional approval procedures. Conditional approval procedures permit approval of a drug based on earlier stage data, but subject continued marketing to the fulfillment of post-market conditions with a designation period of time, such as the completion of additional studies. Therapeutic biologics and small molecule drugs follow similar steps to approval for development and marketing. These steps are similar for drugs that are imported and those that are produced domestically in

China. However, domestically produced drugs must be produced at a facility that also obtains a drug manufacturing license based, in part, on a pre-marketing good manufacturing practice inspection.

At both the clinical trial and MA stages, drug applicants located outside of China must list a regulatory agent on the application. The agent must be an entity in China, and it assists the sponsor and marketing authorization holder, or MAH, with fulfilling its drug regulatory obligations in China. The agent of the MAH is jointly liable with the MAH for these drug regulatory obligations.

Once approved, vaccines may be procured by the CDC through platforms organized by the provincial governments. Vaccines in China must be sold and directly distributed by domestic manufacturers or general distributors appointed to represent overseas makers to municipal level CDCs, which handle allocation and distribution to points of vaccination in China. Distributors of all drugs must possess a MA for the drug they are distributing or a drug distribution license. As is the case with all drugs, once on the market, MAHs will also have post-market obligations, including fulfillment of post-marketing commitments, safety and annual quality reporting and compensation for injuries caused adverse events following inoculation, or AEFIs. MAHs of vaccines that are not part of the National Inoculation Program, or NIP, must bear the cost of injuries determined by experts to be AEFI injuries. The government bears the cost of NIP vaccines and related AEFIs. Vaccine MAHs are also subject to other post-market obligations for drug marketing authorization holders, including recalls, annual reporting, and inspections. Vaccine MAs must typically be renewed every five years, and supplemental applications, notifications, or reports may need to be submitted for minor, moderate and major changes to the original registration (e.g., significant manufacturing changes).

Advertisements of prescription drugs, including vaccines, must be pre-approved and may only be placed in approved medical journals. Other forms of "academic promotion" may be performed by medical representatives who are authorized in writing by MAHs (or their agents) and registered on government designated websites. Medical representatives are permitted to provide information about the drug to health care professionals (in accordance with certain procedural rules) and collect feedback as to drug safety.

b.) *Hong Kong and Macao*

Mainland China's drug regulatory system does not apply in Hong Kong or Macao. These administrative regions are governed by separate laws on the development and approval of drugs, including vaccines. They also have separate laws on the importation and distribution of those vaccines.

H. Turkey

Other countries such as Turkey and those in the Middle East have regulatory review processes and data requirements for medicinal products, including vaccines, similar to those described for the European Union. The regulatory licensing process in these countries may include local marketing authorization requirements, manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Some countries, such as Turkey, have introduced specific emergency authorization regimes for COVID-19 vaccines.

I. Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in-cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs and which may be used in the calculation of reimbursement and/or discounts on marketed products;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- the national anti-bribery laws and laws governing interactions with healthcare professionals of European Union member states;
- the U.K. Bribery Act 2010; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. If any of the physicians or other healthcare providers

or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

J.Current and Future Healthcare Reform Legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. The Biden administration has discussed proposals to control drug pricing and new legislation may be proposed regarding government negotiation of drug pricing that may affect future profitability.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the federal government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government-paid health care costs. For example, the federal government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation, from other countries and bulk purchasing.

K. Packaging and Distribution in the United States

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

L. Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation employers' liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

XV. Intellectual Property

A. Introduction

We pursue a layered intellectual property strategy to protect our various technology platforms and their application to the treatment of serious diseases, such as cancer and infectious diseases including COVID-19. One focus of our intellectual property strategy is to provide protection for our platforms and products as they are developed. We also pursue intellectual property protection for assets that may be used in future development programs and/or that may be of interest to our collaborators, or otherwise may prove valuable in the field.

Various aspects of our technology platforms and our product candidates are claimed by patent filings. We also pursue other modalities of protection, including trademark and trade secret protection, as appropriate. Many of our intellectual property assets were developed and are owned solely by us, some have been developed via collaboration and are jointly owned, and some have been acquired by acquisition and/or licensed from third parties. We expect that we will continue to make additional patent application filings, and will continue to pursue opportunities to acquire and license additional intellectual property assets, technologies, platforms or product candidates, as developments arise or are identified.

Regardless, we cannot be certain that any of the patent filings or other intellectual property rights that we have pursued or obtained will provide protection for any products as commercialized. Our COVID-19 vaccine product has been approved by the FDA in the United States for people 16 and older, and authorized for people 5 to <12 years old; its composition, manufacture, and use (including, e.g., dosage regimen) may yet be adjusted or modified and our filings may not protect it. Our other product candidates are currently in clinical testing, with no certainty that they will be successful, or that significant modification or adjustment may not be required for successful commercialization.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents and other intellectual property; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or violating the valid and enforceable patents and other intellectual property rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities. With respect to both our owned and licensed intellectual property, we cannot be sure that patents will issue with respect to any of the owned or licensed pending patent applications or with respect to any patent applications that we, our co-owners or our licensors may file in the future, nor can we be sure that any of our owned or licensed patents or any patents that may be issued in the future to us or our licensors will be commercially useful in protecting any products that we ultimately attempt to commercialize or any method of making or using such products. Moreover, we may be unable to obtain patent protection for certain of our product candidates generally as well as with respect to certain indications. See "Risk Factors—Risks Related to our Intellectual Property" in this Annual Report on Form 20-F.

As of January 1, 2022, our overall owned and in-licensed patent portfolio included more than 200 patent families, each of which includes at least one filing in the United States or Europe, and several of which are pending or granted in multiple jurisdictions. The patent families include at least 100 patent families that are solely or jointly owned by BioNTech, including certain families acquired through our acquisitions and others that we have licensed from a third party.

An issued patent provides its owner (or possibly its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the "term" of the patent), in the jurisdiction in which the patent is issued. In the United States, and in many other countries, patents have a presumptive term of 20 years from their effective filing date (which is the earliest non-provisional filing date to which the patent claims priority). However, many jurisdictions, including the United States, require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The United States also has provisions that require a patent term to be shortened if its claims are too similar to another patent owned by the same party that has a shorter term. The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that claim a drug or drug product, or its approved use, if the patent was issued before clinical trials were completed and certain other requirements were satisfied. In the United States, such extension is called a Patent Term Extension, or PTE, and it is limited to a period of not more than five years, or the total patent term including the PTE cannot exceed 14 years after the date of regulatory approval; only one patent can be extended per product approval. We did not extend any patent for our COVID-19 vaccine in 2021. The United States also offers a different form of patent term extension, known as Patent Term Adjustment, or PTA, whereby a particular patent's term is automatically extended beyond the 20-year date if the United States Patent and Trademark Office, or the USPTO, caused delay during its examination; however, potentially available PTA is reduced by any amount of any delay caused by the patent applicant.

Below, we provide a summary of the contours of our current patent portfolio as it relates to different aspects of relevant technology, including noting ownership and 20-year terms for filings included in the portfolio that are directed to such aspects. Particularly given our pre-commercial state of development, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for any product we ultimately attempt to commercialize.

B. Patent Portfolio

The patent portfolios for our most advanced programs are summarized below. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO and its foreign equivalents can be significantly narrowed by the time they issue, if they issue at all. We expect this could be the case with respect to some of our pending patent applications referred to below.

1. mRNA

The patent portfolio for our mRNA therapeutic platforms and product candidates includes patent filings directed to features of therapeutic mRNA structures, some of which are included in our COVID-19 vaccine and in current development candidates. Our patent portfolio also includes patent filings directed to mRNA formulations (including their production and use), including the lipoplex formulations currently utilized with our FixVac and iNeST platforms, and the lipid nanoparticles currently utilized with our mRNA, RiboMab and RiboCytokine platforms, as well as patent filings directed to mRNA manufacturing, and to uses of mRNA therapeutics. We provide more detail below regarding the patent filings directed to these features.

mRNA Structure

Our patent portfolio includes patent filings directed to various features of mRNA structure, which may, for example, contribute to increased immunogenicity (e.g., antigen presentation), translation efficiency, and/or stability of mRNA constructs that include them. Such features include, for example, antigen-MHC fusions, 5' cap structures and related features,, 3' UTR structures, polyA tails, reduced-uracil content mRNAs, and modified nucleoside RNAs. Filings directed to each of these features, and/or to RNA constructs that include them (singly or in combination), or collectively, the mRNA Structure Filings, have been made in the United States and various foreign jurisdictions. Some such mRNA Structure Filings are owned solely by BioNTech SE or BioNTech RNA which are referred to collectively in this section as BioNTech, some jointly by BioNTech and one or more third parties, and some by BioNTech licensors, such as Louisiana State University, or LSU, and the terms of the applicable agreement with LSU, are further summarized below in "—C. In-Licensing." We have non-exclusive rights to use certain US and European patent filings owned by University of Pennsylvania and relating to RNA containing modified nucleosides through our sublicense agreements with mRNA RiboTherapeutics, Inc. (MRT) and CellScript, LLC, collectively the MRT-CellScript Sublicenses and summarized below in "--C. In-Licensing". Issued existing mRNA Structure Filings have, and pending existing mRNA Structure Filings, if issued, would have, 20-year terms that extend into the mid-2020s to the early-2040s.

mRNA Formulations

Our patent portfolio includes patent filings directed to various formulations for mRNA delivery, some of which are utilized with current development candidates. For example, our portfolio includes patent filings directed to lipoplex formulations and preparations thereof or collectively, the mRNA Lipoplex Filings. Issued mRNA PlatformLipoplex Filing(s) has/have, and pending existing mRNA Lipoplex Filings, if issued, would have, 20-year terms that extend into the mid to late-2030s. Such mRNA Lipoplex Filings are solely owned by BioNTech.

In addition, our portfolio includes U.S. and foreign patent filings directed to lipid nanoparticles and polyplex technologies, which are jointly owned by BioNTech and TRON, or collectively, the mRNA Lipid Nanoparticle/Polyplex Filings. Issued mRNA Lipid Nanoparticle/Polyplex Filings have, and pending mRNA Lipid Nanoparticle/Polyplex Filings, if issued, would have, 20 year terms that extend into the mid- to late-2030s. Some such mRNA Lipid Nanoparticle/Polyplex Filings were granted in certain foreign jurisdictions, but do not currently include any U.S. issued patents. The terms of the co-ownership of such patent filings with TRON are summarized below in "—C. In-Licensing."

mRNA Manufacturing

As discussed below, we utilize trade secret protection for many aspects of our mRNA manufacturing technologies, including as currently utilized for production of certain of our development candidates. In addition, our patent portfolio includes certain patent filings relevant to mRNA manufacturing, or collectively, the mRNA Manufacturing Filings, which we believe may provide commercial value to protect product candidates and/or support collaborations or other licensing arrangements. For example, our mRNA Manufacturing Filings include U.S. and foreign patent filings relating to certain aspects of mRNA purification and production. These mRNA Manufacturing Filings are either solely owned by BioNTech, or jointly owned by BioNTech and TRON and, if issued, would have 20-year terms that would extend into mid 2030 to early 2040s, although none is currently an issued patent.

mRNA Commercial Products and Product Candidates

Our COVID-19 vaccine. Our COVID-19 vaccine (BNT162b2) is our most advanced mRNA product, and has received full U.S. FDA approval for people 16 and older and emergency use authorization for people 5 to <12 years old, as well as conditional marketing approval in various other jurisdictions. Additional COVID-19 vaccine candidates, as well as various dosing regimens and use in patient populations with certain medical conditions are being tested in clinical trials. Certain mRNA oncology product candidates are also in clinical development and involve various platforms. Our pipeline also includes mRNA product candidates for treatment of certain infectious diseases beyond COVID-19, and mRNA product candidates for protein replacement therapy in certain rare diseases.

BNT162b2 and Other COVID-19 Vaccine mRNA Product Candidates

Our COVID-19 vaccine (BNT162b2) is a nucleoside-modified mRNA formulated in lipid nanoparticles and encodes an optimized SARS-COV-2 full-length spike protein antigen.

Our platform patent filings relevant to our COVID-19 vaccine (BNT162b2), collectively, the "BNT162b2 Platform Filings", include certain mRNA Structure Filings relating to features for increasing translation efficiency and/or stability of mRNA constructs (e.g., certain 3' UTR structures containing a specific sequence element, and interrupted polyA tails), including filings which are jointly owned by BioNTech and TRON; also relevant are certain mRNA Manufacturing Filings. Issued BNT162b2 Platform Filings have, and pending BNT162b2 Platform Filings, if issued, would have 20-year terms extending into the late-2020s to the early-2040s. We also have undertaken various patent filings specifically related to BNT162b2 structure, composition, formulation, packaging, use and/or manufacture, or the BNT162b2 Filings, including filings that have arisen through collaboration with third parties such as Pfizer. Such filings relevant to our COVID-19 vaccine, if issued, would have 20-year terms that would extend into early 2040s; there are presently no issued patents within the BNT162b2 Filings.

As noted above, our MRT-CellScript Sublicenses grant us rights to use certain U.S. and European patents and applications relating to RNAs containing modified nucleosides, including as used in BNT162b2. We also have a non-exclusive license from the National Institutes of Health granting us right to use certain US and European patent filings relating to SARS-COV-2 spike (S) protein variants that lock the S protein in an antigenically preferred prefusion conformation; such a variant is utilized in BNT162b2.

Additionally, we have obtained third-party licenses to technologies relating to certain lipids and/or lipid nanoparticles and formulations used in BNT162b2, including a non-exclusive license from Acuitas Therapeutics Inc., or Acuitas, grants use rights relevant to proprietary lipid nanoparticles and formulations used in BNT162b2.

Additional COVID-19 vaccine mRNA product candidates are being developed and tested in clinical trials, which share with BNT162b2 certain structural elements, and/or features of composition, formulation, packaging, use and manufacture. Thus, some or all of the BNT162b2 Platform Filings and/or BNT162b2 Filings, as well as the in-licensed rights discussed above with respect to BNT162b2, may be relevant to certain of these candidates.

Moreover, we are currently studying safety and efficacy of our COVID-19 vaccine in various dosing regimens (including booster doses) and/or in different age groups and/or individuals with various medicals conditions. Certain BNT162b2 Filings cover such uses being tested in clinical trials; there are presently no issued patents within the BNT162b2 filings.

Oncology mRNA Product Candidates

All our current clinical programs outside of COVID-19 are in oncology. Our most advanced clinical oncology programs involve our iNeST immunotherapy product candidates being developed with our collaborator, Genentech. We also have FixVac product candidates in Phase 1 and Phase 2 clinical trials and have initiated Phase 1 clinical trials of our mRNA-based intratumoral immunotherapy developed through our collaboration with Sanofi.

FixVac

Our FixVac product candidates share many of the structural elements involved in our iNeST product candidates. Thus, some or all of the mRNA Structure Filings relevant to our iNeST product candidates and discussed below are also relevant to our FixVac product candidates. These patent filings, or the FixVac Platform Filings, include mRNA Structure Filings relating to antigen-MHC fusions, certain 5' cap structures, 3' UTR structures containing a specific sequence element, and interrupted polyA tails, which are solely or jointly owned by BioNTech or BioNTech's licensors. Issued FixVAC Platform Filings have, and pending FixVac Platform Filings, if issued, would have, 20-year terms extending into the mid-2020s to the mid-2030s. While we have pursued or obtained patent protection covering components of FixVac product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our FixVac product candidates.

Our patent portfolio further includes U.S. and foreign patent filings relating to combined uses of our FixVac and iNeST product candidates. Such issued patent filings have, and such pending patent filings, if issued, would have, 20-year terms that extend into 2033, and are jointly owned by BioNTech and TRON.

Our current clinical trials for FixVac product candidates are studying such product candidates in treatment of various cancers. While we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of

our FixVac product candidates in the indications of these clinical trials, certain FixVac Platform Filings include specific reference to treatment of these indications, and if issued, would have 20-year terms extending into the mid-2030s.

iNeST

Our patent filings relevant to our iNeST product candidates include mRNA Structure Filings relating to features for increasing antigen presentation (*e.g.*, antigen-MHC fusions) and features for increasing translation efficiency and/or stability of mRNA constructs (*e.g.*, certain 5' cap structures, 3' UTR structures containing a specific sequence element, and polyA tails of a particular length or interrupted polyA tails); mRNA Lipoplex Filings relating to negatively charged lipoplexes (*e.g.*, for spleen targeting); and mRNA Manufacturing Filings, or collectively, the iNeST mRNA Platform Filings. While we have pursued or obtained patent protection covering components of iNeST product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our iNeST product candidates.

Our patent portfolio further includes U.S. and foreign filings directed to the process of identifying neoantigens in patient samples and/or predicting those that will be immunoreactive in an iNeST immunotherapy product, or collectively, the Neoantigen Filings. Certain issued Neoantigen Filings have, and certain pending Neoantigen Filings, if issued, would have 20-year terms that extend into the 2030s. Many of the Neoantigen Filings are solely owned by BioNTech RNA, or jointly owned by BioNTech and TRON; our acquisition of Neon added various Neoantigen Filings, including both BioNTech U.S.-owned and in-licensed filings. BioNTech and TRON jointly own issued EP patent number 2714071, whose claims recite steps relating to neoantigen selection, that were opposed by multiple third parties; claims in the related U.S. case are granted. If we are unsuccessful in these oppositions, the patent claims for our iNeST product candidates may be narrowed, or a patent may not issue at all. See "Risk Factors—Risks Related to our Intellectual Property" in this Annual Report on Form 20-F.

We are currently studying our iNeST product candidates for the treatment of metastatic melanoma in Phase 2 clinical trials and those for the treatment of various solid tumors in Phase 1 clinical trials. Certain iNeST mRNA Platform Filings and Neoantigen Filings cover treatment of each of these indications. However, we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of iNeST product candidates in the indications of these clinical trials.

Intratumoral Immunotherapies

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or FixVac product candidates, as discussed above) are also directed to one or more features of our intratumoral immunotherapies, including our most advanced intratumoral immunotherapy, which we are developing through our collaboration with Sanofi, and which has recently entered Phase 1 clinical trials. For example, mRNA Structure Filings relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech, provide protection to our current intratumoral immunotherapy development candidate. Such issued patent filing(s) has/have, and such pending patent filings, if issued, would have, 20-year terms that extend into the mid-2030s.

Certain patent filings that are relevant to intratumoral immunotherapies include certain patent filings under the MRT-CellScript Sublicenses, which include patent filings directed to nucleotide-modified mRNAs.

Additionally, certain patent filings have arisen from our collaboration relating to compositions including mRNAs encoding particular cytokines for treatment of solid tumors, or the mRNA Cytokine Filings. Such mRNA Cytokine Filings, if issued, would have 20-year terms that would extend into 2038. However, these filings do not currently include any issued patents.

RiboMabs and RiboCytokines

We own or license a number of patent filings directed to our RiboMab and RiboCytokine programs. Many are owned solely by us, some are jointly owned, and some have been acquired or licensed.

Patent filings relevant to our RiboMab and RiboCytokine programs include certain mRNA Structure Filings relevant to our iNeST and/or FixVac product candidates, specifically relating to 3' UTR structures containing a specific sequence

element, interrupted polyA tail structures, and reduced-uracil content mRNAs; mRNA Lipid Nanoparticle/Polyplex Filings; and patent filings under the MRT-CellScript Sublicenses relating to nucleoside-modified mRNAs.

Infectious Diseases beyond COVID-19

As is discussed elsewhere, we have collaborated with third parties, including Pfizer and Penn to develop infectious disease mRNA vaccines.

Certain patent filings that might be useful to our infectious disease mRNA vaccines include certain of the mRNA Structure Filings and the mRNA Lipid Nanoparticle/Polyplex Filings as well as certain patent filings under the MRT-CellScript Sublicenses, which include patent filings directed to nucleotide-modified mRNAs. Self-Amplifying RNA Filings as discussed above may also be relevant.

We have also licensed technologies relating to certain lipids and/or lipid nanoparticles and formulations that may be useful for certain infectious disease mRNA vaccines.

Rare Diseases

We are developing mRNA-based protein replacement therapy for several rare disease indications through our collaboration with Genevant.

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or FixVac product candidates, as discussed above) and patent filings under the MRT-CellScript Sublicenses (including patent filings directed to nucleoside-modified mRNAs) also provide protection for one or more features of mRNA-based protein replacement product candidates. For example, mRNA Structure Filings include patent filings directed to 3' UTR structures containing a specific sequence element, interrupted poly A tail structures and reduced-uracil content mRNAs. As as noted above, such mRNA Structure Filings are solely or jointly owned by BioNTech; such issued patent filing(s) has/have, and such pending patent filings, if issued, would have 20-year terms that would extend into the mid-2030s. However, there are currently no issued patents specific to our rare disease product candidates under development.

Our patent portfolio relating to our rare disease programs also include certain patent filings that we have licensed from Genevant, or the Genevant Filings. Specifically, the Genevant Filings are owned by Arbutus Biopharma Corporation and relate primarily to lipid or non-liposomal formulations that might be useful in these programs, and have been filed primarily in the United States and Europe, with 20-year terms that extend into mid-2020s to mid-2030s for the issued Genevant Filings and the pending Genevant Filings, if issued.

2. Cell Therapy

Engineered Cell Therapy

Our engineered cell therapy product class features use of chimeric antigen receptor, or CAR-, T cell or individualized T cell receptors for oncology therapy. Our patent filings relevant to these platforms and product candidates, or the CAR-T/TCR Filings, are generally co-owned by BioNTech Cell & Gene Therapies GmbH, or BioNTech C&GT, and TRON. For example, the CAR-T/TCR Filings include patent filings directed to various CAR-T formats and methods of enhancing CAR-T cells by nucleic acid vaccination, as well as patent filings directed to processes of identifying and/or making individualized T cell receptors. The CAR-T/TCR Patent Filings, if issued, would have 20-year terms that would extend into the mid- to late-2030s. However, these filings do not currently include any issued patents.

Certain CAR-T programs involve CAR-T cell product candidates that target different members of the claudin family. Our patent portfolio includes certain patent filings specifically relevant to our claudin-specific CAR-T cell product candidates and are jointly owned by BioNTech C&GT, TRON and Ganymed, or the Claudin-Specific CAR-T Cell Filings. The issued Claudin-Specific CAR-T Cell Filings have, and the pending Claudin-Specific CAR-T Cell Filings, if issued, would have, 20-year terms extending into the mid-2030s. However, these filings do not currently include any U.S. issued patents. The terms of our co-ownership of such patent filings with TRON and Ganymed are summarized below in "—C. In-Licensing."

Activated T Cells

Our acquisition of Neon included technologies for using peripheral blood mononuclear cells, or PBMCs, (e.g., collected from apheresis material of patients) as a starting material to induce and/or expand ex vivo functional T cells specific for therapeutically-relevant neoantigens.

Our BNT221 program, formerly Neon's NEO-PTC-01 program, is a personalized adoptive T cell therapy, which uses multiple T cell populations expanded from an individual patient's PBMCs that together target a set of neoantigens expressed by that patient's tumor.

Patent filings relevant to BNT221, referred to herein as the T Cell Induction/Expansion Filings, are generally solely owned by BioNTech US, or co-owned by BioNTech US and the Netherlands Cancer Institute (NKI). For example, the T Cell Induction/Expansion Filings include patent filings directed to therapeutic T cell compositions and methods of ex vivo induction and/or expansion of antigen-specific T cells, for example, using T cells of specific phenotypes for induction/expansion. An issued subsisting T Cell Induction/Expansion Filing in the United States has, and pending subsisting T Cell Induction/Expansion Filings, if issued, would have, 20-year terms that extend into the late-2030s to early-2040s.

Certain of the Neoantigens Filings may also be relevant to BNT221.

3. Antibodies

Our antibodies product class features bispecific checkpoint immunomodulators for oncology therapy, which are developed through collaboration with Genmab. Our development candidates include bispecific antibodies that are designed to activate 4-1BB upon simultaneous binding to PD-L1 or CD-40. Our patent portfolio includes certain patent filings relevant to such bispecific antibodies, or the Bispecific Checkpoint Modulator Filings, co-owned by us and Genmab. Such Bispecific Checkpoint Modulator Filings, if issued, would have 20-year terms that would extend into the late-2030s and do not currently include any issued patents.

We own patent assets acquired from MabVax Therapeutics Holding, Inc., or the MabVax Filings, that relate to various antibodies, including certain antibodies targeting sialyl Lewis A and ganglioside GD2, as well as nucleic acid encoding them. Issued MabVax Filings have, and the pending MabVax Filings, if issued, would have, 20-year terms that extend into the mid-2030s.

4. Small Molecule Immunomodulators

Our small molecule therapeutics product class features oncology treatment using small molecule product candidates that activate the immune system via TLR7 agonism. Our patent portfolio includes patent filings relevant to these TLR7 agonists, or the TLR7 Agonist Filings. Certain TLR7 Agonist Filings are directed to substituted imidazoquinolines, and, if issued, would have 20-year terms that would extend into the late 2030s. However, these filings do not currently include any issued patents.

C. In-Licensing

Some of our intellectual property assets have been acquired by acquisition and/or in-licensing.

We have pursued a strategy of identifying and in-licensing third-party patents that we believe are complementary to or otherwise interact synergistically with our own intellectual property portfolio. We have entered into material intellectual property licensing or option arrangements with TRON, Louisiana State University and MRT-CellScript.

The key terms of these arrangements are summarized below.

TRON Agreements

In 2015, we and our subsidiaries BioNTech RNA (now merged into BioNTech SE), BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH and JPT Peptide Technologies GmbH entered into a Master Agreement for Research Services with TRON. Concurrently with this Master Agreement for Research Services, or the TRON Research Agreement, we entered into a License Agreement with Ganymed, TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, or the TRON License Agreement. The TRON Research Agreement and TRON License Agreement together replaced and

superseded our 2008 Cooperation, Purchase and Licensing Agreement with the University Mainz, or the 2008 Cooperation Agreement. In 2019, we and our subsidiaries BioNTech RNA (now merged into BioNTech SE), BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH and JPT Peptide Technologies GmbH, entered into a Framework Collaboration Agreement with TRON, or the TRON Collaboration Agreement.

TRON Research Agreement

Under the TRON Research Agreement, TRON from time to time performs certain services for us under work orders, which may comprise innovative applied research projects, pre-defined research and development or clinical research services. We and TRON meet at regular intervals, but no less than annually, to prepare an overall non-binding project plan, which sets the scope, period and costs for the relevant projects contemplated for that period. Individual work orders set the specific binding terms of each project or service. TRON is obligated to render services in accordance with the scientific standards, all applicable laboratory and legal provisions and with the care customary in the industry.

We are entitled to the exclusive rights to all inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Research Agreement, except to the extent they constitute improvements of the technologies applied by TRON in the relevant projects. Under the TRON Research Agreement, TRON granted us a non-exclusive, royalty-free license to use TRON Improvements if such TRON Improvements are necessary for the continued development and exploitation of the Results or the manufacture or marketing of products which contain any of the Results and are covered by a patent claiming any of the Results.

Under the TRON Research Agreement, TRON's services rendered in the field of applied research are invoiced at cost. For other services, fixed prices are to be set forth in the individual work orders. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Research Agreement that is covered by a patent claiming any of the Results.

The TRON Research Agreement limits each party's liability to the other to intentional and grossly negligent actions and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Research Agreement has an indefinite term, but may be terminated by either party on six months' notice. If one of our subsidiaries terminates its role in the TRON Research Agreement, the agreement will survive and continue without that subsidiary.

In November 2017, we and TRON entered into an agreement to include certain research and development activities regarding neoepitope RNA immunotherapies as work included in the TRON Research Agreement.

TRON License Agreement

The TRON License Agreement governs the ownership of and licenses under certain patents, inventions, know-how, technologies and other knowledge (together, the Development Results) filed and created before January 1, 2015 in the course of our collaboration with TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz (collectively, the University Parties) and Ganymed pursuant to the 2008 Cooperation Agreement.

The TRON License Agreement sets forth the parties' rights with respect to the Development Results, mainly depending on which parties have contributed to such Development Results. Ownership of the Development Results and any patents and other intellectual property in certain shares to TRON, on the one hand, and BioNTech and/or Ganymed, on the other hand included therein is allocated. Each party may assign its share in the co-owned Development Results to its affiliates provided that such party provide notice of the transfer and the identity of the new co-owner to the other co-owners. However, in case of an assignment of such share to a third party (except in case of a material asset sale), the assigning party must obligate the assignee to comply with the terms of the TRON License Agreement and the assigning

party will remain bound by the obligations of the TRON License Agreement unless the other co-owners have consented to discharge the assigning party from such obligations.

The parties to the TRON License Agreement grant licenses to each other under their shares in the Development Results substantially as follows. Ganymed is exclusively entitled to use the Development Results for certain antibodies and antibody fragments that bind to certain defined targets, or the Ganymed Field of Use. We are exclusively entitled to use the Development Results in any other field of use (including immunological therapeutics, small molecule compounds, siRNA-based therapeutics, micro-proteins, antibody based *in vitro* (except for those in the Ganymed Field of Use), diagnostics and therapeutics based on long-chain RNA as well as other cell therapy applications, immune cells transgenized with recombinant directed against certain defined targets or chimeric antigene receptors and RNA-based pharmaceuticals). The University Parties may use the Development Results for internal research purposes only. We have an obligation to use reasonable efforts to develop and commercialize products in our field of use worldwide.

Under the TRON License Agreement, we and Ganymed must agree on which party will have the primary role in filing, prosecuting, maintaining and defending jointly owned patents. We and Ganymed each have the exclusive right to enforce the Development Results in our respective fields of use, subject to certain step-in rights of the other parties.

We are obligated to pay to the University Parties low single-digit tiered royalties on net sales on any product that is covered by certain of the patents including in the Development Results. If licenses are granted to third parties, we are obligated to pay to the University Parties a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. Regarding upfront payments only, the University Parties' share will be offset against subsequent license fees on net sales. In addition, we are obligated to pay certain development and regulatory milestones up to a low seven-figure amount to Johannes Gutenberg-Universität Mainz.

The TRON License Agreement contains a limitation on liability as between the parties, wherein the parties will only be liable to each other for intentional and grossly negligent actions, and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify the University Parties and Ganymed for third-party claims of product liability or violation of applicable law based on our distribution of our products or if we breach the TRON License Agreement or if we or one of our agents acts culpably.

The TRON License Agreement will remain in effect as long as there are any obligations on us or Ganymed to pay license fees. After expiry of the TRON License Agreement, each party will have a perpetual, non-exclusive, royalty-free license to use the Developments Results. The TRON License Agreement may be terminated by any party on six months' notice. The licenses granted between the parties will survive such termination. The TRON License Agreement also grants all parties termination rights for uncured material breaches. If only one party terminates its role in the Agreement, the Agreement will survive and continue between the other parties.

TRON Collaboration Agreement

Under the TRON Collaboration Agreement, TRON from time to time undertakes certain projects in collaboration with us under separate project specific agreements, comprising innovative non-clinical research and development projects. We and TRON meet regularly to review and update project plans, and no less than annually to agree the budget for the on-going projects for the coming calendar year. Individual project agreements set the specific binding terms of each project. TRON is obligated to perform its obligations in accordance with the scientific standards, all applicable technical laboratory and legal provisions and with the care customary in the non-clinical biotechnology research industry.

Except for the results of a particular research project which has been funded exclusively by TRON, or the RNT Project, all of the inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Collaboration Agreement are jointly owned. The Results of the RNT Project are owned exclusively by TRON. Under the TRON Collaboration Agreement, TRON grants us an exclusive, worldwide, sublicensable license under its interest in the Results to research and have researched, develop and have developed, make and have made, use, and otherwise commercialize or have commercialized, and otherwise commercially exploit, products in a field that is specified in the corresponding project agreement. The field of use is either (a) the prophylaxis, diagnosis and treatment of all indications in humans and animals; (b) the prophylaxis, diagnosis and treatment of oncological diseases, infectious diseases and rare genetic diseases; or (c) in the case of the Results from the RNT Project only, the prophylaxis, diagnosis and treatment of rectal neuroendocrine tumors in humans. We are required to use our reasonable efforts to develop and commercialize products that exploit the Results.

Under the TRON Collaboration Agreement, TRON's activities are invoiced at cost. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Collaboration Agreement that is covered by a patent claiming any of the Results or, in certain circumstances, by a patentable invention forming part of the Results which we elect to maintain as a trade secret. If licenses under Results are granted to third parties, we are obligated to pay to TRON a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. In addition, we are obligated to pay a one-time only milestone of a low seven-figure amount to TRON the first time annual sales of a product developed under the TRON Collaboration Agreement reach a low nine-figure number.

The TRON Collaboration Agreement limits each party's liability to the other to cases of willful misconduct and gross negligence and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Collaboration Agreement came into force with retroactive effect from January 2015 and has an indefinite term, but may be terminated by either party on nine months' notice. If one of our subsidiaries terminates its role in the TRON Collaboration Agreement, the agreement will survive and continue without that subsidiary.

LSU License Agreement

In May 2015, we entered into a Patent License Agreement with the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, or LSU, and the University of Warsaw, or UW. The agreement (which we refer to as the LSU Agreement) replaces and supersedes the earlier license agreement between the parties.

Under the LSU Agreement, UW and LSU granted to us an exclusive royalty-bearing license under certain patent rights relating to mRNA cap analogs and the synthesis and use of anti-reverse phosphorothioate analogs of the mRNA cap in the United States, certain jurisdictions in the European Union and other countries. As consideration for the license granted, we are obligated to pay running royalties in the low single digits on all net sales of products utilizing the licensed patents and to pay annual maintenance fees to LSU.

We are obligated to use commercially reasonable efforts to develop one or more marketable products utilizing the licensed patents, upon which we would owe additional milestone payments to LSU.

The LSU Agreement remains in effect until expiration of the licensed patents. We have the right to terminate the LSU Agreement for convenience with 60 days' prior notice, and LSU and UW may terminate for our uncured material breach.

CellScript and mRNA Ribotherapeutics License Agreement

BioNTech RNA (now merged into BioNTech SE) entered into the two MRT-CellScript Sublicenses discussed above. Together, the MRT-CellScript Sublicenses grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn Modified mRNA Patent Rights (as defined in the MRT-CellScript Sublicenses) to research, develop, make, import, use and commercialize products for in vivo uses in humans and non-human animals, including therapeutic and prophylactic applications, and for certain uses in the diagnostic and prognostic field of use and certain laboratory research or screening uses. Under these sublicenses, BioNTech RNA has the right to grant sublicenses to affiliates and third parties.

BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicenses. Furthermore, BioNTech RNA is obliged to pay MRT and CellScript development milestone payments of up to approximately $26 million as well as royalties in the low to mid-single digits on net sales of licensed products, depending on the field of use.

The agreements continue until the expiration or abandonment of the last licensed patent to expire or be abandoned. BioNTech RNA may terminate the agreement for convenience with respect to all or certain patent rights with 60 days' prior written notice. MRT or CellScript may terminate the respective sublicense agreement for payment default, uncured material breach or the bankruptcy of BioNTech RNA.

Acuitas License Agreement

In April 2020 we entered into a Non-Exclusive License Agreement with Acuitas, or the Acuitas License Agreement. Under the Acuitas License Agreement Acuitas grants us a non-exclusive worldwide license, with the right to sublicense (subject to certain conditions) under Acuitas's LNP technology to develop, manufacture and commercialize licensed products directed to the SARS-CoV-2 surface glycoprotein. We have the option to convert the non-exclusive licenses to exclusive licenses subject to certain additional financial obligations.

Under the Acuitas License Agreement, we must pay Acuitas up to between approximately $1.6 million and $2.45 million in development milestone payments, $2.5 million and $3.75 million in regulatory milestone payments and $2.5 million and $3.75 million in commercial milestone payments upon the occurrence of certain milestone events. We are further required to pay Acuitas a low single-digit tiered percentage royalty on net sales of licensed products, subject to certain potential customary reductions. Our royalty obligations continue under the Acuitas License Agreement on a country-by-country and product-by-product basis until the later of (i) the expiration of the last-to-expire licensed valid patent claim covering such licensed product in such country, (ii) expiration of any data exclusivity, market exclusivity or supplemental protection certificates period for such product in such country, and (iii) certain years following the first commercial sale of such product in such country.

The Acuitas License Agreement will continue on a product-by-product and a country-by-country basis until there are no more payments owed to Acuitas for such product in such country. Upon expiration of the Acuitas License Agreement, the license will become fully paid up and will remain in effect. We have the right to terminate the Acuitas License Agreement for convenience following a certain notice period. Either party may terminate the Acuitas License Agreement in the event of a material breach by the other party following a cure period. Alternatively, instead of exercising our right to terminate in the event of Acuitas's material breach, we may elect to instead continue the license but reduce our milestone and royalty payment obligations to Acuitas by a certain percentage. [FF3] In the event of termination of an Acuitas License Agreement by us for convenience or by Acuitas for our material breach, the licenses granted under such agreement will terminate, except that we will have the right to sell off any remaining inventories of licensed products for a certain period of time.

D. Trademark Portfolio

Certain features of our business and our product candidates are protected by trademarks. Our trademark portfolio includes, but is not limited to, registrations for each of COMIRNATY®, FixVac®, IVAC®, RiboCytokine®, RiboMab®, RECON®, NEO-STIM®, Precision NEO-STIM® and MAPTAC®, as well as certain other trademarks, including design versions of some of these trademarks.

E. Trade Secret Protection

Certain of our technologies, including in particular certain proprietary manufacturing processes or technologies and/or neoantigen prediction technologies, are protected as trade secrets.

In addition to patent protection, we rely upon unpatented trade secrets and confidential know-how and continuing technological innovation to develop and maintain our competitive position. We protect certain of our technologies, including, in particular, certain proprietary manufacturing processes and technologies and/or neoantigen prediction technologies, as trade secrets. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, by using confidentiality agreements with any future collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

XVI. Competition

We compete in an industry characterized by rapidly advancing technologies, intense competition and a complex intellectual property landscape. We face substantial competition from many different sources, including large and specialty

pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions.

Many of our competitors and potential competitors, either alone or with their collaborators, have greater scientific, research and product development capabilities as well as greater financial, marketing, sales and human resources and experience than we do. In addition, smaller or early-stage companies, including immunotherapy-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Some of our collaborators, such as Genmab, Pfizer and Sanofi, may also be competitors within the same market or other markets. Accordingly, our competitors may be more successful than us in developing and potentially commercializing technologies and achieving widespread market acceptance. In addition, our competitors may design technologies that are more efficacious, safer or more effectively marketed than ours or have fewer side effects, or may obtain regulatory approvals more quickly than we are able, which could eliminate or reduce our commercial potential. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that the key competitive factors affecting our technologies will be efficacy, safety, cost and convenience, ease of distribution, storage and administration, as well as our ability to build a fully-integrated biotechnology company. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. The timing of market introduction of our products and competitive products will also affect competition among products. We expect the relative speed with which we can develop our products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Specifically, BNT162b2 competes with, and any other COVID-19 vaccines we and Pfizer develop would compete with, other COVID-19 vaccines that have been approved or authorized for temporary or emergency use and a large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates.

XVII. Legal Proceedings

As of December 31, 2021, certain claims were pending or threatened against us or our subsidiaries, mainly related to purported obligations arising out of use or alleged use of third party intellectual property. Our best estimate of potential outflow of economic resources from such proceedings amounts to €177.9 million, which is expected not to be settled within the next twelve months and is therefore included in non-current provisions in our consolidated statements of financial position as of December 31, 2021 and was recognized in cost of sales in our consolidated statements of profit or loss (nil as of December 31, 2020). This assessment is based on assumptions deemed reasonable by management including those about future events and uncertainties. The outcome of these matters is ultimately uncertain, such that unanticipated events and circumstances might occur that might cause us to change those assumptions and give rise to a material adverse effect on our financial position in the future.

In addition to the above, from time to time, in the normal course and conduct of our business, we may be involved in discussions with third parties about considering, for example, the use and/or remuneration for use of such third party's IP. As of December 31, 2021, none of such IP-related considerations that we have been notified of and for which potential claims could be brought against us or our subsidiaries in the future, fulfill the criteria for recording a provision. We will continue to evaluate whether, if circumstances were to change in the future, the recording of a provision may be needed and whether potential indemnification entitlements exist against any such claim. It is currently not practical to estimate the potential liability, if any.

C. Organizational Structure

See Item 18.

D. Property, Plant and Equipment

Our headquarters are located in Mainz, Germany, where we occupy:

- Approximately 9,416 square meters (equivalent to approximately 101,353 square feet) of laboratory, GMP manufacturing, storage and office space under a lease for the entire building located at An der Goldgrube 12, 55131 Mainz under a lease that has an initial term that expires on October 31, 2027, but which we have the option to extend until April 30, 2029.
- Approximately 4,398 square meters (equivalent to approximately 47,340 square feet) of office space including a storage facility and cafeteria under a lease for the entire building located at Freiligrathstr. 6, 55131 Mainz under a lease that has an initial term that expires on December 31, 2024, but which we have the option to extend.
- Approximately 860 square meters (equivalent to approximately 9,257 square feet) of office container space located at An der Goldgrube 12, 55131 Mainz under a lease that expires on March 31, 2022. The office containers are planned to be fully replaced and outfitted by July 2022.
- Approximately 1,069 square meters (equivalent to approximately 11,507 square feet) of office and GMP manufacturing space under a lease for part of the building located at Kupferbergterrasse 15, 17019, 44116 Mainz under a lease that expires in March 31, 2022.
- Approximately 4,882 square meters (equivalent to approximately 52,549 square feet) of flexible use space intended for laboratory and office use located at Adam-Opel-Straße 10, 55129 Mainz, which is owned by us, as well as 9,278 square meters (equivalent to approximately 99,868 square feet) of undeveloped land intended for construction of a laboratory and office building of up to 8,000 square meters in size.
- Approximately 3,318 square meters (equivalent to approximately 35,717 square feet) of office and storage space under a lease for part of the building located at Robert-Koch- Straße 50, 55129 Mainz under a lease that expires in December 31, 2025.
- Approximately 806 square meters (equivalent to approximately 8,676 square feet) of office space under a lease for part of the building located at Hechtsheimer Straße 37, 55131 Mainz under a lease that expires in November 30, 2026.
- Approximately 1,799 square meters (equivalent to approximately 19,364 square feet) of office space under a lease for part of the building located at Haifa Allee 38, 55128 Mainz under a lease that expires in November 30, 2026.
- Approximately 82,881 square meters (equivalent to approximately 892,124 square feet) of office space and a further area of land associated with this office space of approximately 12,600 square meters (equivalent to approximately 135,625 square feet), which is owned by BioNTech.
- Approximately 360 square meters (equivalent to approximately 3,875 square feet) of office space under a lease for part of the building located at Heiligkreuzweg 90, 55130 Mainz under a lease that expires in December 31, 2022.
- We also own a plot of land of approximately 8,753 square meters (equivalent to approximately 94,216 square feet) at Hechtsheimer Straße, 55131 Mainz, where construction for a GMP manufacturing facility has commenced early last year.

In addition, our BioNTech IMFS facility in Idar-Oberstein, Germany, occupies approximately 2,800 square meters (equivalent to approximately 30,140 square feet). This includes 650 square meters (approximately 7,000 square feet) of clean room area, and 700 square meters (approximately 7,500 square feet) of development and quality control laboratories. We occupy approximately 575 square meters (equivalent to approximately 6,200 square feet) of this space, which is used primarily for storage, under a lease that has an initial expiry date of October 1, 2021, but which we have extended until September 30, 2026. We occupy approximately 100 square meters (equivalent to approximately 1,075 square feet) of this space, which is used primarily for storage, under a lease that can be terminated by either party on six months' written notice (but not earlier than May 1, 2020). We occupy approximately 80 square meters (equivalent to approximately 860 square feet) of this space, which is used as office space, under a lease that can be terminated by either party on three months' written notice. The rest of this facility, including the GMP-certified manufacturing suites, is owned by BioNTech. We also recently purchased a building of approximately 802 square meters (equivalent to approximately 8,632 square feet) near our IMFS facility in Idar-Oberstein, which will be used as office space. We have also added 1,940 square meters of container office space (equivalent to approximately 20,882 square feet) at Vollmersbachstraße under a lease which expires June 30, 2023.

We have added 2,106 square meters of container space for QA and QC processes (equivalent to approximately 22,669 square feet) at Vollmersbachstraße under a lease which expires July 31, 2025.

We have completed construction of two new buildings at our BioNTech IMFS facility in Idar-Oberstein, Germany, occupy an additional 780 square meters (equivalent to approximately 8,395 square feet) of clean room space and 550 square meters (equivalent to approximately 5,900 square feet) of laboratory space, expanding our capacity for GMP cell therapy manufacturing and 650 square meters (equivalent to approximately 7,000 square feet) of office space.

At our manufacturing facility in Marburg, Germany, we occupy approximately 10,240 square meters (equivalent to approximately 110,220 square feet), including 4,589 square meters (equivalent to approximately 49,400 square feet) of GMP space, 2,422 square meters (equivalent to approximately 26,070 square feet) of technical and storage facilities, 540 square meters (equivalent to approximately 5,810 square feet) of laboratory space and 2,690 square meters (equivalent to approximately 28,960 square feet) of offices. That lease will expire December 31, 2034.

Additional space in Marburg, Germany that is occupied by us includes:

- Approximately 920 square meters (equivalent toapproximately9,903 square feet) of office space under a lease which will expire May 31, 2026.
- Approximately 2,040 square meters (equivalent to 21,958 approximately square feet) of GMP and office space under a lease which will expire April 30, 2032.
- We are also currently expanding into a new facility of 2,882 square meters (equivalent to approximately 31,022 square feet) at the Marburg site under a lease which is due to expire November 30, 2023.

At our JPT facility in Berlin, Germany, we occupy approximately 1,794 square meters (equivalent to approximately 19,299 square feet) of office, laboratory and other space. Approximately 250 square meters of that space (equivalent to approximately 2,690 square feet) is occupied under a lease, which has an expiry date of June 20, 2020 and will continue for further six-month periods, unless terminated by either party on three months' prior written notice. Approximately 1,523 square meters (equivalent to approximately 16,199 square feet) are occupied under a lease for an indeterminate period but which may be terminated by either party on 12 months' prior written notice. The remaining approximately 20 square meters (equivalent to approximately 215 square feet) of storage space is occupied under a lease on a monthly basis and can be terminated by either party giving two weeks' written notice. Construction of a new laboratory and office building at Adlershof in Berlin, which is owned by JPT, is currently being planned. Construction application is due to be submitted in March 2022.

In Berlin we have leased approximately 474 square meters (equivalent to approximately 5,105 square feet) of office space under a lease for part of the building located at Friedrichstraße 101, 10117 Berlin, which will expire September 30, 2026.

In Martinsried, Germany, outside Munich, we occupy approximately 1,862 square meters (equivalent to approximately 20,042 square feet) under a lease that had an initial term which expired on December 31, 2020, but which we extended until December 31, 2026.

In Neuried, Germany, outside Munich, we occupy approximately 1,732 square meters (equivalent to approximately 18,643 square feet) of laboratory and office space under a lease that was due to expire on December 31, 2021, but where we chose the option to expand and extend the lease until November 30, 2031.

In Halle (Saale), Germany, we have since the beginning of 2020 occupied approximately 415 square meters (equivalent to approximately 4,467 square feet) of office and other space under a lease that expires on February 28, 2023. We further occupy 90 square meters (equivalent to approximately 968 square feet) of laboratory space under a lease that also expires on February 28, 2023. Each lease will renew automatically for an additional one-year period until terminated by either party on six months' prior written notice to expire at the end of the lease period (or any extension thereof).

In Fussgoenheim, Germany, we occupy approximately 9,138 square meters (equivalent to approximately 98,361 square feet) of freezer farm space under a lease that has an initial term that expires on December 31, 2021, and with the option to extend until December 31, 2025.

In Mutterstadt, Germany, we occupy approximately 5,269 square meters (equivalent to approximately 56,715 square feet) of freezer farm space under a lease that has an initial term that expires on December 31, 2024, and with the option to extend until December 31, 2025.

In Vienna, Austria, we occupy approximately 300 square meters (equivalent to approximately 3,229 square feet) of laboratory and office space at Leberstraße 20, 1110 Vienna, Austria. The lease is due to expire on May 31, 2022. New office space has been found and a lease contract is under negotiation.

In Shanghai, China, we have leased 548 square meters (equivalent to approximately 5,899 square feet) of office space located at HKRI Centre One, HKRI Taikoo Hui HKRI Center, Shanghai, which we will occupy as of April 2022. The lease will expire July 31, 2024 and may be extended for an additional three years.

In Cambridge, Massachusetts we occupy:

- Approximately 2,490 square meters (equivalent to approximately 26,802 square feet) of laboratory and office space under a lease for part of a building located at 40 Erie Street that has an initial term that expires on September 30, 2024, but which we have the option to extend until September 30, 2029.
- Approximately 1,672 square meters (equivalent to approximately 18,000 square feet) of laboratory and office space for part of a building located at 45-75 Sidney Street under a lease which will expire December 31, 2024.
- Approximately 929 square meters (equivalent to approximately 10,000 square feet) of office space for part of a building located at 60 Hamilton Street under a lease which will expire June 30, 2023.

In Gaithersburg, Maryland we are leasing approximately 5,476 square meters (equivalent to approximately 60,022 square feet) under a lease that had an initial term which expired on September 30, 2030, but which the option to extend until July 31, 2033 was exercised.

We intend to expand our capacity as follows:

- In January 2022, we commenced construction of a four-story building at our BioNTech Campus at An der Goldgrube 12 in Mainz, Germany, which we will own. We have planned laboratory space for research and development, offices, storage facilities, a conference center and cafeteria. As a result, we will occupy an additional 24,000 square meters (equivalent to approximately 258,300 square feet) of laboratory space and office space.
- On January 13, 2022 we purchased property and will commence construction of a new office building adjacent to the planned iNeST GMP manufacturing facility. Upon completion of the construction project, we will occupy up to approximately 6100 additional square meters (equivalent to approximately 65,650 square feet) of useable floor space for offices, storage, meeting areas and cafeteria.
- We anticipate completing the construction of a new building complex for our JPT business in Berlin, Germany, possibly as early as 2023. Upon completion of the construction project, we will occupy up to approximately 5,000 additional square meters (equivalent to approximately 53,820 square feet) of useable floor space split between laboratories, offices and storage.

We are committed to the continued development of world-class laboratory and manufacturing operations to support our research and development and clinical manufacturing needs, to prepare for commercial scale manufacturing of our product candidates, and to realize external commercial opportunities. Our planned laboratory and manufacturing investments include:

- expansion of storage capacities at our BioNTech IMFS facility
- our planned commercial scale facility in Mainz, which will occupy more than 100,000 square feet and will house cleanrooms, laboratories and offices;
- an expansion of our JPT facility, which is designed to more than double our capacity; and
- an expansion of our laboratory space for research and development of approximately 4,200 square meters (equivalent to approximately 45,208 square feet) on our Mainz campus by Q3 2022.

Item 4A. Unresolved Staff Comments

There are no written comments from the staff of the U.S. Securities and Exchange Commission which remain unresolved before the end of the fiscal year to which the Annual Report relates.

Item 5. Operating and Financial Review and Prospects

The following "Operating and Financial Review and Prospects" should be read together with the information in our financial statements and related notes included elsewhere in this Annual Report. The following discussion is based on our financial information prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including U.S. GAAP. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described in "Risk Factors" and elsewhere in this Annual Report. Please also see "Cautionary Statement Regarding Forward-Looking Statements."

A. Operating Results

Financial Operations Overview

The following table shows our consolidated statements of profit or loss for each period presented:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Revenues			
Research & development revenues	€102.7	€178.8	€84.4
Commercial revenues	18,874.0	303.5	24.2
Total revenues	**€18,976.7**	**€482.3**	**€108.6**
Cost of sales	(2,911.5)	(59.3)	(17.4)
Research and development expenses	(949.2)	(645.0)	(226.5)
Sales and marketing expenses	(50.4)	(14.5)	(2.7)
General and administrative expenses	(285.8)	(94.0)	(45.5)
Other operating expenses	(94.4)	(2.4)	(0.7)
Other operating income	598.4	250.5	2.7
Operating income / (loss)	**€15,283.8**	**€(82.4)**	**€(181.5)**
Finance income	67.7	1.6	4.1
Finance expenses[1]	(305.1)	(65.0)	(2.0)
Profit / (loss) before tax	**€15,046.4**	**€(145.8)**	**€(179.4)**
Income taxes	(4,753.9)	161.0	0.2
Profit / (loss) for the period	**€10,292.5**	**€15.2**	**€(179.2)**
Earnings per share[2]			
Basic profit / (loss) for the period per share	€42.18	€0.06	€(0.85)
Diluted profit / (loss) for the period per share	€39.63	€0.06	€(0.85)

(1) Finance expenses disclosed separately in prior periods have been condensed. Please refer to Note 7.8 for further details on finance expenses.

(2) Capital increase due to 1:18 share split occurred on September 18, 2019. Retroactive effect is reflected in number of shares which relate to the period before the share split.

Important Financial and Operating Terms and Concepts

Revenues

Prior to December 2020, our revenue was primarily derived from our collaborations and license agreements in the research and development phase. Research and development revenues were derived from upfront payments, development milestone payments and reimbursement of development expenses.

Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Consequently, we have progressed from earning revenues primarily from research and development to earning revenues from commercial sales.

Our commercial revenues are primarily collaboration revenues from earnings based on our partners' gross profit, which is shared under the respective collaboration agreements and sales milestone payments in addition to revenue from other sales transactions and services sold to third-party customers. We recognize revenues from selling COVID-19 vaccine manufactured by us to collaboration partners for further processing and to external customers in markets within our territory. Revenues for our share of the collaboration partners' profit is recognized as sales occur which is when the performance obligation has been satisfied. As described further in "Critical Accounting Policies and Use of Estimates" and Note 3 to our consolidated financial statements included elsewhere in this Annual Report, we use certain information from our collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available.

Our ability to generate revenue from sales of pharmaceutical products and sustain profitability depends upon our and our collaborators' ability to further successfully commercialize our product candidates and products. Our ability to generate COVID-19 vaccine revenues depends, in part, upon the development of the COVID-19 pandemic, our production capacity, as well as vaccine acceptance or hesitancy, among other factors as listed in our risk factors of this annual report. The timing of product manufacturing and delivery will determine the period in which revenue may be recognized.

To the extent that existing or potential future collaborations generate revenue, our revenue may vary due to many uncertainties in the development of further product candidates and other factors.

For further information on our revenue recognition policy, see "- Critical Accounting Policies and Use of Estimates - Revenue Recognition."

Cost of sales

Our cost of sales include royalty expenses, purchased services, personnel-related expenses and laboratory supplies, which are generally expensed in the period in which the associated revenue occurs. Cost of sales also includes amounts paid to collaboration partners for their share of profits earned in collaboration arrangements where we are the principal in the transaction.

Our cost of sales will increase further, subject to us increasing our commercial activities with respect to our COVID-19 vaccine.

Research and Development Expenses

The nature of our business and primary focus of our activities, including development of our platforms and manufacturing technologies, generate a significant amount of research and development expenses.

Research and development expenses represent costs incurred for the following:

- costs to develop our platforms;

- discovery efforts leading to product candidates;
- clinical development expenses for our programs;
- costs related to pre-launch products;
- costs to develop our manufacturing technology and infrastructure; and
- digital infrastructure costs.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits, share-based compensation expense and social security expense;
- shared development expenses incurred under collaboration agreements with our partners;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, CROs that conduct our preclinical studies and clinical trials, and in-licensing arrangements;
- costs of acquiring, developing and manufacturing materials for preclinical studies and clinical trials, including both internal manufacturing and CMO;
- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- facilities, depreciation and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

We cannot reasonably estimate the nature, timing and amount of research and development expenses required to complete the development of the product candidates we are currently developing or may develop in the future. A change in expectations or outcomes of any of the known or unknown risks and uncertainties may materially impact our expected research and development expenditures.

Continued research and development is central to the ongoing activities of our business. Product candidates in later stages of clinical development generally have higher development expenses than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect these costs to continue to increase in the future as our product candidates progress through the development phases and as we identify and develop additional programs. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates or products, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

Sales and Marketing Expenses

Our sales and marketing expenses mainly consist of purchased services and personnel-related costs.

Our sales and marketing expenses is expected to continue to increase, subject to us progressing our commercial activities with respect to our COVID-19 vaccine.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs including salaries, benefits, share-based compensation expense and social security expense for finance, legal, human resources, business development and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs. These costs relate to the operation of the business, unrelated to the research and development function or any individual program.

We anticipate general and administrative expenses will continue to increase as research, development and commercial activities expand. This increase will likely relate to additional personnel and increased purchased service costs related in

part to finance, legal and intellectual property-related matters along with increased expenses related to administrating our commercial activities with respect to our COVID-19 vaccine.

Other Operating Income / Expenses

Our other operating income and expenses consists primarily of income from government grants, foreign exchange differences arising on operating items such as trade receivables and trade payables which are either shown as other operating income or expenses on a cumulative basis and derivative instruments at fair value through profit or loss.

Finance Income / Expenses

Our finance income and expenses consist of interest income and interest expenses on cash, fair value changes on certain financial liabilities as well as foreign exchange differences arising on financing items such as loans and borrowings as well as foreign exchange differences arising on cash and cash equivalents which are either shown as finance income or expenses on a cumulative basis.

Income Taxes

Income taxes mainly include current income taxes incurred on our taxable income of our German tax group as well as deferred taxes recorded on differences between financial reporting and tax bases of assets and liabilities.

The realization of deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are subject to uncertainties. We may become subject to income tax audits and adjustments by local tax authorities. The assessments as to the recoverability of deferred tax assets and the nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial.

For further information on our income tax policy, see "—Critical Accounting Policies and Use of Estimates—Income Tax."

Comparison of the year ended December 31, 2021 and year ended December 31, 2020

Revenues

The following is a summary of revenues recognized for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2021**	**2020**	**€**	**%**
Revenues				
Research & development revenues from collaborations	**€102.7**	**€178.8**	**€(76.1)**	**(43)**
Genentech Inc.	*45.9*	*49.2*	*(3.3)*	*(7)*
Pfizer Inc.	*43.4*	*121.6*	*(78.2)*	*(64)*
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	*7.4*	*5.1*	*2.3*	*45*
Other	*6.0*	*2.9*	*3.1*	*107*
Commercial revenues	**€18,874.0**	**€303.5**	**€18,570.5**	**n.m.**
COVID-19 vaccine revenues	18,806.8	270.5	18,536.3	n.m.
Sales to collaboration partners[(1)]	*970.9*	*61.4*	*909.5*	*n.m.*
Direct product sales to customers	*3,007.2*	*20.6*	*2,986.6*	*n.m.*
Share of collaboration partners' gross profit and sales milestones	*14,828.7*	*188.5*	*14,640.2*	*n.m.*
Other sales	67.2	33.0	34.2	104
Total revenues	**€18,976.7**	**€482.3**	**€18,494.4**	**n.m.**

[(1)] Represents sales to our collaboration partner of products manufactured by us.

Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Consequently, from the year ended December 31, 2020 to the year ended December 31, 2021, our total revenues from contracts with customers increased by €18,494.4 million from €482.3 million to €18,976.7 million.

Research & Development Revenues from Collaborations

From the year ended December 31, 2020 compared to the year ended December 31, 2021, research and development revenues from collaborations decreased by €76.1 million or 43% from €178.8 million to €102.7 million. This was mainly due to our COVID-19 vaccine collaboration with Pfizer which led to significant research and development revenues during the year ended December 31, 2020 and less research and development revenues for the year ended December 31, 2021 as we progressed to the commercial phase. The decrease was partially offset by €45.9 million of research and development revenues, for the year ended December 31, 2021 from deferred upfront payments based on progress incurred and upon meeting certain development milestones under our influenza collaboration with Pfizer. Additionally, upon receiving the authorization for emergency use and launching our COVID-19 vaccine in Hong Kong, development and regulatory milestones of €7.4 million were achieved and recognized as research and development revenues from our collaboration with Fosun Pharma for the year ended December 31, 2021. In comparison, for the year ended December 31, 2020, €5.1 million research and development revenues were derived from a non-refundable upfront cash payment received as well as development milestones achieved under the collaboration, respectively.

Commercial Revenues

From the year ended December 31, 2020 compared to the year ended December 31, 2021 commercial revenues increased by €18,570.5 million from €303.5 million to €18,874.0 million, mainly due to the high demand for our COVID-19 vaccine. We are the marketing authorization holder in the United States, the European Union, the United Kingdom, Canada and other countries, and holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries, submissions to pursue regulatory approvals on those countries where emergency use authorizations or equivalent were initially granted are ongoing. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Turkey. Fosun Pharma has marketing and distribution rights in China, Hong

Kong special administrative region, or SAR, Macau SAR and the region of Taiwan. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal.

Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and the COVID-19 vaccine is transferred, the vaccine is sold from one partner to the other. During the years ended December 31, 2021 and 2020, we recognized €970.9 million and €61.4 million of revenues, respectively, from selling drug product batches manufactured by us to our partners.

By supplying our territories during the years ended December 31, 2021 and 2020, we recognized €3,007.2 million and €20.6 million of revenues, respectively, from direct COVID-19 vaccine sales in Germany and Turkey. The share of gross profit that we owe our collaboration partner Pfizer based on our sales is recognized as cost of sales.

Based on COVID-19 vaccine sales in the collaboration partners' territories, we are eligible to receive a share of their gross profit which represents a net figure and is recognized as collaboration revenues during the commercial phase together with sales milestones that are recorded once the underlying thresholds are met. During the year ended December 31, 2021, €14,352.1 million gross profit share and €476.6 million of sales milestones have been recognized as revenues. During the year ended December 31, 2020, €188.5 million gross profit share has been recognized as revenues. In order to determine our share of our collaboration partners' gross profits, we used certain information from our collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available. The true-up recognized prospectively during the year ended December 31, 2021, with respect to the prior year was not material.

Cost of Sales

The following table summarizes our cost of sales for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2021**	**2020**	**€**	**%**
Cost of sales				
Cost of sales related to COVID-19 vaccine revenues	€2,855.6	€35.6	€2,820.0	n.m.
Cost related to other sales	55.9	23.7	32.2	136
Total cost of sales	**€2,911.5**	**€59.3**	**€2,852.2**	**n.m.**

From the year ended December 31, 2020 to the year ended December 31, 2021, cost of sales increased by €2,852.2 million from €59.3 million to €2,911.5 million, mainly due to recognizing cost of sales from our COVID-19 vaccine sales, which included the share of gross profit that we owe our collaboration partner Pfizer based on our sales.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2021**	**2020**	**€**	**%**
Research and development expenses				
Purchased services	€572.6	€359.9	€212.7	59
Wages, benefits and social security expense	233.1	126.3	106.8	85
Laboratory supplies	53.8	107.8	(54.0)	(50)
Depreciation and amortization	32.9	30.2	2.7	9
Other	56.8	20.8	36.0	173
Total research and development expenses	**€949.2**	**€645.0**	**€304.2**	**47**

From the year ended December 31, 2020 to the year ended December 31, 2021, our research and development expenses increased by €304.2 million or 47% from €645.0 million to €949.2 million, mainly due to increased research and development expenses from the BNT162 clinical trials launched and conducted in the year ended December 31, 2021,

recorded as purchased services with respect to those expenses, which are initially incurred by Pfizer and subsequently charged to us under the collaboration agreement. The increase was further driven by an increase in wages, benefits and social security expenses resulting from an increase in headcount, recording expenses incurred under our share-based-payment arrangements as well as from recognizing inventor remuneration expenses.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2021**	**2020**	**€**	**%**
Sales and marketing expenses				
Purchased services	€26.5	€10.9	€15.6	143
Wages, benefits and social security expense	4.3	1.6	2.7	169
Other	19.6	2.0	17.6	880
Total sales and marketing expenses	**€50.4**	**€14.5**	**€35.9**	**248**

From the year ended December 31, 2020 to the year ended December 31, 2021, our sales and marketing expenses increased by €35.9 million or 248% from €14.5 million to €50.4 million, mainly due to an increase in purchased service which we incurred in connection with progressing our commercial activities with respect to our COVID-19 vaccine.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2021**	**2020**	**€**	**%**
General and administrative expenses				
Wages, benefits and social security expense	€90.5	€33.0	€57.5	174
Purchased services	70.2	26.0	44.2	170
Insurance premiums	30.4	4.8	25.6	533
IT and office equipment	25.1	7.4	17.7	239
Depreciation and amortization	7.3	5.1	2.2	43
Other	62.3	17.7	44.6	252
Total general and administrative expenses	**€285.8**	**€94.0**	**€191.8**	**204**

From the year ended December 31, 2020 to the year ended December 31, 2021, our general and administrative expenses increased by €191.8 million or 204% from €94.0 million to €285.8 million, mainly due to an increase in wages, benefits and social security expenses resulting from an increase in headcount and expenses incurred under the share-based-payment arrangements, increased expenses for purchased management consulting and legal services as well as higher insurance premiums caused by the increased business volume. Our M&A as well as our business development transactions also contributed to the increase in general and administrative expenses.

Other Operating Income / Expenses

The following table summarizes our other result, including other operating income and expenses, for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2021**	**2020**	**€**	**%**
Other result				
Other operating income	**€598.4**	**€250.5**	**€347.9**	**139**
Foreign exchange differences, net	446.3	—	446.3	—
Government grants	137.2	239.0	(101.8)	(43)
Income from derivative instruments at fair value through profit and loss	5.7	—	5.7	—
Bargain purchase	2.2	7.0	(4.8)	(69)
Other	7.0	4.5	2.5	56
Other operating expenses	**€(94.4)**	**€(2.4)**	**€(92.0)**	**n.m.**
Loss on derivative instruments at fair value through profit or loss	(86.3)	—	(86.3)	—
Other	(8.1)	(2.4)	(5.7)	238
Total other result	**€504.0**	**€248.1**	**€255.9**	**103**

From the year ended December 31, 2020 to the year ended December 31, 2021, our total other result increased by €255.9 million or 103% from €248.1 to €504.0 million, mainly due to recording higher foreign exchange differences arising on operating items. The increase reflects the change in foreign exchange rate and relates to our U.S. dollar denominated trade receivables which were mainly incurred under our COVID-19 collaboration with Pfizer, U.S. dollar denominated trade payables as well as U.S. dollar denominated other financial liabilities which mainly relate to obligations incurred from our license agreements. The amounts were partly offset by recording the change in fair value of foreign exchange forward contracts that were entered into during the year ended December 31, 2021 to manage some of our transaction exposures but were not designated as hedging instruments under IFRS. Further, other operating income included the proportion that relates to the year ended December 31, 2021 of the government grant for which we became eligible during the year ended December 31, 2020 as part of an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support our COVID-19 vaccine program.

Finance Income / Expenses

The following table summarizes our finance result for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2021**	**2020**	**€**	**%**
Finance result				
Finance income	**€67.7**	**€1.6**	**€66.1**	**n.m.**
Foreign exchange differences, net	66.2	—	66.2	—
Interest income	1.5	1.6	(0.1)	(6)
Finance expenses	**€(305.1)**	**€(65.0)**	**€(240.1)**	**369**
Fair value adjustments of financial instruments measured at fair value	(277.8)	(17.3)	(260.5)	n.m.
Amortization of financial instruments	(21.9)	(3.1)	(18.8)	606
Interest expenses related to lease liabilities	(2.9)	(2.0)	(0.9)	45
Interest expenses related to financial assets	(2.5)	—	(2.5)	—
Foreign exchange differences, net	—	(42.6)	42.6	(100)
Total finance result	**€(237.4)**	**€(63.4)**	**€(174.0)**	**274**

From the year ended December 31, 2020 to the year ended December 31, 2021, our total financial result decreased by €174.0 million from a negative financial result of €63.4 million to a negative financial result of €237.4 million, mainly due to increased expenses arising from fair value measurement adjustments of the derivative embedded within the convertible note. The change in fair value was mainly driven by the increase in our share price and was recognized as finance expenses in our statements of profit or loss. In February 2022 we gave notice to Temasek that we will exercise our early redemption option and fully redeem the convertible note on March 1, 2022 (see the description of "Liquidity and Capital Resources" in this Item 5 of this Annual Report as well as in Note 12 of our consolidated financial statements included elsewhere in this Annual Report). The effect was offset by recording positive foreign exchange differences during the year ended December 31, 2021 compared to negative foreign exchange differences recorded during the year ended December 31, 2020, each time mainly arising on cash and cash equivalents denominated in U.S. dollar.

Income Taxes

The following table summarizes our income taxes for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2021**	**2020**	**€**	**%**
Current income taxes	€4,535.0	€—	€4,535.0	—
Deferred taxes	218.9	(161.0)	379.9	(236)
Income taxes	**€4,753.9**	**€(161.0)**	**€4,914.9**	**n.m.**

Our current income taxes represent mainly corporate and trade taxes derived by our German tax group. The increase in profit during the year ended December 31, 2021 led to taxable income for the year ended December 31, 2021 for the German tax group. Corporate and trade tax charge will become due once tax declarations have been filed and assessed. For the year ended December 31, 2020 the German tax group incurred net tax losses thus no income taxes for the German tax group became due.

Up until the year ended December 31, 2020, deferred tax assets on tax losses had not been recognized as there was not sufficient probability in terms of IAS 12 that there would have been future taxable profits available against which the unused tax losses could have been utilized.

As of December 31, 2021, our accumulated tax losses comprised tax losses of German entities not within the tax group (as of December 31, 2021: BioNTech Innovation and Services Marburg GmbH, BioNTech Innovation GmbH i.G., BioNTech Real Estate Verwaltungs GmbH and the Real Estate partnerships; as of December 31, 2020: reSano GmbH, BioNTech Manufacturing Marburg GmbH, BioNTech Real Estate Verwaltungs GmbH and the Real Estate partnerships) and U.S. tax group. Up until the year ended December 31, 2020, our accumulated tax losses comprised also those of the German tax group.

Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Therefore as of December 31, 2020, it was considered highly probable that taxable profits for the German tax group would be available against which the tax losses could be utilized. On this basis, we had recognized deferred tax assets and liabilities with a net amount of €161.0 million for the cumulative tax losses and temporary differences determined for the German tax group as of December 31, 2020. During the year ended December 31, 2021, deferred tax assets on tax losses which had been recognized for the losses incurred by the German tax group were fully utilized (as per the end of each quarter during the year ended December 31, 2021, a proportionate amount of the deferred tax assets related to the tax loss carryforward was utilized). The change in deferred taxes was also supplemented by deferred taxes on temporary differences.

As of December 31, 2021, we have not recognized deferred tax asset for unused tax losses and temporary differences at amount of €81.0 million (December 31, 2020: €50.5 million, December 31, 2019: €136.0 million) as there is not sufficient probability in terms of IAS 12 that there will be future taxable income available against which the unused tax losses and temporary differences can be utilized.

These amounts included tax losses at an amount of €238.1 million US federal tax losses and €147.4 million US state tax losses (December 31, 2020: €136.8 million US federal tax losses and €60.9 million US state tax losses, December 31, 2019: nil) related to the US tax group, thereof €20.9 million US federal losses that begin to expire at various dates beginning in 2033. All other unused tax losses and temporary differences can be carried forward indefinitely.

The realization of deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are subject to uncertainties. We may become subject to income tax audits and adjustments by local tax authorities. The assessments of the recoverability of deferred tax assets and the nature of uncertain tax positions is subject to significant judgment by management and subject to change.

Comparison of the year ended December 31, 2020 and year ended December 31, 2019

Revenues

The following is a summary of revenues recognized for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2020**	**2019**	**€**	**%**
Revenues				
Research & development revenues from collaborations	**€178.8**	**€84.4**	**€94.4**	**112**
Pfizer Inc.	*121.6*	*14.3*	107.3	750
Genentech Inc.	*49.2*	*64.0*	(14.8)	(23)
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	*5.1*	—	5.1	—
Other	*2.9*	*6.1*	(3.2)	(52)
Commercial revenues	**€303.5**	**€24.2**	**€279.3**	**n.m.**
COVID-19 vaccine revenues	270.5	—	270.5	—
Sales to collaboration partners[(1)]	*61.4*	—	*61.4*	—
Direct product sales to customers	*20.6*	—	*20.6*	—
Share of collaboration partners' gross profit and sales milestones	*188.5*	—	*188.5*	—
Other sales	*33.0*	24.2	8.8	36
Total revenues	**€482.3**	**€108.6**	**€373.7**	**344**

(1) Represents sales to our collaboration partner of products manufactured by us.

During the year ended December 31, 2019 compared to the year ended December 31, 2020, our total revenues from contracts with customers increased by €373.7 million or 344% from €108.6 million to €482.3 million, mainly due to revenues recognized for the first time under our two new collaboration agreements which we entered into during the year ended December 31, 2020 relating to the development of our COVID-19 vaccine and ultimately led to the recognition of COVID-19 vaccine commercial revenues.

Cost of Sales

The following table summarizes our cost of sales for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2020**	**2019**	**€**	**%**
Cost of sales				
Cost of sales related to COVID-19 vaccine revenues	€35.6	€—	€35.6	—
Cost related to other sales	23.7	17.4	6.3	36
Total cost of sales	**€59.3**	**€17.4**	**€41.9**	**241**

During the year ended December 31, 2019 compared to the year ended December 31, 2020, our cost of sales increased by €41.9 million or 241% from €17.4 million to €59.3 million, mainly due to recognizing cost of sales from our COVID-19 vaccine sales for the first time, which included the share of gross profit that we owe our collaboration partner Pfizer based on our sales.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2020**	**2019**	**€**	**%**
Research and development expenses				
Purchased services	€359.9	€65.6	€294.3	449
Wages, benefits and social security expense	126.3	83.2	43.1	52
Laboratory supplies	107.8	37.2	70.6	190
Depreciation and amortization	30.2	27.5	2.7	10
Other	20.8	13.0	7.8	60
Total research and development expenses	**€645.0**	**€226.5**	**€418.5**	**185**

During the year ended December 31, 2019 compared to the year ended December 31, 2020, our research and development expenses increased by €418.5 million or 185% from €226.5 million to €645.0 million. The increase was mainly due to an increase in research and development expenses from our BNT162 program.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2020**	**2019**	**€**	**%**
Sales and marketing expenses				
Purchased services	€10.9	€0.2	€10.7	n.m.
Wages, benefits and social security expense	1.6	1.9	(0.3)	(16)
Other	2.0	0.6	1.4	233
Total sales and marketing expenses	**€14.5**	**€2.7**	**€11.8**	**437**

During the year ended December 31, 2019 compared to the year ended December 31, 2020, our sales and marketing expenses increased by €11.8 million from €2.7 million to €14.5 million, mainly due to an increase in purchased service which we incurred in connection with progressing our commercial activities with respect to our COVID-19 vaccine.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2020**	**2019**	**€**	**%**
General and administrative expenses				
Wages, benefits and social security expense	€33.0	€19.1	€13.9	73
Purchased services	26.0	6.4	19.6	306
IT and office equipment	7.4	4.6	2.8	61
Depreciation and amortization	5.1	4.9	0.2	4
Insurance premiums	4.8	1.1	3.7	336
Other	17.7	9.4	8.3	88
Total general and administrative expenses	**€94.0**	**€45.5**	**€48.5**	**107**

During the year ended December 31, 2019 compared to the year ended December 31, 2020, our general and administrative expenses increased by €48.5 million or 107% from €45.5 million to €94.0 million. The increase was mainly influenced by higher expenses for purchased management consulting and legal services as well as an increase in headcount leading to higher wages, benefits and social security expenses and higher insurance premiums.

Other Operating Income / Expenses

The following table summarizes our other result, including other operating income and expenses, for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2020**	**2019**	**€**	**%**
Other result				
Other operating income	**€250.5**	**€2.7**	**€247.8**	**n.m.**
Government grants	239.0	1.5	237.5	n.m.
Bargain purchase	7.0	—	7.0	—
Other	4.5	1.2	3.3	275
Other operating expenses	**(2.4)**	**(0.7)**	**(1.7)**	**243**
Other	(2.4)	(0.7)	(1.7)	243
Total other result	**€248.1**	**€2.0**	**€246.1**	**n.m.**

From the year ended December 31, 2019 to year ended December 31, 2020, our total other result increased by €246.1 million from €2.0 million to €248.1 million. The increase mainly results from government grants.

Finance Income / Expenses

The following table summarizes our finance result for the periods indicated:

	Years ended December 31,		Change	
(in millions)	**2020**	**2019**	**€**	**%**
Finance result				
Finance income	**€1.6**	**€4.1**	**€(2.5)**	**(61)**
Foreign exchange differences, net	—	2.3	(2.3)	(100)
Interest income	1.6	1.8	(0.2)	(11)
Finance expenses	**€(65.0)**	**€(2.0)**	**€(63.0)**	**n.m.**
Fair value adjustments of financial instruments measured at fair value	(17.3)	—	(17.3)	—
Amortization of financial instruments	(3.1)	(0.3)	(2.8)	933
Interest expenses related to lease liabilities	(2.0)	(1.7)	(0.3)	18
Foreign exchange differences, net	(42.6)	—	(42.6)	—
Total finance result	**€(63.4)**	**€2.1**	**€(65.5)**	**n.m.**

From the year ended December 31, 2019 to the year ended December 31, 2020, our financial result decreased by €65.5 million from €2.1 million finance income, net to €63.4 million finance expenses, net. The latter included €17.3 million in expenses arising from fair value measurement adjustments of the derivative embedded within the convertible note. Furthermore, €42.6 million net negative foreign exchange differences occurred during the year ended December 31, 2020 compared to foreign exchange gains that had been recorded during the year ended December 31, 2019.

Income Taxes

As of December 31, 2020, we had accumulated tax losses with respect to corporate tax and trade tax. Our accumulated tax losses amounted to €596.4 million with respect to corporate income tax and €513.6 million with respect to trade tax comprising tax losses of our German tax group, German entities not within the tax group and our U.S. tax group.

Under German law, tax losses do not expire. Deferred tax assets on tax losses had not been capitalized in previous years, as there was not sufficient probability in terms of IAS 12 that there would have been future taxable profits available against which the unused tax losses could have been utilized. Following the authorization and approval of our COVID-19 vaccine for emergency or temporary use or having been granted conditional marketing authorization in over 65 countries worldwide, we re-evaluated previously unrecognized tax losses. Based on our product-based business plan, including commercial supply commitments agreed with various governments and health ministries under which we either directly supply the COVID-19 vaccine or, if they relate to territories which have been allocated to Pfizer, we receive the profit share to which we are eligible, was then considered highly probable that taxable profits for the German tax group would be available against which the tax losses could be utilized. On this basis, we had recognized deferred tax assets and liabilities with a net amount of €161.0 million for the cumulative tax losses and temporary differences determined for the German tax group as of December 31, 2020.

Our forecast for the U.S. tax group did not provide sufficient probability for the use of existing tax loss carryforwards in the near future. Therefore, the requirements set out by IAS 12 were not fulfilled for the U.S. tax group. As of December 31, 2020, deferred tax assets were only recognized to the extent of deferred tax liabilities.

Information about our operating segments

Decisions with respect to business operations and resource allocations are made by our Management Board, as the chief operating decision maker (CODM) based on BioNTech as a whole. Accordingly, we operate and make decisions as a single operating segment, which is also our reporting segment.

Related Party Transactions

Related party transactions that occurred during the years ended December 31, 2021 and 2020 are explained in Item 7. of this Annual Report as well as in Note 21 of our consolidated financial statements included elsewhere in this Annual Report.

Impact of COVID-19

As we advance our clinical programs, we are in close contact with our principal investigators and clinical sites, and are assessing the impact on the clinical trials, expected timelines and costs on an ongoing basis. We have modified the business practices in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. In addition, for certain programs, including BNT111, BNT113, BNT122, BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines) and BNT161 (Influenza), delays in the commencement of trials were experienced, due to slowed patient enrollment and other delays as a result of the COVID-19 pandemic. After several months of delay to focus efforts on our COVID-19 vaccine in 2020, in 2021 we have started four Phase 2 clinical trials that include our FixVac product candidates BNT111 and BNT113 and our iNeST program BNT122 as well as the bispecific antibody program BNT311. Since beginning of 2021, we started 5 Phase 1 clinical trials that include BNT211 (CARVac), BNT221 (NEO-PTC-01, a neoantigen-based T-cell therapy), BNT151 and BNT152+153 (RiboCytokines) as well as BNT141 (Ribomab). The delays, even though they were temporary, may negatively impact our operations and overall business by delaying further progress of these clinical trials and preclinical studies. Our operations, including research and manufacturing, could also be negatively impacted due to the potential impact of staff absences as a result of self-isolation procedures or extended illness. Such factors were evaluated and considered when preparing this Annual Report for the year ended December 31, 2021. We will continue to evaluate observed and potential effects of the COVID-19 pandemic.

COVID-19 Collaborations

In response to the COVID-19 pandemic, we initiated our COVID-19 vaccine development program in late January 2020, leveraging our proprietary mRNA platform, and assembled a global consortium of partners including Pfizer (worldwide collaboration outside of China) and Fosun Pharma (China).

Details about our COVID-19 collaborations are described further in Items 4 and 5 as well as the notes to our consolidated financial statements included elsewhere in this Annual Report.

Critical Accounting Policies and Use of Estimates

Our consolidated financial statements for the years ended December 31, 2021 and 2020 have been prepared in accordance with IFRS, as issued by the IASB. Our accounting policies employed are described in Note 3 to our consolidated financial statements included elsewhere in this Annual Report. We have reviewed these critical accounting policies and estimates with the Audit Committee of our Supervisory Board.

In applying these policies, we make estimates and assumptions that affect the reported amounts of assets and liabilities, contingent assets and liabilities as well as revenues and expenses arising during the fiscal year. When evaluating which judgments to make, or which estimates and assumptions to apply, we consider the sensitivity of each as a range of various outcomes is possible. We ultimately base our assumptions and estimates on the most appropriate parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond our control. Hence, the actual outcome may differ from those estimates.

Some of these policies require a high level of judgment because the areas are especially subjective or complex. The most critical accounting policies and significant areas of judgment and estimation are in the areas discussed in further detail below.

The accounting policies applied and the estimates and assumptions used when preparing the consolidated financial statements have not changed compared to prior year.

With respect to revenue recognition and research and development expenses, our judgments and estimates made in evaluating cut-off may impact the financial results between periods. Fair values in business combinations, share-based

payment arrangements and financial instruments are determined using valuation models which could differ in outcome depending on input parameters used. We have estimated fair values based on reasonable assumptions as described below.

Revenue from Contracts with Customers

We recognize revenue through collaboration and license agreements, rendering of services and sales of products based on the facts and circumstances of each contractual agreement.

Identification and Determination of Performance Obligations

Our collaboration and license agreements, described in more detail in "Business—XIII. Third-Party Collaborations", typically contain multiple elements, and have been determined as qualifying as contracts with customers. At inception of each agreement, we apply judgment when determining which promises represent distinct performance obligations. When licenses are granted, we determined that the grant of the license is the predominant promise within the combined performance obligations and the promise to grant a license is accounted for as a performance obligation satisfied over time as our customer simultaneously receives and consumes the benefits from our performance.

Measurement of the Transaction Price

Milestone payments are contingent upon the occurrence of a future event and represent variable consideration. As there are usually only two possible outcomes (*i.e.*, milestone is reached or not), we have assessed that the method of the most likely amount is the best method to predict the amount of consideration to which we will be entitled. At contract inception, the most likely amount for milestone payments is estimated to be zero. At each reporting date, we use judgment to determine when to include variable consideration in the transaction price, such that it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. We have concluded that future milestone payments are fully constrained at the end of the current fiscal year.

Allocation of the Transaction Price to Performance Obligations and Revenue Recognition as Performance Obligations are Satisfied

We allocate the transaction price to performance obligations based on their relative standalone selling prices, which are generally based on our best estimates and interpretations of facts and circumstances of each contractual agreement and may require significant judgment to determine appropriate allocation.

Upfront payments and reimbursement for expenses are initially deferred on our consolidated statements of financial position. We assessed that no significant financing component exists within our collaboration agreements since the overall business purpose of advanced payments is to support the payment structure other than to provide a significant benefit of financing. For performance obligations in which the costs vary based on progress, an input-based measure considering cost incurred depicts most reliably the progress of the related research activities. In other cases, revenue recognition on a straight-line basis may most reliably depict our performance toward complete satisfaction. If the contractual activities progress, the achievement of development milestones will be used to measure the progress toward complete satisfaction. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net loss in the period of adjustment.

Upon successfully commercializing a pharmaceutical product, the collaboration and license agreements also provide for additional profit-sharing or tiered royalties earned when customers recognize net sales of licensed products as well as sales milestone payments. Revenue is recognized based on the sales-based or usage-based royalty exemption; *i.e.* when, or as, the underlying sales occur, which is when the performance obligation has been satisfied.

Principal-Agent Considerations

Collaboration agreements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations. Under our current collaboration agreements, the allocation of marketing and distribution rights defines territories in which the collaboration partner acts as a principal respectively. We recognize revenue net based on the collaboration partners' gross profit in territories where the partner is responsible for supply and on a gross basis when directly supplying our customers in our territories when control has been

transferred. Amounts paid to collaboration partners for their share of our profits earned where we are the principal in the transaction are recorded as cost of sales.

Pfizer Agreement Characteristics

With respect to our collaboration with Pfizer, commercial revenue is recognized based on our collaboration partners' gross profit from COVID-19 vaccine sales, which is shared under the respective collaboration agreement. In determining commercial revenue pursuant to this collaboration agreement, we are reliant on our collaboration partner for detail regarding its gross profit for the period at hand. Certain of the information which our collaboration partner provides us with to identify the gross profit are, by necessity, preliminary and subject to change. This is mainly due to the fact that our partner's financial reporting cycle differs from ours. Pfizer's subsidiaries outside the United States have a fiscal year-end of November 30; hence the Pfizer Quarter is equal to the Calendar Quarter with respect to the U.S. territory but is deferred by one month with respect to the territories outside the United States. This implies that the details on sales are required by us in advance of Pfizer closing the respective reporting periods. As a result, our determination of our share of such gross profit especially for this last month of the calendar cycle needs to be estimated for the purposes of recognizing revenues and is subject to the risk that amounts reported might vary from actual amounts reported once our collaboration partner's final financial results are available.

Pfizer's gross profit shares are calculated based on sales and include consideration of transfer prices. The latter includes manufacturing and shipping costs, which represent standard prices and include mark-ups on manufacturing costs as specified by the terms of the agreement. Manufacturing and shipping cost variances were considered as far as those have been identified. Nevertheless, those input parameters may be adjusted once actual costs are determined. The sales as reported by Pfizer for the Pfizer quarter, as well as sales preliminary reported for last month of the calendar quarter and territories outside the United States have been used to estimate license obligations in terms of royalties and sales milestones. Sales milestones and royalties are recognized as they are earned by the partners. Sales milestones are shared equally, while royalty payments are shared on the basis of revenue in the territories for which the partners are responsible. The estimated royalty fees applied to net sales reflect the license obligations to the extent currently identified from third party contractual arrangements. Changes in estimates are accounted for prospectively, when determined.

These estimated figures are likely to change prospectively in future periods as we receive final data from Pfizer. Those changes in our share of the collaboration partner's gross profit will be recognized prospectively as changes to our commercial revenues. To the extent that Pfizer does not provide such preliminary information in the future, our provisional sales figures for territories outside of the United States will be subject to a greater level of estimation and judgment.

Historically, adjustments to these estimates to reflect actual results or updated expectations, have not been material to our overall business. The adjustment to the estimated amounts as of December 31, 2020, which was recorded during the three months ended March 31, 2021 was 5% of revenues and the extent of the adjustments decreased throughout the year ended December 31, 2021 (i.e., adjustments were between 1% and 3% of revenues with respect to the first three quarters during 2021).

Pfizer's determination of manufacturing and shipping costs also affects the transfer prices that have been charged to COVID-19 vaccine supplies that it manufactures and supplies to us and may be subject to adjustment whenever manufacturing and shipping cost variances are identified. Likewise, our own cost of sales and the respective gross profit share owed to our partner may be adjusted prospectively, when changes are determined.

For further information regarding our revenue recognition policy, please refer to Note 2.3.4 to our consolidated financial statements included elsewhere in this Annual Report.

Research and Development Expenses

The nature of our business and primary focus of our activities, including development of our platforms and manufacturing technologies, generate a significant amount of research and development expenses. Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, the capitalization criteria are met. We have entered into agreements under which third parties grant licenses to us. If those licenses grant access to technologies, both parties jointly perform research or development activities and both are exposed to significant risks and rewards of the activities, costs incurred with the agreements are not treated differently from costs related to own product candidates. If the agreements grant us rights to use certain patents and technologies that meet

the definition of an identifiable assets, they are treated as acquired intangible assets. Due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, management has determined that these criteria are not met before regulatory approval is achieved. The related expenditure is reflected in the consolidated statements of profit or loss in the period in which the expenditure is incurred. Sales-based milestone or royalty payments incurred under license agreements relating to self-developed intangibles after the approval date of the respective pharmaceutical product are recognized as expenses as incurred. Prior to initial regulatory approval, costs relating to production of pre-launch products are expensed as research and development expenses in the period incurred. If pre-launch products are sold, the respective product gross margin may be higher compared to the expected recurring margin as the underlying costs will not be included in cost of sales.

Business Combinations

The allocation of the purchase price for business acquisitions to the identifiable assets acquired and liabilities assumed based on their respective fair values, requires use of accounting estimates and judgment. Acquired intangible assets are valued using valuation models such as the Multi Period Excess Earnings Method under which fair values are derived from future net cash flows, which are discounted to the acquisition date using an appropriate discount factor. We have estimated fair values of assets acquired, liabilities assumed and contingent considerations based on reasonable assumptions. We continue to collect information and reevaluate these provisional estimates and assumptions in accordance with IFRS 3. Any adjustments to these provisional estimates and assumptions are recorded against goodwill provided they arise within the measurement period. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the consolidated statements of profit or loss.

For further information regarding our business combination policy, please refer to Note 2.3.1 to our consolidated financial statements included elsewhere in this Annual Report.

Share-Based Payments

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions. We used valuation models like a binomial or Monte-Carlo simulation model for the measurement of the cash- and equity-settled transactions' fair value considering certain assumption relating to, *e.g.*, the volatility of stock price, the determination of an appropriate risk-free interest rate, expected dividends and the probability of reaching a minimum hurdle to exercise the relevant options. For awards which were granted prior to the initial public offering, at a time where no quoted market prices existed, the valuation model assumptions included the option's underlying share price. For awards which were granted post the initial public offering, the grant date's share prices on the Nasdaq Global Select Market were included in the valuation.

For further information regarding our share-based payments accounting policy and disclosures, see Note 2.3.16 and Note 17 to our consolidated financial statements included elsewhere in this Annual Report.

Embedded Derivatives

Defining the fair value of the embedded derivative which was bifurcated from the convertible note, as host contract, requires significant judgment. We used the Cox-Rubinstein binomial tree model when determining the fair value of the conversion right, the embedded derivative which was bifurcated from the convertible note, as host contract. The primary inputs used in the model include stock price volatility, credit spreads, risk-free interest rate and foreign exchange forward rates. Stock price volatility is based on our implied volatility, credit risk is model implied and adjusted for movement in credit spreads for B-rated corporates at each valuation date, the risk-free interest rate is based on currency specific time congruent IBOR and swap rates whereas the foreign exchange forward rates are based on observable market data.

For further information regarding our financial instrument policy and disclosures relating to financial instruments, see Note 2.3.11 and Note 12 to our consolidated financial statements included elsewhere in this Annual Report.

Income Taxes

When determining whether sufficient future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized, significant management judgment is required. This includes management's assessment on the character and amounts of taxable future profits, the periods in which those profits

are expected to occur, and the availability of tax planning opportunities. As a matter of policy, convincing evidence supporting the recognition of deferred tax assets is required if an entity has suffered a loss in either the current or the preceding periods.

As of December 31, 2021, our management continued to determine that deferred tax assets on tax losses carried forward that relate to subsidiaries which have a loss making history cannot be recognized. This includes the assessment that those subsidiaries neither have any taxable temporary difference nor any tax planning opportunities available that could support the recognition of deferred tax assets.

For further disclosures relating to income taxes, see Note 2.3.6 to our consolidated financial statements included elsewhere in this Annual Report.

B. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are given in Item 4 and under the description of the "Operating Results" in this Item 5 within this Annual Report.

C. Trend Information

See the description of "Operating Results" in this Item 5 within this Annual Report.

D. Liquidity and Capital Resources

Prior to December 2020 we funded our operations primarily from private placements of our ordinary shares, issuances of ordinary shares (including in the form of American Depositary Shares, or ADSs) in connection with our public offerings, generation of proceeds under our collaboration agreements, secured bank loans and issuance of a convertible note. Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Consequently, we have progressed from earning revenues primarily from research and development to earning revenues from commercial sales. On the R&D front, we are focused on developing next generation COVID-19 vaccines to maintain leadership and pandemic preparedness as well as broaden the label of and access to the vaccine. We also plan to invest heavily to build out our global development organization, bringing in talent with clinical and regulatory expertise needed to rapidly advance our diversified clinical pipeline. We are also taking the opportunity to diversify our therapeutic area footprint which will enable us to fully leverage the potential of all technology platforms across autoimmune diseases, inflammatory diseases, cardiovascular disease, neurodegenerative diseases, and regenerative medicines. In addition, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. To support our future trajectory, growing the organization and expanding our team is of utmost importance. We are on the way to develop our global footprint in key regions including Europe, the United States, Asia and Africa. Additionally, investing in manufacturing capabilities for key technologies and deploying our pandemic response capabilities remain priorities for us. As of December 31, 2021, we had cash and cash equivalents of €1,692.7 million. Cash deposits with an original term of six months are presented as other financial assets. Within our interim condensed consolidated financial statements as of, and for the three and nine months ended, September 30, 2021, cash deposits in an amount of €367.0 million with a term of six months at inception had been classified as cash and cash equivalents. The presentation as other financial assets in our consolidated statements of financial position and cash flow used in investing activities in our consolidated statements of cash flows was corrected as of and for the year ended December 31, 2021. As of December 31, 2021 the remaining term until maturity for the investments made was on average less than one month and the cash deposits in the amount of €375.2 million, were returned to cash and cash equivalents during January and February 2022. When analyzing our liquidity, we anticipate certain significant balance sheet items that are expected to improve our cash and cash equivalents balance subsequent to the end of the reporting period. Our trade receivables remained outstanding as of December 31, 2021 mainly due to the contractual settlement of the gross profit share under our COVID-19 collaboration with Pfizer as described in Note 6.2 to our consolidated financial statements included elsewhere in this Annual Report. As of December 31, 2021, our trade receivables included in addition to the profit share for the fourth quarter of 2021, trade receivables which related to the gross profit share for the third quarter of 2021. The payment settling our gross profit share for the third quarter of 2021 (as defined by the contract) was received from our collaboration partner subsequent to the end of the reporting period in January 2022. From our trade receivables outstanding as of December 31, 2021, we had already collected €4,693.6 million in cash by January 16, 2022.

Cash and cash equivalents are invested in accordance with our investment policy, primarily with a focus on liquidity and capital preservation, and consist primarily of cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are stated at fair value.

We maintain two secured loans with Deutsche Bank AG, or Deutsche Bank, a €9.5 million secured credit facility at a rate of 2.1% and maturing on September 30, 2028 to finance the buildouts of our JPT Peptide Technologies GmbH facility and a €10.0 million secured credit facility at a rate of 2.15% and maturing on December 30, 2027, of Innovative Manufacturing Services GmbH facility, respectively. As of December 31, 2021, the full amounts under these facilities were drawn down and were started to be repaid. Each of these facilities is secured by liens over our property. Subsequent to the end of the reporting period, we agreed to repay both Deutsche Bank loans as of February 25, 2022.

In July 2020, we offered 5,500,000 ADSs each representing one of our ordinary shares, in a public, underwritten offering on the Nasdaq Global Select Market at a public offering price of $93.00 per ADS, or the Underwritten Offering. In August 2020, following the Underwritten Offering, we issued 16,124 ADSs each representing one of our ordinary shares, in a rights offering at the same public offering price of $93.00 per ADS, or the Rights Offering. The Underwritten Offering and the Rights Offering are part of a single, global offering which we refer to as the Global Offering. The gross proceeds of the Global Offering were $513.0 million (€436.3 million).

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor participated in a private investment which we refer to as the June 2020 Private Placement. The private placement includes an investment in a four years mandatory convertible note and an investment in ordinary shares. The €100.0 million four-year mandatory convertible note has a coupon of 4.5% per annum and a conversion premium of 20% above the reference price. In February 2022, we gave notice to Temasek that we will exercise our early redemption option and fully redeem the convertible note on March 1, 2022, the redemption date. The early redemption will be fulfilled by issuing the number of our ordinary shares calculated pursuant to the early redemption provisions of the convertible note, plus paying any fractional share and accrued but unpaid interest up to (but excluding) the redemption date. The early redemption was already expected and reflected in the presentation of the financial liability and our estimates for future cash flows and conversion effects under the convertible note as of December 31, 2021.

In September 2020, we became eligible to receive up to €375.0 million in funding from an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the *BMBF*) to support our COVID-19 vaccine program, BNT162. The BMBF funding was granted to accelerate our vaccine development, to upscale manufacturing capabilities in Germany and compensate costs that incurred while continuing to test the COVID-19 vaccine in clinical trials. During the year ended December 31, 2021 the final draw downs were made.

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC and SVB Leerink LLC, as sales agents, to establish an at-the-market offering program, pursuant to which we may sell, from time to time, ADSs representing ordinary shares for aggregate gross proceeds of up to $500.0 million. During the year ended December 31, 2020, we sold 735,490 ADSs, each representing one of our ordinary shares and previously held in treasury, under the Sales Agreement for aggregate gross proceeds of $92.9 million (€76.5 million). In addition, during the year ended December 31, 2021, we sold 995,890 ADSs, each representing one of our ordinary shares that had previously been held in treasury, under the Sales Agreement for aggregate gross proceeds of $200.0 million (€163.6 million). As of December 31, 2021, the remaining capacity under the Sales Agreement is $207.1 million. Under the at-the-market offering program ADSs are sold via the stock exchange and therefore no shareholders' subscription rights are affected.

We expect our Management Board and Supervisory Board to authorize a share repurchase program of ADSs, pursuant to which we may repurchase ADSs in the amount of up to $1.5 billion over the next two years. We expect to use all or a portion of the ADSs we repurchase and hold in treasury to satisfy upcoming settlement obligations under our share-based payment arrangements.

We will propose a special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which corresponds to an aggregate of approximately €486.0 million, based on the shares outstanding as of March 30, 2022, pending approval at our Annual General Meeting to be held in June 2022 which we expect to serve as the record date for the dividend.

In January 2022, we announced a new research, development and commercialization collaboration with Pfizer to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV). Under the terms of the agreement, Pfizer will pay $225.0 million in upfront payments, including a cash payment and an equity investment as we will pay Pfizer $25.0 million for the company's proprietary antigen technology. In addition, we are eligible to receive future regulatory and sales milestone payments of up to $200.0 million as well as a share of gross profits arising from future product sales. The issuance of 497,727 ordinary shares with the nominal amount of €0.5 million was registered with the commercial register (*Handelsregister*) on March 24, 2022.

Cash Flow

The following table summarizes the primary sources and uses of cash for each period presented:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Net cash flows from (used in):			
Operating activities	€889.7	€(13.5)	€(198.5)
Investing activities	(566.1)	(144.8)	(77.2)
Financing activities	94.2	894.7	383.3
Total cash inflow	**€417.8**	**€736.4**	**€107.6**

Operating Activities

We derive cash flows from operations primarily from collaborations, the sale of products and services rendered. Our cash flows from operating activities are significantly influenced by our use of cash for operating expenses and working capital to support the business. Historically we have experienced negative cash flows from operating activities as we have invested in the development of our technologies and manufacturing capabilities, as well as in our clinical and preclinical development of our product candidates. During the year ended December 31, 2021, our cash flows from operating activities became positive, as we received the settlement payment of our gross profit share of the first and second quarter of 2021 from our collaboration partner which was mainly reduced by the tax payments we made for the year ended December 31, 2021 as well as the amounts spent on our operating activities. As described previously in this Item 5 within this Annual Report and in Note 6.2 to the consolidated financial statements included elsewhere in this Annual Report, the contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. Therefore, subsequent to the end of the reporting period, in January 2022, we further improved our cash position as we received the settlement payment of our gross profit share for the third quarter of 2021 (as defined by the contract).

Net cash from operating activities for the year ended December 31, 2021 was €889.7 million, comprising a profit before tax of €15,046.4 million, positive non-cash adjustments of €42.6 million, and a net negative change in assets and liabilities of €10,730.4 million. Non-cash items primarily included finance expenses related to our convertible bond fair value update which were offset by net foreign exchange differences and movements in government grants. The net negative change in assets and liabilities was primarily due to an increase in trade receivables related to our COVID-19 collaboration with Pfizer, as previously discussed in this Item 5 within this Annual Report and as described in Note 6.2 to the to the consolidated financial statements included elsewhere in this Annual Report.

Net cash used in operating activities for the year ended December 31, 2020 was €13.5 million, comprising a loss before tax of €145.8 million, non-cash adjustments of €227.1 million, and a net negative change in assets and liabilities of €93.1 million. Non-cash items primarily included movements in government grant, depreciation and amortization as well as share-based compensation expenses and non-cash effective finance expenses. The net negative change in assets and liabilities was primarily due to an increase in trade receivables and a decrease in payables and liabilities as well as inventories.

Net cash used in operating activities for the year ended December 31, 2019 was €198.5 million, comprising a loss before tax of €179.4 million, non-cash adjustments of €64.9 million, and a net negative change in assets and liabilities of €83.5 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net negative change in assets and liabilities was primarily due to a decrease in contract liabilities and trade payables.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 was €566.1 million, comprising the effect from €375.2 million cash deposits, presented as financial assets as of December 31, 2021 due to their original term of six months, were shown as cash flow used in investing activities during the year ended December 31, 2021 but were returned to cash and cash equivalents during January and February 2022. In addition, €127.5 million was attributable to the purchase of property, plant and equipment including the amounts spent with respect to our acquired facility in Gaithersburg, Maryland, United States as well as €20.8 million spent upon the acquisition of our new subsidiary in Vienna, Austria.

Net cash used in investing activities for the year ended December 31, 2020 was €144.8 million, of which €66.0 million was attributable to the purchase of property, plant and equipment and €60.6 million were mainly attributable to the acquisition of our new manufacturing facility in Marburg, Germany.

Net cash used in investing activities for the year ended December 31, 2019 was €77.2 million, of which €32.5 million was attributable to the purchase of intangible assets, including the final installment payment for the license agreement for the CellScript patent, and €38.6 million was attributable to the purchase of property, plant and equipment.

Financing Activities

Our primary financing activities consist of issuances of share capital, proceeds from bank loans and payments of lease liabilities.

Net cash from financing activities for the year ended December 31, 2021 was €94.2 million, primarily generated from the sale of treasury shares under the at-the-market offering program net of transaction cost, as previously discussed in this Item 5 within this Annual Report and as described in Note 16 to the consolidated financial statements included elsewhere in this Annual Report and offset by the amount spent when repaying our financing arrangement which was entered with the European Investment Bank, or the EIB, and explained in Note 12 to the consolidated financial statements included elsewhere in this Annual Report .

Net cash from financing activities for the year ended December 31, 2020 was €894.7 million, primarily generated from proceeds from the issuance of shares in the amount of €753.0 million and proceeds from loans and borrowings in the amount of €156.0 million, partially offset by the payment of lease liabilities in the amount of €12.7 million.

Net cash from financing activities for the year ended December 31, 2019 was €383.3 million, primarily generated from proceeds from the issuance of shares in the amount of €375.4 million and proceeds from loans and borrowings in the amount of €11.0 million, partially offset by the payment of lease liabilities in the amount of €3.1 million.

Operation and Funding Requirements

Prior to December 2020, we incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. As of December 31, 2020, our accumulated losses amounted to €409.6 million. Those have been offset by the profit generated during the year ended December 31, 2021 and our retained earnings as of December 31, 2021 amounted to €9,882.9 million.

We expect to continue to incur significant and increasing operating expenses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or increase our manufacturing capacity or capability;
- change or add additional suppliers;

- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as a public company and our product development and commercialization efforts, including expansion of sites in Germany and new sites in the United States, and potentially others globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;
- develop our sales, marketing, and distribution infrastructure for our COVID-19 vaccine and any other products for which we may obtain marketing approval or emergency use authorization;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- acquire other companies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We are a party to license and research and development agreements with universities and other third parties, as well as patent assignment agreements, under which we have obtained rights to patents, patent applications and know-how. We enter into contracts in the normal course of business with CROs for clinical trials, clinical and commercial supply manufacturing, with vendors for preclinical research studies and for other services and products for operating purposes. We work together with CMOs, who manufacture our product candidates and products and enter into lease agreements to lease laboratory, GMP manufacturing, storage and office spaces. Purchase obligations under our agreements to the extent that they are quantifiable and not cancellable have been considered when defining our guidance for future cash commitments. Most of the committed cash outflow in 2022 is related to CMO purchase obligations amounting to €354.4 million and lease payments amounting to €31.3 million. Further, we have purchase obligations with an amount of €199.3 million and lease payment obligations of €178.0 million for the years 2023 and beyond.

We are subject to all of the risks related to the development and commercialization of pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement, misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;

- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs; and
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

E. Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

F. Tabular Disclosure of Contractual Obligations

During 2020, the Securities and Exchange Commission (SEC) voted to adopt amendments to certain financial disclosure requirements in Regulation S-K (also referred to as "November 19, 2020 amendments to Regulation S-K") which resulted in omitting the presentation of contractual obligations in a tabular form.

G. Safe Harbor

See the beginning of this Item and "Cautionary Statement Regarding Forward-Looking Statements" included elsewhere in this Annual Report.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Management Board (*Vorstand*)

The following table sets forth the names and functions of the current members of our Management Board, their ages as of December 31, 2021 and their terms:

Name	Age	Term Expires	Position
Prof. Ugur Sahin, M.D.	56	2022	Chief Executive Officer
Sean Marett	56	2022	Chief Business Officer and Chief Commercial Officer
Dr. Sierk Poetting	48	2026	Chief Operating Officer
Prof. Özlem Türeci, M.D.	54	2025[1]	Chief Medical Officer
Ryan Richardson	42	2022	Chief Strategy Officer
Jens Holstein[2]	58	2025	Chief Financial Officer

(1) Initial term expires May 31, 2022 (renewed beginning March 1, 2022 through May 31, 2025).

(2) Appointed effective as of July, 1 2021.

The business address of the members of our Management Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the business experience of the members of our Management Board:

Prof. Ugur Sahin, M.D. co-founded BioNTech in 2008 and has served as our Chief Executive Officer since that time. He is a physician, immunologist and leader in the development of novel approaches to fight cancer and infectious diseases. Ugur Sahin is one of the world's foremost experts on messenger ribonucleic acid (mRNA) medicines. He has pioneered several breakthroughs enabling the development of mRNA vaccines and other types of immunotherapies. He initiated and oversees "Project Lightspeed," the historic development of the first mRNA vaccine for COVID-19, moving from lab and clinical testing to conditional approval within an unprecedented 11-month period. He also leads BioNTech's research and development of neoantigen specific mRNA cancer vaccines which are individually tailored and produced on

demand according to the profile of non-synonymous mutations identified by next-generation sequencing in patients' tumors. Ugur Sahin is co-inventor of more than 500 filed patents applications and patents. His academic credentials include serving as a Full Professor (W3) in Translational Oncology & Immunology at Johannes Gutenberg University in Mainz, Germany, where he was the supervisor for more than 50 PhD students. He also holds the role of Chairman of the Scientific Management Board of the Helmholtz Institute for Translational Oncology (HI-TRON), also in Mainz. Based on his contributions to scientific discovery, Dr. Sahin has received numerous awards and recognitions, including the German Sustainability Award, the Mustafa Prize, and the German Cancer Award. He is married to Prof. Özlem Türeci, M.D..

Sean Marett joined BioNTech in 2012. Prior to joining BioNTech, he worked in global strategic and regional marketing and sales roles at GlaxoSmithKline in the United States and Pfizer in Europe before taking business development executive roles at Evotec and Lorantis, the latter of which he helped to successfully sell to Celldex Therapeutics, Inc. He has successfully executed complex licensing transactions with large pharmaceutical companies, negotiated M&A transactions and raised finance from investors. Sean Marett built and ran a contract clinical manufacturing organization with operations across Europe and the United States for over half a decade for the contract manufacturer, NextPharma. Sean Marett has been Chairman of PHMR Ltd, a company specializing in market access and pharmaceutical reimbursement, since 2017. He became a member of the supervisory board of AiCuris AG in February 2021. He previously held non-executive directorship of KWS BioTest Ltd (successfully sold to Charles River) from 2011 until 2018 and was a member of the investment committee of Mann BioInvest Ltd, a fund dedicated to biotechnology and pharmaceutical company investments from 2013 until 2016. He holds a BSc (Hons) in Biochemistry from Kings College London and an MBA from Manchester Business School.

Dr. Sierk Poetting is our Chief Operating Officer. He joined BioNTech in September 2014 from Novartis, where he served from May 2012 to August 2014 as Vice President and Chief Financial Officer for the Sandoz Division in North America. Sierk Poetting started his career as a consultant with McKinsey & Company. A German citizen, he holds a Master of Science in Optical Sciences from the University of Arizona and a Ph.D. in Physics from the Ludwig-Maximilians University in Munich.

Prof. Özlem Türeci, M.D. Co-founder and Chief Medical Officer of BioNTech, is a physician, immunologist, and cancer researcher with translational and clinical experience. She has helped lead the discovery of cancer antigens, the development of mRNA-based individualized and off-the-shelf vaccine candidates and other types of immunotherapies which are currently in clinical development. Özlem Türeci leads the clinical development of BioNTech's "Project Lightspeed," the company's successful effort to develop and distribute an mRNA-based vaccine against COVID-19, a historic achievement completed in less than one year. She previously served as CEO and Chief Medical Officer of Ganymed Pharmaceuticals AG, which she co-founded with Ugur Sahin and Christoph Huber. The company was acquired by Astellas in 2016. She is also a professor for Personalized Immunotherapy at the University Medical Center Mainz and the Helmholtz Institute for Translational Oncology Mainz (HI-TRON) and currently serves as President of the Association for Cancer Immunotherapy (CIMT) in Germany. She is a recent recipient of the German Sustainability Award, among other notable recognitions. Özlem Türeci is married to Prof. Ugur Sahin, M.D. .

Ryan Richardson is our Chief Strategy Officer. He brings more than 15 years of experience in the finance and healthcare industries to BioNTech. Prior to joining BioNTech in 2018 as the Senior Vice President, Corporate Development & Strategy, Ryan was an Executive Director in the Global Healthcare Investment Banking team at J.P. Morgan in London, where he advised companies in the biotech and life sciences industry on M&A, equity and debt capital financings. Earlier in his career, Ryan spent five years as a Management Consultant to biopharmaceutical companies in the U.S. and Europe, where he worked on a wide range of strategic and operational projects in the areas of commercial strategy, pricing and market access, new product planning, and R&D operations. Ryan holds an MBA from the University Of Chicago Booth School Of Business, an MSc from the London School of Economics, and a BS in Biology from the University of Kansas.

Jens Holstein is our Chief Financial Officer. Prior to joining BioNTech, Jens was CFO of dual-listed MorphoSys AG where he was instrumental in building a fully integrated biopharmaceutical company. Before joining MorphoSys in 2011, Jens served in multiple CFO positions as well as general management roles within the Fresenius SE Group. He served as Regional CFO for the region EME (Europe/Middle East) and as Managing Director of Fresenius Kabi Deutschland GmbH. From 2006 to 2010, he was Regional CFO of Fresenius Kabi Asia Pacific Ltd., based in Hong Kong. Prior to this appointment, Jens Holstein was Managing Director of Fresenius ProServe GmbH, and CFO and Labor Director of the company's subsidiary Wittgensteiner Kliniken AG. Earlier positions within Fresenius included General Manager of hospitalia care GmbH, Commercial Manager of the Projects & Service business unit of Fresenius AG and Commercial Manager of hospitalia international GmbH. Jens Holstein also spent several years in the consulting industry, including in

M&A with positions in Frankfurt and London. Jens Holstein holds a Diploma in Business Administration from the University of Münster, Germany. He is also a Non-Executive Member of the Board of Directors at global genomic diagnostics company Veracyte Inc.

Supervisory Board (*Aufsichtsrat*)

The following table sets forth the names and functions of the current members of our Supervisory Board, their ages as of December 31, 2021, their terms (which expire on the date of the relevant year's general shareholders' meeting) and their principal occupations outside of our Company:

Name	Age	Term Expires	Principal Occupation
Helmut Jeggle (Chairman Supervisory Board)	51	2023	Managing partner and entrepreneurial venture capital investor of Salvia GmbH (Supervisory Board member 4SC AG, AiCuris AG, AFFiRiS AG, APK AG and Tonies SE)
Michael Motschmann (Supervisory Board member)	64	2023	Member of the Management Board and head of equity investments of MIG Capital AG (Supervisory Board member AFFiRiS AG, APK AG, HMW-Emissionshaus AG and HMW-Innovations AG)
Prof. Christoph Huber, M.D. (Supervisory Board member)	77	2023	Professor emeritus at the Johannes-Gutenberg University Mainz (Deputy Chairman of the Supervisory Board Tirol Kliniken GmbH)
Dr. Ulrich Wandschneider (Deputy Chairman Supervisory Board)	60	2023	Managing director of beebusy capital GmbH and independent consultant to companies in the lifescience and healthcare sector (from January 1 till December 31, 2021 Supervisory Board member Vanguard AG)

The business address of the members of our Supervisory Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the prior business experience of the members of our Supervisory Board:

Helmut Jeggle has been Chairman of our Supervisory Board since its foundation in 2008. He has a degree in business administration from the University of Applied Sciences in Neu-Ulm and an MBA (Master of Business Administration) from the Stuttgart Institute of Management and Technology. From 2000 to 2007, Helmut Jeggle held various positions at Hexal AG. From 2007 onwards, he was, among other things, in charge of Direct Investments at ATHOS KG, the family office of the Strüngmann family, from which he resigned as general partner (*Komplementär*) in April 2021. Since 2014, Helmut Jeggle has been Managing Director of Salvia GmbH, where he acts as an entrepreneurial venture capital investor. He is currently a member of two other supervisory boards of listed companies, including 4SC AG and Tonies SE.

Michael Motschmann has served as a member of our Supervisory Board since 2008. He co-founded MIG Verwaltungs AG, or MIG, in 2004, where he serves on the Management Board and as Head of Equity Investments. In his role with MIG, Michael. Motschmann currently serves on the supervisory boards of several private portfolio companies.

Prof. Christoph Huber, M.D. is a co-founder of BioNTech and has served as a member of our Supervisory Board since 2008. Christoph Huber has more than 50 years of professional experience in hematology, oncology and translational immunology. He served as Chairman of the Department of Hematology and Oncology at the Johannes-Gutenberg University Mainz from 1990 to 2009 and, since 2009, has served as Chairman Emeritus of the Department of Hematology and Oncology. He was a co-founder of Ganymed Pharmaceuticals AG, now a subsidiary of Astellas. Christoph Huber is an executive board member of CIMT and a board member of Ci3. From 2018 to April 2019, He served as a member of the supervisory board of TRON. Christoph Huber earned his M.D. at the University of Innsbruck.

Dr. Ulrich Wandschneider, Ph.D. has served as a member of our Supervisory Board since 2018. He has more than 20 years of experience in the healthcare sector as a manager in the operative business and as a member of boards and committees. He was a Partner at Arthur Andersen until 2002 and at Deloitte from 2002 to 2004 in the healthcare and life science sector for many years. From 2004 to 2016 Ulrich Wandschneider served as Chief Executive Officer first of Mediclin AG later of Asklepios Kliniken GmbH & Co. KGaA. He currently serves on various supervisory and advisory boards.

B. Compensation

Remuneration of Supervisory Board Members

The remuneration system of our Supervisory Board as included in our Articles of Association is structured as purely fixed compensation. While retaining the system for the compensation of Supervisory Board members, the compensation of Supervisory Board members was adjusted during the year ended December 31, 2021 to maintain its competitiveness. The new provisions were approved by the Annual General Meeting on June 22, 2021 and were applied on a pro-rata basis from July 23, 2021, the date of entry of the corresponding amendment to the Articles of Association in our Commercial Register. Pursuant to Sec. 113 para. 3 AktG, as amended by the Act Implementing the Second Shareholder Rights Directive, the Annual General Meeting of a listed company must pass a resolution on the compensation of the members of the Supervisory Board at least every four years.

Until July 23, 2021, the annual remuneration for each member of the Supervisory Board amounted to €50,000. However, the chairman was entitled to receive €150,000 per year and the vice chairman €75,000 per year. In addition, the chairman of the audit committee was entitled to be paid €20,000 per year.

From July 23, 2021, the members of the Supervisory Board receive an annual compensation of €70,000, the Chairman €210,000 and the Vice Chairman €105,000. The Chairman of the Audit Committee shall receive an additional annual compensation of €30,000. The respective Chairman of another committee shall receive an additional annual compensation of €10,000.

All members of the Supervisory Board are reimbursed for their expenses.

in thousands	**Helmut Jeggle**	**Michael Motschmann**	**Prof. Christoph Huber, M.D.**	**Dr. Ulrich Wandschneider**
Base Compensation				
2021	€177	€59	€59	€88
2020	150	50	50	75
Committee Compensation				
2021	4	4	—	24
2020	—	—	—	20
Total				
2021	**€181**	**€63**	**€59**	**€112**
2020	**€150**	**€50**	**€50**	**€95**

Members of the Supervisory Board who are only members of the Supervisory Board for part of the financial year or who chair or vice-chair the Supervisory Board or the Audit Committee or another committee shall receive the respective compensation on a pro-rata basis. The same applies insofar as this regulation or this regulation in a specific version is only in force during part of the financial year. Therefore, the amounts disclosed above consider the pro-rata application of the adjusted provisions of the Supervisory Board remuneration system.

If the reimbursement of expenses or the compensation is subject to value-added tax, the value-added tax shall be paid in addition.

The Supervisory Board members are included in our D&O liability insurance and are co-insured at our expense.

There are no arrangements or understandings between us and any member of our Supervisory Board providing for benefits upon termination of their service as director.

Remuneration of the Members of Our Management Board

We have entered into agreements with all current members of our Management Board.

We believe that the agreements between us and the members of our Management Board provide for payments and benefits (including upon termination of employment) that are in line with customary market practice.

The following sets forth the effective and termination dates of the current service agreements of our Management Board:

- Prof. Ugur Sahin, M.D.: September 1, 2019 – December 31, 2022
- Sean Marett: September 1, 2019 – September 30, 2022
- Dr. Sierk Poetting: September 1, 2019 – November 30, 2026 (renewed as of December 1, 2021)
- Prof. Özlem Türeci, M.D.: September 1, 2019 – May 31, 2022 (renewed as of March 1, 2022 until May 31, 2025)
- Ryan Richardson: January 1, 2020 – December 31, 2022
- Jens Holstein: July 1, 2021 – June 30, 2025

From January 1, 2019 until August 31, 2019, the annual base salaries for our Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Prof. Özlem Türeci, were €210,000, €360,000, €300,000 and €300,000, respectively. Effective September 1, 2019, the annual fixed compensation for our Management Board members, Prof. Ugur Sahin, Sean Marett and Prof. Özlem Türeci was €360,000, €400,000 and €360,000, respectively. Effective January 1, 2020, the annual fixed compensation of Ryan Richardson is €320,000. Effective December 1, 2021, Dr. Sierk Poetting's annual fixed compensation was increased from €360,000 to €550,000 which led to an effective annual fixed compensation of €375,833 during the year ended December 31, 2021. Effective as of his appointment to the Management Board on July 1, 2021, Jens Holstein's annual fixed compensation was €550,000 which led to an effective annual fixed compensation of €275,000 during the year ended December 31, 2021.

The service agreements with our Management Board provide for a short-term incentive compensation which is an annual performance-related bonus for the years of their respective service periods. Effective January 1, 2020, the maximum short-term incentive compensation for our Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Prof. Özlem Türeci was 50% of their annual fixed compensation. The same applied to Ryan Richardson's maximum short-term incentive compensation effective since January 1, 2020. Effective July 1, 2021, the maximum short-term incentive compensation for Jens Holstein was defined as €300,000. Effective January 1, 2022, the maximum short-term incentive compensation for Dr. Sierk Poetting has been increased to €300,000. The payout amount of the short-term incentive compensation depends on the achievement of certain financial performance criteria and non-financial performance criteria (performance targets) of the Group in a particular financial year, which goals are set uniformly for all members of the Management Board. 50% percent of the compensation are paid following the determination on the actual achievement of the performance targets (first installment), with the remaining amount payable one year after such determination, subject to adjustment relative to the performance of the price of the American Depositary Shares representing our ordinary shares during that year (second installment).

The service agreements with our Management Board provide for a long-term incentive compensation in terms of an annual grant of options to purchase BioNTech shares for the years of their respective service periods. The options granted each year will be subject to the terms, conditions, definitions and provisions of our Employee Stock Ownership Plan (ESOP) and the applicable option agreement thereunder. Effective January 1, 2020, the number of options to be granted each year to Prof. Ugur Sahin, Sean Marett, Prof. Özlem Türeci and Ryan Richardson are to be calculated based on a value of €750,000, €300,000, €300,000 and €260,000, respectively. The value used to calculate the number of options for Ryan Richardson increases to €280,000 for the year 2022. Effective December 1, 2021, with entering into a new service contract, the value on which the number of options to be granted each year to Dr. Sierk Poetting is based was increased from €300,000 to €550,000 for new awards. Effective as of his appointment to the Management Board on July 1, 2021, the

number of options to be granted each year to Jens Holstein was to be calculated based on a value of €550,000. In each case the values must be divided by the amount by which a certain target share price exceeds the exercise price.

Taking the requirements of Sec. 87a para. 1 AktG into account, the Supervisory Board adopted a slightly modified compensation system for the members of the Management Board on May 7, 2021. The compensation system for members of the Management Board was approved by the AGM on June 22, 2021 and becomes effective whenever new service agreements are entered into, existing service agreements are extended or specific compensation components are initiated.

The comprehensive remuneration system as approved by the AGM on June 22, 2021 includes specific provisions with respect to benefits upon termination and is available online on our website www.biontech.de. .

During the years ended December 31, 2021 and 2020, the members of our Management Board received the aggregate remuneration of €20.4 million and €23.7 million, respectively.

in thousands	**Prof. Ugur Sahin, M.D.**	**Sean Marett**	**Dr. Sierk Poetting**	**Prof. Özlem Türeci, M.D.**	**Ryan Richardson[1]**	**Jens Holstein[2]**
Fixed compensation						
2021	€360	€400	€376	€360	€320	€275
2020	360	400	360	360	320	—
Fringe benefits[3]						
2021	6	22	4	—	16	3
2020	6	11	11	3	4	—
Short-term incentive – first installment						
2021	90	100	90	90	80	75
2020	90	100	90	90	80	—
Short-term incentive – second installment[4]						
2021	223	248	243	223	200	186
2020	148	164	148	148	133	—
Share-based payments (incl. long-term incentive)[5]						
2021	10,907	1,709	1,977	454	517	869
2020	15,912	1,612	1,612	433	1,128	—
Total						
2021	**€11,586**	**€2,479**	**€2,690**	**€1,127**	**€1,133**	**€1,408**
2020	**€16,516**	**€2,287**	**€2,221**	**€1,034**	**€1,665**	**€—**

(1) Ryan Richardson was appointed to the Management Board as Chief Strategy Officer (CSO) and Managing Director effective as of January 12, 2020. Expenses from a bonus arrangement agreed with Ryan Richardson in advance of his appointment to the Management Board are included in the share-based payments amount. During the year ended December 31, 2020, the arrangement was modified from an all-equity share-based payment arrangement into a partly cash and partly equity settled share-based payment arrangement including 4,534 ordinary shares which were issued during the year ended December 31, 2021.

(2) Jens Holstein was appointed to the Management Board as Chief Financial Officer (CFO) effective as of July 1, 2021. As of his appointment, the Supervisory Board granted Jens Holstein a one-time signing bonus of €800,000 by awarding 4,246 phantom shares which are included in the share-based payments amount. The phantom shares vest in four equal installments on July 1 of 2022, 2023, 2024 and 2025 but will only be settled in cash on July 1, 2025. As of December 31, 2021, the cash payment is subject to an effective settlement closing price cap. This means that the settlement closing price shall effectively be adjusted to ensure that the current price of an ADS as of the settlement date does not exceed 800% of the closing price applied when the award was initially granted. In addition, the total cash payment under the award shall not exceed €6.4 million.

(3) Includes social security, health and additional insurance, company bike and travel expenses.

(4) The fair value of the second installment of the short-term incentive compensation which has been classified as cash-settled share-based payment arrangement was determined pursuant to the regulations of IFRS 2 “Share-based Payments.” This table shows the pro-rata share of personnel expenses for the respective financial year that are recognized over the award’s vesting period beginning as of the service commencement date (date when the respective service agreement becomes effective) until each separate determination date and are remeasured until settlement date.

(5) The fair value of the share-based payments was determined pursuant to the regulations of IFRS 2 “Share-based Payments.” This table shows the pro-rata share of personnel expenses resulting from stock-based compensation for the respective financial year. It includes the share-based payment arrangements explained in footnote (1) and (2) and those explained in "Share-Based Payment Arrangements" in this Item 6 in this Annual Report.

The table below provides an overview of the share options and other share-based payment instruments granted to our Management Board which are outstanding as of December 31, 2021:

	Grant Date / (Estimated) Allocation Date	Number of Ordinary Shares Underlying Share Options / Number of Phantom Share Options [2]	Option Exercise Price (€) [9]	Earliest Option Exercise Date[12]	Option Expiration Date	Name of the Program
Prof. Ugur Sahin, M.D.	11/15/2018[1]	1,830,348	10.14	9/16/2022	9/17/2026	ESOP 2018
	10/10/2019 [3]	4,374,963	13.60	10/10/2023	10/10/2029	CEO Grant 2019
	2/13/2020[4]	97,420	28.32	2/13/2024	2/13/2030	LTI 2020[13]
	05/12/2021[5]	17,780	163.54	5/12/2025	5/12/2031	LTI 2021[13]
	2022[10]	11,696	229.00	—	2032	LTI 2022[13]
Sean Marett	11/15/2018[1]	610,110	10.14	9/16/2022	9/17/2026	ESOP 2018
	2/13/2020[4]	38,968	28.32	2/13/2024	2/13/2030	LTI 2020[13]
	5/12/2021[5]	7,112	163.54	5/12/2025	5/12/2031	LTI 2021[13]
	2022[10]	3,509	229.00	—	2032	LTI 2022[13]
Dr. Sierk Poetting	11/15/2018[1]	610,110	10.14	9/16/2022	9/17/2026	ESOP 2018
	2/13/2020[4]	38,968	28.32	2/13/2024	2/13/2030	LTI 2020[13]
	5/12/2021[5]	7,112	163.54	5/12/2025	5/12/2031	LTI 2021[13]
	2022[10]	8,577	229.00	—	2032	LTI 2022[13]
	2023[10]	8,424	233.16	—	2033	LTI 2023[13]
	2024[10]	8,340	235.52	—	2034	LTI 2024[13]
	2025[10]	8,177	240.21	—	2035	LTI 2025[13]
	2026[10]	7,314	246.18	—	2036	LTI 2026[13]
Prof. Özlem Türeci, M.D.	11/15/2018[6]	1,952,334	10.14	9/16/2022	9/17/2026	ESOP 2018
	2/13/2020[4]	38,968	28.32	2/13/2024	2/13/2030	LTI 2020[13]
	5/12/2021[5]	7,112	163.54	5/12/2025	5/12/2031	LTI 2021[13]
	2022[10]	1,949	229	—	2032	LTI 2022[13]
Ryan Richardson [7]	11/15/2018 [8]	149,508	10.14	9/16/2022	9/17/2026	ESOP 2018
	2/13/2020[4]	33,772	28.32	2/13/2024	2/13/2030	LTI 2020[13]
	5/12/2021[5]	6,163	163.54	5/12/2025	5/12/2031	LTI 2021[13]
	2022[10]	4,366	229.00	—	2032	LTI 2022[13]
Jens Holstein	5/17/2021[5]	6,463	164.96	5/17/2025	5/17/2031	LTI 2021[13]
	7/1/2021[11]	4,246	n/a [11]	7/1/2025[11]	n/a [11]	Signing Bonus
	2022[10]	8,577	229.00	—	2032	LTI 2022[13]
	2023[10]	8,424	233.16	—	2033	LTI 2023[13]
	2024[10]	8,340	235.52	—	2034	LTI 2024[13]
	2025[10]	4,088	240.21	—	2035	LTI 2025[13]

(1) Options fully vest on September 16, 2022.

(2) 18-for-1 stock split of our ordinary shares, which became effective on September 18, 2019 upon registration with the commercial register (*Handelsregister*) is reflected in share amounts granted in advance.

(3) Options vest in four equal installments on October 10 of 2020, 2021, 2022 and 2023 but will not become exercisable until October 10, 2023.

(4) Options vest in four equal installments on February 13 of 2021, 2022, 2023 and 2024 but will not become exercisable until February 13, 2024.

(5) Options were issued as phantom share options and vest in four equal installments on May 12 of 2022, 2023, 2024 and 2025 for all Management Board members but Jens Holstein and May 17 of 2022, 2023, 2024 and 2025 for Jens Holstein. The options will not become exercisable until May 12, 2025 and May 17, 2025, respectively.

(6) Options fully vested on March 16, 2019, however these options will not become exercisable until September 16, 2022.

(7) Ryan Richardson was appointed to the Management Board as Chief Strategy Officer (CSO) and Managing Director on January 12, 2020. The share options granted on November 15, 2018 under the Employee Stock Ownership Plan were granted before his appointment to the Management Board.

(8) Options fully vested on October 10, 2019, however these options will not become exercisable until September 16, 2022.

(9) As of December 31, 2021, all options other than those granted to Ryan Richardson before he was appointed to the Management Board are subject to an effective exercise price cap. This means that the exercise price shall effectively be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. As of December 31, 2021, with respect to the phantom share options issued in May 2021, all agreements include an additional maximum compensation clause limiting the total cash payment that the Management Board members are entitled to receive to €20.0 million for Ugur Sahin as Chief Executive Officer (CEO) or €10.0 million for all other Management Board members, less other compensation components received by each such board member in the respective grant year.

(10) As of December 31, 2021, the assessment about options expected to be granted in 2022 till 2026 dependent on whether service contracts have been signed with the respective Management Board members was based on estimated allocation dates in the middle of the years 2022 till 2026. For the awards with estimated allocation dates the exercise prices and the numbers of options expected to be allocated have been derived from the Monte-Carlo simulation model. Those parameters will be adjusted until the actual allocation has occurred and the number of options granted and the exercise price has ultimately been determined. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be exercisable four years after the allocation date.

(11) As of July 1, 2021 when Jens Holstein was appointed to the Management Board as Chief Financial Officer (CFO), the Supervisory Board granted Jens Holstein a one-time signing bonus of €800,000 by awarding 4,246 phantom shares. The phantom shares vest in four equal installments on July 1 of 2022, 2023, 2024 and 2025 but will only be settled in cash on July 1, 2025. As of December 31, 2021, the cash payment is subject to an effective settlement closing price cap. This means that the settlement closing price shall effectively be adjusted to ensure that the current price of an ADS as of the settlement date does not exceed 800% of the cash payment which in respect of all phantom shares shall not exceed €6.4 million.

(12) Indicates end of the respective waiting period, additional restrictions with respect to exercise windows may apply.

(13) Management Board Grant (Long-Term Incentive) in the respective years.

Share-Based Payment Arrangements

Employee Stock Ownership Plan

Based on a pertinent authorization of the general meeting on August 18, 2017, we established a share option program under which we granted selected employees options to receive our shares. The program is designed as an Employee Stock Ownership Plan, or ESOP. We have offered the participants a certain number of rights by explicit acceptance of the participants. The exercise of the option rights in accordance with the agreement gives the participants the right to obtain shares against payment of the exercise price. The option rights (other than Prof. Özlem Türeci's and Ryan Richardson's options referred to in the above table and footnotes) generally fully vest after four years and can only be exercised if: (i) the waiting period of four years has elapsed; and (ii) at the time of exercise, the average closing price of the shares of the Company or the average closing price of the right or certificate to be converted into an amount per share on the previous ten trading days preceding the exercise of the option right exceeds the strike price by a minimum of 32%, with this percentage increasing by eight percentage points as of the fifth anniversary of the respective issue date and as of each subsequent anniversary date. The option rights can be exercised at the latest eight years after the allocation date. If they have not been exercised by that date, they will forfeit without compensation.

As of December 31, 2021, with respect to the Management Board members, other than Ryan Richardson who was not a Management Board member at the time the options were granted, the options are subject to an effective exercise price cap. This means that the exercise price shall effectively be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price.

By way of shareholders' resolution of the general meeting on August 19, 2019, the authorization to issue such option rights was amended such, that, in order for the options to be exercisable, the average closing price of the Company's shares

or the average closing price of the right or certificate to be converted into an amount per share on the ten trading days immediately preceding the exercise must exceed the strike price by a minimum of 28%, with this percentage increasing by seven percentage points as of the fifth anniversary of the issue date and as of each subsequent anniversary date. Also, in addition to the aforementioned requirements, the exercise is only possible if the share price (calculated by reference to the price of the ordinary share underlying the ADS) has performed similar to or better than the Nasdaq Biotechnology Index. The changes made do not affect option rights already issued.

Chief Executive Officer Grant

In September 2019, we granted Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, an option to purchase 4,374,963 of our ordinary shares, subject to Prof. Sahin's continuous employment with us. The option is subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder. The options' exercise price per share is the Euro translation of the public offering price from our initial public offering, $15.00 (€13.60) which, as of December 31, 2021, is subject to the effective exercise price cap. The option will vest annually in equal installments after four years commencing on the first anniversary of our initial public offering and will be exercisable four years after our initial public offering. The vested option rights can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the Target Price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, $8.5 billion divided by the total number of the shares outstanding immediately following the initial public offering (other than shares owned by us), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. The option rights can be exercised up to ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

Management Board Grant (Long-Term Incentive)

The service agreements with our Management Board provide for a long-term incentive compensation in terms of an annual grant of options to purchase BioNTech shares for the years of their respective service periods. The options granted each year will be subject to the terms, conditions, definitions and provisions of our Employee Stock Ownership Plan (ESOP) and the applicable option agreement thereunder.

The allocation of the number of issued options in 2020 occurred in February 2020 (2020 allocation date). In May 2021 (2021 allocation date), phantom options equivalent to the number of options the Management Board members would have been entitled to receive for the year 2021 were granted under the Management Board Grant. During the year 2021, the options were issued as phantom share options As of December 31, 2021, the assessment about options expected to be allocated in future years was based on estimated allocation dates in the middle of the respective years.

The per share exercise price of the options is the Euro equivalent of the arithmetic mean of the closing prices of the ten last trading days prior to the allocation date. For the awards allocated as of February 2020, the exercise price has been determined to be $30.78 (€28.32), calculated as of grant date using the foreign exchange rate as published by the German Central Bank (*Deutsche Bundesbank*). As of December 31, 2021, the awards allocated as of February 2020 are subject to the effective exercise price cap. For the awards allocated as of May 12, 2021 and May 17, 2021 the exercise price has been determined to be $185.23 (€163.54) and $186.83 (€164.96), respectively (both amounts calculated as of December 31, 2021, using the foreign exchange rate as published by the German Central Bank (*Deutsche Bundesbank*)). For the awards with estimated allocation dates the exercise prices of options expected to be allocated have been derived from the Monte-Carlo simulation model. Those will be adjusted until the actual allocation has occurred and the exercise price has ultimately been determined. With respect to the phantom share options issued in May 2021, as of December 31, 2021, all agreements include the effective exercise price cap and an additional maximum compensation clause limiting the total cash payment that the Management Board members are entitled to receive to €20.0 million for Ugur Sahin as Chief Executive Officer (CEO) or €10.0 million for all other Management Board members, less other compensation components received by each such board member in the respective grant year. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be exercisable four years after the allocation date. The vested options can only be exercised if and to the extent that each of the following performance criteria has been achieved:

(i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, $8.5 billion divided by the total number of the ordinary shares outstanding immediately following the initial public offering (other than ordinary shares owned by BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. The options expire ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

C. Board Practices

Two-Tiered Board Structure

We are a European public company with limited liability (*Societas Europaea* or SE) (also referred to as European stock corporation, and in the official terminology of the European legislation referred to as European public limited-liability company), having its seat in Germany. We have chosen to have a two-tiered SE structure. Hence, our corporate bodies are the Management Board (*Vorstand*), the Supervisory Board (*Aufsichtsrat*) and the shareholders' meeting (*Hauptversammlung*). Our Management and Supervisory Boards are entirely separate, and, as a rule, no individual may simultaneously be a member of both boards.

Our Management Board is responsible for the day-to-day management of our business in accordance with applicable laws, our Articles of Association (*Satzung*) and the Management Board's internal rules of procedure (*Geschäftsordnung*). Our Management Board represents us in our dealings with third parties.

The principal function of our Supervisory Board is to supervise our Management Board. The Supervisory Board is also responsible for appointing and removing the members of our Management Board, representing us in connection with transactions between a current or former member of the Management Board and us, and granting approvals for certain significant matters.

Our Management Board and our Supervisory Board are solely responsible for and manage their own areas of competency (*Kompetenztrennung*); therefore, neither board may make decisions that, pursuant to applicable law, our Articles of Association or the internal rules of procedure are the responsibility of the other board. Members of both boards owe a duty of loyalty and care to us. In carrying out their duties, they are required to exercise the standard of care of a prudent and diligent businessperson. If they fail to observe the appropriate standard of care, they may become liable to us.

In carrying out their duties, the members of both boards must take into account a broad range of considerations when making decisions, including our interests and the interests of our shareholders, employees, creditors and, to a limited extent, the general public, while respecting the rights of our shareholders to be treated on equal terms. Additionally, the Management Board is responsible for implementing an internal monitoring system for risk management purposes.

Our Supervisory Board has comprehensive monitoring responsibilities. To ensure that our Supervisory Board can carry out these functions properly, our Management Board must, among other duties, regularly report to our Supervisory Board regarding our current business operations and future business planning (including financial, investment and personnel planning). In addition, our Supervisory Board or any of its members is entitled to request special reports from the Management Board on all matters regarding the Company, our legal and business relations with affiliated companies and any business transactions and matters at such affiliated companies that may have a significant impact on our position at any time.

Under German law, our shareholders have, as a general rule, no direct recourse against the members of our Management Board or the members of our Supervisory Board in the event that they are believed to have breached their duty of loyalty and care to us. Apart from when we are unable to fulfill our third party obligations, tortious conduct to board members or other special circumstances, only we have the right to claim damages against the members of our two boards.

We may waive these claims to damages or settle these claims only if at least three years have passed since a claim associated with any violation of a duty has arisen and only if our shareholders approve the waiver or settlement at a shareholders' meeting with a simple majority of the votes cast, provided that no shareholders who in the aggregate hold one-tenth or more of our share capital oppose the waiver or settlement and have their opposition formally recorded in the meeting's minutes.

Supervisory Board

German law requires that the Supervisory Board consists of at least three members, while a company's articles of association may stipulate a certain higher number. Our Supervisory Board currently consists of four members.

As we are not subject to co-determination, the members of our Supervisory Board are all elected by the shareholders' meeting in accordance with the provisions of the SE Regulation and the German Stock Corporation Act (*Aktiengesetz*). German law does not require the majority of our Supervisory Board members to be independent and neither our Articles of Association (*Satzung*) nor the rules of procedure for our Supervisory Board provide otherwise. As per our Supervisory Board's assessment, an appropriate number of shareholder representatives on the Supervisory Board (i.e. the entire Supervisory Board) are independent if the Supervisory Board has two independent members. In addition to Dr. Ulrich Wandschneider, the Supervisory Board considers Helmut Jeggle, Michael Motschmann and Prof. Christoph Huber, M.D. to be independent irrespective of the fact that they will soon have been members of the Supervisory Board for a period of more than 13 years. As stated in the declaration to the German Corporate Governance Code, or the Corporate Governance Code, (*Entsprechenserklärung*) published by the Company on March 29, 2022 pursuant to Section 161 para. 1 of the German Stock Corporation Act (*Aktiengesetz*), which in accordance with the Corporate Governance Code is issued in connection with the Declaration pursuant to Section 315d in conjunction with Section 289f of the German Commercial Code (HGB), the length of membership does not give rise to any fears of material conflicts of interest on the part of the members of the Supervisory Board and therefore does not stand in the way of their independence. However, the rules of procedure for our Supervisory Board provide that the Supervisory Board should have an independent member with expertise in the field of accounting, internal control processes and auditing. Dr. Ulrich Wandschneider fulfills this role.

Under European law, a member of a supervisory board of an SE may be elected for a maximum term to be specified in the articles of association, which must not exceed six years. Re-election, including repeated re-election, is permissible. The shareholders' meeting may specify a term of office for individual members or all of the members of our Supervisory Board which is shorter than the standard term of office and, subject to statutory limits, may set different start and end dates for the terms of members of our Supervisory Board. Our Articles of Association provide for a term of approximately five years, depending on the date of the annual general shareholders' meeting in the year in which the term of the relevant member is to expire.

The shareholders' meeting may, at the same time as it elects the members of the Supervisory Board, elect one or more substitute members. The substitute members replace members who cease to be members of our Supervisory Board and take their place for the remainder of their respective terms of office. Currently, no substitute members have been elected or have been proposed to be elected.

Members of our Supervisory Board may be dismissed at any time during their term of office by a resolution of the shareholders' meeting adopted by at least a simple majority of the votes cast. In addition, any member of our Supervisory Board may resign at any time by giving one month's written notice – or, in the event of cause, giving written notice with immediate effect – of his or her resignation to the Management Board.

Our Supervisory Board elects a chairperson and a deputy chairperson from its members. The deputy chairperson exercises the chairperson's rights and obligations whenever the chairperson is unable to do so. The members of our Supervisory Board have elected Mr. Helmut Jeggle as chairperson and Dr. Ulrich Wandschneider as deputy chairperson, each for the term of their respective membership on our Supervisory Board.

The Supervisory Board meets at least twice each calendar half-year. Our Articles of Association provide that a quorum of the Supervisory Board members is present if at least three of its members participate in the vote. Members of our Supervisory Board are deemed present if they attend the meeting via telephone or other (electronic) means of communication (including via video conference) or submit their written vote through another member. Additionally, our Articles of Association allow for resolutions to be taken via telephone or other (electronic) means of communications (including via video conference).

Resolutions of our Supervisory Board are passed by the vote of a simple majority of the votes cast unless otherwise required by law, our Articles of Association or the rules of procedure of our Supervisory Board. In the event of a tie, the chairperson of the Supervisory Board has the casting vote. Our Supervisory Board is not permitted to make management decisions, but in accordance with European and German law and in addition to its statutory responsibilities, it has determined that certain matters require its prior consent, including:

- entering into certain large transactions;
- creating or holding any interest in businesses (except wholly owned subsidiaries) or disposing of shares in businesses (except for a sale of JPT);
- issuing shares from authorized capital, unless the shares are issued pursuant to a redemption of stock appreciation rights; and
- acquiring treasury shares in return for valuable consideration.

Each member of the Supervisory Board shall disclose any conflicts of interest to the Supervisory Board, especially those that may arise from providing advice or holding any offices or board positions at customers, suppliers, creditors or other third parties. Material conflicts of interest that are not merely temporary and that are specific to a particular Supervisory Board member shall result in this particular member leaving office. Our Supervisory Board also puts in place adequate measures to limit, prevent or resolve conflicts of interest in accordance with applicable legal requirements and the Company's Conflicts of Interest Policy.

Our Supervisory Board conducted a self-assessment together with an external consultant for the year ended December 31, 2021. It covered all key aspects of the Supervisory Board's work, including its committees, and was conducted with all members in the form of virtual interviews. The results of the self-assessment were subsequently presented to the Supervisory Board by the external consultant and evaluated, discussed and possible suggestions for improvement discussed together with the Supervisory Board. This confirmed the professional, very good cooperation within the Supervisory Board and with the Executive Board, which is characterized by a high level of trust. No fundamental need for change was identified.

Supervisory Board Practices

Decisions are generally made by our Supervisory Board as a whole, however decisions on certain matters may be delegated to committees of our Supervisory Board to the extent permitted by law. The chairperson, or if he or she is prevented from doing so, the deputy chairperson, chairs the meetings of the Supervisory Board and determines the order in which the agenda items are discussed, the method and order of voting, as well as any adjournment of the discussion and passing of resolutions on individual agenda items after a due assessment of the circumstances. Our Supervisory Board may designate further types of actions as requiring its approval.

In addition, each member of the Supervisory Board is obliged to carry out his or her duties and responsibilities personally, and such duties and responsibilities cannot be generally and permanently delegated to third parties. However, the Supervisory Board and its committees have the right to appoint independent experts for the review and analysis of specific circumstances in accordance with its control and supervision duties under applicable European and German law. We would bear the costs of any such independent experts that are retained by the Supervisory Board or any of its committees.

Pursuant to Section 107 para. 3 of the German Stock Corporation Act (*Aktiengesetz*), the supervisory board may form committees from among its members and charge them with the performance of specific tasks. The committees' tasks, authorizations and processes are determined by the supervisory board. Where permissible by law, important powers of the supervisory board may also be transferred to committees.

By resolution, the Supervisory Board has established an Audit Committee, a Compensation, Nominating and Governance Committee and a Capital Markets Committee. Set forth in the table below are the current members of the Audit Committee, the Compensation, Nominating and Corporate Governance Committee and the Capital Markets Committee.

Name of Committee	Current Members
Audit Committee	Dr. Ulrich Wandschneider (Deputy Chairman Supervisory Board), Michael Motschmann (Supervisory Board member) and Prof. Christoph Huber, M.D. (Supervisory Board member)
Compensation, Nominating and Corporate Governance Committee	Michael Motschmann (Supervisory Board member), Prof. Christoph Huber, M.D. (Supervisory Board member) and Dr. Ulrich Wandschneider (Deputy Chairman Supervisory Board)
Capital Markets Committee	Helmut Jeggle (Chairman Supervisory Board) and Michael Motschmann (Supervisory Board member)

Audit Committee

Our Audit Committee consists of Dr. Ulrich Wandschneider, Michael Motschmann and Prof. Christoph Huber. Dr. Ulrich Wandschneider is the chair of the Audit Committee. The Audit Committee assists the Supervisory Board in overseeing the accuracy and integrity of our financial statements, our accounting and financial reporting processes and audits of our financial statements, the effective functioning of our internal control system, our risk management system, our compliance with legal and regulatory requirements, our independent auditor's qualifications and independence, the performance of the independent auditor and the effective functioning of our internal audit functions, and, subject to certain limitations, adopts and implements pertinent decisions on behalf of the Supervisory Board. The Audit Committee's duties and responsibilities to carry out its purpose, include, among others:

- considering the commissioning of the audit engagement, as well as the compensation, retention and oversight of the independent auditor;
- evaluating the qualifications, independence and quality of performance of the independent auditor;
- reviewing and pre-approving the audit and non-audit services to be performed by the independent auditor;
- reviewing and discussing with the independent auditor and management the annual audit plan, as well as critical accounting policies and practices to be used;
- reviewing and discussing with the independent auditor and management the adequacy and effectiveness of our internal accounting controls and critical accounting policies;
- reviewing and discussing with the independent auditor and management the results of our annual audit;
- reviewing and discussing with the independent auditor and management any quarterly or annual earnings announcements;
- reviewing any related party transactions and reviewing and monitoring potential conflict of interest situations on an ongoing basis for compliance with our policies and procedures; and
- overseeing procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters.

Within the limits of applicable European and German law, the Audit Committee shall have the resources and authority appropriate to discharge its duties and responsibilities, including the authority to select, retain, terminate, and approve the fees and other engagement terms of special or independent counsel, accountants or other experts and advisors, as it deems necessary or appropriate for so discharging its duties and responsibilities, without seeking approval of the Management Board or Supervisory Board.

All members of the Audit Committee qualify as "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that Dr. Ulrich Wandschneider qualifies as an "audit committee financial expert" as that term is defined under the Exchange Act. In addition, as Chairman of the Audit Committee, he has the special knowledge and experience required by the German

Corporate Governance Code. In addition, both Dr. Ulrich Wandschneider and Michael Motschmann have expertise in the field of accounting and expertise in the field of auditing.

Compensation, Nominating and Corporate Governance Committee

Our Compensation, Nominating and Corporate Governance Committee consists of Michael Motschmann, Prof. Christoph Huber, M.D. and Dr. Ulrich Wandschneider. Mr. Motschmann is the chair of the committee. The Compensation, Nominating and Corporate Governance Committee's duties and responsibilities to carry out its purpose include, among others:

- preparing and discussing with management policies relating to the remuneration of the members of our Management Board;
- reviewing and supervising corporate goals and objectives for the remuneration of the members of the Management Board, including evaluation of the performance of the members of the Management Board in light of these goals and proposals to the Supervisory Board for remuneration based on such evaluations;
- reviewing all equity-based compensation plans and arrangements and making recommendations to the Supervisory Board regarding such plans;
- assisting with identifying and recruiting candidates to fill positions on the Management Board and the Supervisory Board;
- considering any corporate governance issue that arises and developing appropriate recommendations for the Supervisory Board; and
- overseeing the evaluation of the Supervisory Board and reporting on its performance and effectiveness.

Capital Markets Committee

Our Capital Markets Committee consists of Helmut Jeggle and Michael Motschmann. Mr. Jeggle is the chair of the committee. The Capital Markets Committee advises and makes recommendations to the Supervisory Board on issues in connection with capital measures and takeover, merger and acquisition activities. Its responsibilities include the following tasks:

- overseeing the activities of the Company relating to its capital structure and capital raising, including preparation for and implementation of public offerings and share issuances; and
- overseeing the activities of the Company relating to takeovers, mergers and acquisitions activities.

Management Board and Senior Management

Our Management Board consists of at least two members. Our Supervisory Board determines the exact number of members of our Management Board. Pursuant to the Articles, the Supervisory Board may also appoint a chairperson or a spokesman of the Management Board. Prof. Ugur Sahin, M.D. has been appointed the chair of the Management Board.

The members of our Management Board are appointed by our Supervisory Board for a term of up to five years. They are eligible for reappointment or extension, including repeated re-appointment and extension, after the completion of their term in office, in each case again for up to an additional five years. Under certain circumstances, such as a serious breach of duty or a vote of no confidence by the shareholders in a shareholders' meeting, a member of the Management Board may be removed from office by our Supervisory Board prior to the expiration of his or her term.

The members of our Management Board conduct the daily business of the Company in accordance with applicable laws, our Articles of Association and the rules of procedure for the Management Board adopted by our Supervisory Board. They are generally responsible for the management of our company and for handling our daily business relations with third parties, the internal organization of our business and communications with our shareholders.

A member of the management board of an SE governed by German law may not deal with or vote on matters relating to proposals, arrangements or contractual agreements between himself or herself and the Company, and a member of our Management Board may be liable to us if he or she has a material interest in any contractual agreement between the Company and a third party which is not disclosed to and approved by our Supervisory Board.

The rules of procedure for our Management Board provide that certain matters require a resolution of the entire Management Board, in addition to transactions for which a resolution adopted by the entire Management Board is required by law or required by our Articles of Association. In particular, the entire Management Board shall decide on, among others:

- the budget plan for the following year, which is to be presented by the Management Board to the Supervisory Board by December 20 of each year;
- reporting to the Supervisory Board;
- all measures and transactions that require the Supervisory Board's approval;
- all measures and transactions relating to a business area that is of extraordinary importance to us or involving an extraordinary economic risk;
- taking on new lines of business or discontinuing existing lines of business;
- acquisitions or sales of interests or holdings; and
- certain large transactions.

Code of Conduct and Conflicts of Interest Policy

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees. The full text of the Code of Conduct is available on our website at https://www.biontech.de. The information and other content appearing on our website are not incorporated by reference into this Annual Report and our website address is included in this report as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

We have also adopted a Conflicts of Interest Policy which sets forth the procedures by which we manage potential and actual conflicts of interest. Under the Conflicts of Interest Policy, which applies to all of our Supervisory Board Members, Management Board members, directors of our subsidiaries and employees, an actual, potential or perceived conflict of interest must be disclosed when it first arises. If the conflict is transactional in nature and involves a member of the Management Board or the Supervisory Board, the Management or Supervisory Board, as the case may be, with the abstention of the conflicted member, shall decide whether to approve the transaction.

In addition, we have implemented compliance policies that describe the compliance management systems that have been implemented for us and our subsidiaries. Our compliance policies are designed to ensure compliance with applicable legal requirements, while at the same time implementing high ethical standards that are mandatory for both management and each employee. The overall responsibility for the compliance management system lies with the Management Board. The Audit Committee will receive regular reports on the operation of the compliance management system.

D. Employees

As of December 31, 2021, we had 3,082 full-time equivalent employees working for us, of whom 631 hold a doctoral degree or higher. The following tables provide breakdowns of our full-time equivalent employees as per the periods indicated by function and by region:

Function	December 31, 2021	December 31, 2020	December 31, 2019
Clinical Research & Development	143	118	89
Scientific Research & Development	1,000	624	454
Operations	1,015	657	412
Quality	290	211	141
Supporting Functions	551	286	138
Commercial & Business Development	83	45	76
Total	**3,082**	**1,941**	**1,310**

Region	December 31, 2021	December 31, 2020	December 31, 2019
Mainz, Germany (Headquarters)	1,712	1,161	952
Munich, Germany	71	45	42
Idar-Oberstein, Germany	348	254	212
Halle, Germany	17	9	—
Berlin, Germany	134	109	101
Marburg, Germany	546	268	—
Cambridge, United States	175	95	3
Gaithersburg, United States	59	—	—
Istanbul, Turkey	1	—	—
Singapore, Singapore	1	—	—
Shanghai, China	1	—	—
Vienna, Austria	17	—	—
Total	**3,082**	**1,941**	**1,310**

None of our employees has engaged in any labor strikes. We apply the federal collective bargaining agreements of the chemical industry at our Marburg site. Further, we maintain a couple of company agreements (*Betriebsvereinbarungen*) with respect to certain topics at our Idar-Oberstein, Mainz, Marburg and Berlin sites. We have a workers' council at our Idar-Oberstein, Mainz, Marburg and Berlin (JPT Peptide Technologies GmbH) sites as well as a Group workers' council (*Konzernbetriebsrat*). However, we consider our relationship with our employees to be positive and have not experienced any major labor disputes.

E. Share Ownership

The share ownership information with respect to Management Board and Supervisory Board members is presented in Item 7 below.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table presents information, as of December 31, 2021, regarding the beneficial ownership of our ordinary shares for:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding shares;
- each member of our Supervisory Board;
- each member of our Management Board; and
- all members of our Supervisory Board and Management Board as a group.

The number of ordinary shares beneficially owned by each entity, person, and member of our Supervisory Board and our Management Board is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days of December 31, 2021 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person. All of our ordinary shares and ADSs representing our ordinary shares vote on an equal basis.

The percentage of outstanding ordinary shares is computed on the basis of 242,521,489 ordinary shares outstanding as of December 31, 2021. This amount excludes 3,788,592 shares held in treasury. Amounts presented in this section include ordinary shares held in the form of ADSs. Unless otherwise indicated, the address for each beneficial owner is An der Goldgrube 12, D-55131 Mainz, Germany.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
5% shareholders		
AT Impf GmbH[1]	106,114,901	43.8 %
Medine GmbH [2]	41,505,853	17.1 %
All 5% shareholders, as a group	**147,620,754**	**60.9 %**
Members of the Supervisory Board and the Management Board		
Prof. Ugur Sahin, M.D. [3]	41,505,853	17.1 %
Sean Marett [4]	705,936	[9]
Dr. Sierk Poetting [5]	526,062	[9]
Prof. Özlem Türeci, M.D.	—	—
Ryan Richardson	4,534	[9]
Jens Holstein	—	—
Helmut Jeggle [6]	1,925,967	[9]
Michael Motschmann	—	[9]
Prof. Christoph Huber, M.D. [7]	2,002,040	[9]
Dr. Ulrich Wandschneider [8]	1,480	[9]
All members of our Supervisory Board and Management Board, as a group	**46,671,872**	**19.2 %**

[1] Information herein is based upon a Schedule 13G jointly filed with the SEC on February 11, 2022 by ATHOS KG, AT Impf GmbH and Thomas Maier. Consists of 106,114,901 ordinary shares held by AT Impf GmbH. The sole member of AT Impf GmbH is ATHOS KG, and, as a result, ATHOS KG is deemed to be the beneficial owner of the securities held by AT Impf GmbH. As of December 31, 2021 Thomas Maier is a general partner (*Komplementär*) of ATHOS KG and may be deemed to be beneficial owners

of the securities held by AT Impf KG. Helmut Jeggle resigned as general partner (*Komplementär*) in April 2021. Mr. Maier disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein.

(2) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 14, 2022 by Medine GmbH and Prof. Sahin. The sole shareholder of Medine GmbH is Prof. Sahin, and, as a result, Prof. Sahin is deemed to be the beneficial owner of the securities held by Medine GmbH. Consists of 41,505,853 ordinary shares held by Medine GmbH, 2,394,463 of which are held for benefit of a former colleague pursuant to a trust arrangement. Pursuant to this arrangement, Medine GmbH retains voting power, but not dispositive power, over such shares for so long as such shares are held in trust and accordingly Medine GmbH and Prof. Ugur Sahin, M.D. each may be deemed beneficially to own such shares.

(3) Consists of the shares described in note 2 above. Prof. Sahin is the sole shareholder of Medine GmbH.

(4) Consists of 705,936 ordinary shares held by RLG GmbH. Mr. Marett is the sole shareholder of RLG GmbH.

(5) Consists of (a) 524,387 ordinary shares held by Tofino GmbH (Dr. Poetting is sole shareholder of Tofino GmbH) and (b) 1,675 ordinary shares held by immediate family members of Dr. Poetting.

(6) Consists of (a) 332,316 ordinary shares held directly by Mr. Jeggle and (b) 1,593,651 ordinary shares held by Salvia GmbH.

(7) Consists of 2,002,040 ordinary shares held by CHuber 2008 GmbH. Prof. Huber is the majority shareholder of CHuber 2008 GmbH.

(8) Consists of 1,480 ordinary shares held by beebusy Capital GmbH. Dr. Wandschneider is sole shareholder of beebusy Capital GmbH.

(9) Less than one percent.

Holdings by U.S. Shareholders

We estimate that as of December 31, 2021, 36.1% of our outstanding ordinary shares are held by 2 U.S. record holders.

B. Related Party Transactions

Agreements with Santo Service GmbH

We have several agreements with Santo Service GmbH, or Santo Service, pursuant to which Santo Service provides us with certain real property and custodial services. Santo Service is wholly owned by AT Impf GmbH, one of our major shareholders. During the year ended December 31, 2021, the aggregate value of transactions with Santo Service amounted to €0.9 million pursuant to these agreements (€4.6 million during the year ended December 31, 2020).

Agreement with Medine GmbH

On August 29, 2019, we entered into an agreement with Medine GmbH, or Medine, pursuant to which we acquired from Prof. Dr. Ugur Sahin, M.D. all of the outstanding shares of reBOOST Management GmbH (subsequently renamed to reSano GmbH), or reBOOST, which owned certain intellectual property, in exchange for a total consideration of €0.3 million. Medine is wholly-owned by Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, who was also the Managing Director of reBOOST at the time of the acquisition and is the Managing Director of Medine.

Series B 2019 Financing

In June and August 2019, we issued an aggregate of 12,465,288 ordinary shares (excluding 5,524,506 ordinary shares which were issued to a Hong Kong-based investor and subsequently transferred to us for no consideration) to certain new and existing shareholders at a price of $18.10 per share for aggregate proceeds of €198.6 million ($225.6 million).

The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

Participant	Number of Ordinary Shares	Aggregate Purchase Price ($)
AT Impf GmbH (1)	1,657,332	29,999,550.68

(1) See "Major Shareholders" under this Item 7 for additional information about ordinary shares held by this entity or the parent company of this entity.

Initial Public Offering

In October 2019, we sold 10,517,408 ADSs representing 10,517,408 of our ordinary shares to certain new and existing shareholders at a price of $15.00 per ADS for proceeds of €135.4 million ($149.1 million) in our initial public offering. The following table sets forth the aggregate number of ADSs that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

Participant	Number of ADS representing Ordinary Shares	Aggregate Purchase Price ($)
AT Impf GmbH [1]	2,800,000	42,000,000.00
Helmut Jeggle [1]	51,219	768,285.00

[1] See "Major Shareholders" under this Item 7 for additional information about ordinary shares held by this entity, the parent company of this entity or Supervisory Board member.

Global Offering

On July 27, 2020 we issued 5,500,000 ADS each representing one of our ordinary shares at a public offering price of $93.00 per ADS for proceeds of €5.5 million ($6.4 million), which we refer to as the Underwritten Offering. On August 27, 2020, following the Underwritten Offering, we issued 16,124 ADS each representing one of our ordinary shares at a public offering price of $93.00 per ADS for proceeds of €16 thousand ($19 thousand), which we refer to as the Rights Offering.

Participant	Number of ADS representing Ordinary Shares	Aggregate Purchase Price ($)
AT Impf GmbH [1]	268,818	25,000,074.00

[1] See "Major Shareholders" under this Item 7 for additional information about ordinary shares held by this entity, the parent company of this entity.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

See Item 18.

B. Significant Changes

Not applicable.

Item 9. The Offer and Listing

A. Offer Listing Details

Not applicable.

B. Plan of Distribution

Not applicable.

C. Markets

ADSs representing our ordinary shares have been listed on the Nasdaq Global Select Market under the symbol "BNTX" since October 10, 2019.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

General

We were incorporated as a German stock corporation (*Aktiengesellschaft*) with the legal name Petersberg 91. V AG under the laws of the Federal Republic of Germany on June 2, 2008. We changed our name to BioNTech AG on December 11, 2008. Effective as of March 8, 2019, the date on which the change of legal form and company was registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Germany, we converted to a *Societas Europaea* with the legal name BioNTech SE. We completed our initial public offering in October 2019. The principal legislation under which we operate and our shares are issued are the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), the German Law on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE) (SE-Ausführungsgesetz—SEAG)*) and the German Stock Corporation Act (*Aktiengesetz*), in each case as amended.

We are registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) in Mainz, Germany, under number HRB 48720. Our statutory seat is in Mainz, Germany, and our registered office is An der Goldgrube 12, 55131 Mainz, Germany. Copies of our Articles of Association (*Satzung*) will be publicly available from the commercial register (*Handelsregister*) at the local court of Mainz, Germany, electronically at www.unternehmensregister.de and as an exhibit to this Annual Report.

Share Capital

We have share capital registered in the commercial register (*Handelsregister*) in the amount of €246,807,808, which is divided into 246,807,808 registered shares (*Namensaktien*). All shares are shares with no par value (*Stückaktien ohne Nennbetrag*) with a notional amount attributable to each ordinary share of €1. Each issued ordinary share is fully paid.

Form, Certification and Transferability of Shares

The form and contents of our share certificates, collective share certificates and global share certificates are determined by our Management Board. A shareholder's right to certification of its shares is excluded, to the extent permitted by law and to the extent that certification is not required by the stock exchange on which the shares or rights or certificates representing them are admitted to trading. We are permitted to issue collective share certificates and global share certificates that represent multiple or all of our shares.

Our shares are freely transferable under German law.

Changes in Our Share Capital During the Last Three Fiscal Years

Our share capital as registered with the commercial register (*Handelsregister*) amounts to €246,807,808, including an amount of €3,788,592 relating to 3,788,592 ordinary shares held in treasury. Since January 1, 2019, our share capital has changed as follows:

- On January 29, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 282,678 shares;
- On April 24, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 131,933 shares against contributions in kind (swap of shares in our company against shares in one of our subsidiary companies);
- On June 26, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 666,123 shares;
- On August 16, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 333,310 shares;
- On September 18, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 206,595,492 shares by way of a capital increase from our funds; thus, no contribution by investors was made;
- On September 26, 2019, our share capital as registered with the commercial register (Handelsregister) was increased by issuing 3,038,674 shares;
- On October 14, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 10,000,000 shares;
- On November 6, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 517,408 shares;
- On April 23, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,580,777 shares;
- On May 5, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 2,377,446 shares;
- On May 8, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,935,488 shares;
- On July 24, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 5,500,000 shares;
- On August 24, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 16,124 shares; and
- On September 8, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 2,595,996 shares.
- On March 24, 2022, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 497,727 shares.

Anti-takeover Provisions of Our Charter Documents

Our Articles of Association (*Satzung*) do not include any provisions that would have a direct effect of delaying, deferring or preventing a change of control. However, in the event of a hostile takeover, we could use our authorized capital to increase our share capital to issue new shares to an investor at a premium. An increase in the number of shares outstanding could have a negative effect on a party's ability to carry out a hostile takeover. The provisions of German law relating to public bids and takeovers that require any such bids to be carried out in a manner designed to safeguard equal and fair treatment to all shareholders and give them a right to be bought out at an adequate compensation where a party acquires "control" (as such term is defined in such provisions) over the relevant company do not apply.

Future Changes to the Share Capital

Authorized Capital

Under the relevant law, the general meeting of a European stock corporation (*Societas Europaea*) governed by German law can authorize the Management Board, with the consent of the Supervisory Board, to issue shares in a specified aggregate nominal amount of up to 50% of the issued share capital of such company at the time the resolution becomes effective. The shareholders' authorization becomes effective upon registration in the commercial register (*Handelsregister*) and may extend for a period of no more than five years thereafter. Under § 4(5) of our Articles of Association (*Satzung*), the Management Board is authorized to increase our share capital, on one or more occasions, by a total of up to €122,657,313 by issuing, on one or more occasions, up to 122,657,313 new, registered shares with no par value (*Genehmigtes Kapital*), in each case with consent of the Supervisory Board. This authorization expires on June 21, 2026.

Any new shares issued from the authorized capital will participate in the profits starting with the fiscal year for which the annual financial statements have not yet been submitted to the general meeting at the time of registration of the implementation of the capital increase. Further details of a capital increase from the authorized capital may be specified by the Management Board.

Conditional Capital

Pursuant to § 4(6) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €16,212,917 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2017/2019*). The conditional capital may only be used to issue shares to the holders of option rights granted under our ESOP to members of our Management Board and to certain of our employees.

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised and such stock options are not serviced by our providing treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to the said § 4(6) of our Articles of Association (*Satzung*) shall be entitled to dividends from the beginning of the previous financial year in case they are created by the exercise of subscription rights until the start of the Annual General Meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Pursuant to § 4(7) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €87,499,260 through issuance of new, registered shares with no par value (*Bedingtes Kapital WSV 2019*). The conditional capital may only be used to issue shares to the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that we exercise a right to choose to grant our shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilized for servicing.

Any new shares issued under the said conditional capital pursuant to the said § 4(7) of our Articles of Association shall carry an entitlement to dividends from the beginning of the financial year in which they are created; however, as far as the law permits, the Management Board can confer dividend rights for new shares in derogation of the foregoing.

Pursuant to § 4(8) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €8,418,091 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2021*). The conditional capital serves exclusively to grant rights to the holders of stock options issued by the Company in accordance with the authorization granted by the Annual General Meeting on June 22, 2021 under agenda item 6 letter d) (the "Authorization 2021").

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised the holders of the stock options issued by the Company on the basis of Authorization 2021and such stock options are not serviced by the Company providing treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to the said § 4(8) of our Articles of Association (*Satzung*) shall participate in profits from the beginning of the preceding financial year in case they are created by the exercise of subscription rights until the start of the annual general meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Preemptive Rights

German law generally provides shareholders with preemptive rights when new shares convertible bonds, bonds with warrants, profit participation rights or participating bonds are issued. This requirement, however, may also be satisfied by way of a credit institution subscribing for the securities and then offering them to the shareholders for purchase (*mittelbares Bezugsrecht*).

Further, it is possible for a shareholder resolution approved by three-quarters of the share capital voting on the resolution to exclude preemptive rights both where the general meeting itself resolves that the new securities to be issued and in relation to the authorized capital, *i.e.,* an authorization to the Management Board to, with the consent of the Supervisory Board, resolve on the issuance of new securities; provided, however, that in each case the exclusion or the authorization to so exclude preemptive rights, respectively, must be justified by specific facts, in accordance with established case law of the German Federal Court of Justice (*BGH*). The German Federal Court of Justice (*BGH*) considers the exclusion of subscription rights justified if it (i) serves a purpose in the company's interests, (ii) is suitable for attaining such purpose, and (iii) is necessary and appropriate. Additionally, the management board must submit a written report to the shareholders' meeting in which it presents the reasons for the exclusion of the subscription rights.

Accordingly, under our Articles of Association (*Satzung*), the Management Board may, with the consent of the Supervisory Board, exclude such preemptive rights in a capital increase from the authorized capital in the following circumstances:

- to exclude fractional amounts from the subscription right;
- in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the market price of the company's shares already listed on the stock exchange at the time the issue price is finally determined. However, this authorization shall only apply subject to the provision that the shares issued excluding subscription rights in accordance with Section 186(3) Sentence 4 AktG may not exceed a total of 10% of the share capital either at the time this authorization takes effect or, if this amount is lower, at the time this authorization is exercised. This limit of 10% of the share capital includes shares which are issued or disposed of during the term of this authorization until the date of its exercise in direct or equivalent application of Section 186(3) Sentence 4 AktG. Shares which are used to service bonds with convertible or option rights or convertible obligations are to be offset against the 10% limit if these bonds were issued under exclusion of shareholder subscription rights in accordance with Section 186(3) Sentence 4 AktG during the entitlement period. Treasury shares are to be offset against the 10% limit, where they were disposed of by the company during the term of this authorization with the exclusion of subscription rights pursuant to or in analogous application of Section 186(3) Sentence 4 AktG;
- in the case of capital increases in exchange for contributions in kind, in particular in order to be able to offer the shares to third parties when purchasing companies, parts of companies or interests in companies as well as licenses or industrial property rights;
- in order to grant subscription rights to new shares to holders of conversion or option rights in respect of bonds issued by the company or its subordinated domestic or foreign Group companies, to the extent to which they would be entitled after exercising their conversion or option rights or after fulfilling an agreed conversion obligation;
- to implement an election dividend by which shareholders are given the option to contribute their dividend entitlements (either in whole or part) as a contribution in kind against issuance of our new shares;
- in capital increases, in each case if excluding subscription rights, according to the assessment by the Management Board, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock ex-change price at the time the Management Board adopts the resolution on using authorized capital, according to the assessment by the Management Board, does not exceed the extent necessary for a successful placement and in any case does not exceed 10% of either the latest available closing price at the time when the issue price is fixed or the volume-weighted average price over a period of up to five trading days ending on the day on which the issue price is so fixed;
- in case shares are to be issued to a member of our Management Board or to another person who is employed by us or one of our affiliates and a minimum holding period of at least one year and the obligation to transfer back

the shares in the event that the beneficiary is not employed by us or one of our affiliated companies for the entire duration of the holding period or any other agreed period is agreed upon. Additional restrictions with regard to the shares issued may be agreed upon; and

- in order to be able to satisfy an option to acquire additional ordinary shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of our shares in the form of American Depositary Shares.

The total number of new shares issued from the authorized capital and under exclusion of subscription rights pursuant to bullets one through three and six above may not exceed 20% of the share capital, either at the time that the amendment to the Articles of Association (*Satzung*), resolved upon by the general meeting of June 26, 2020, came into effect or, if lower, at the time of utilization of the authorization. To be counted against the aforementioned 20% limit are: (i) those shares issued or to be issued to service conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as, to a certain extent (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of certain exceptions of the resolution to item no. 8 of the general meeting of August 19, 2019).

Corporate Purpose of our Company

Our business objective, as described in § 2 of our Articles of Association (*Satzung*), is to research and develop, as well as to manufacture and market immunological and RNA-based drugs and test methods for the diagnosis, prevention and treatment of cancer, infectious diseases and other serious diseases.

Shareholders' Meetings and Voting Rights

Pursuant to our Articles of Association (*Satzung*), shareholders' meetings may be held at our seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by our Management Board, or our Supervisory Board. Shareholders representing in the aggregate at least five percent of our ordinary shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of our ordinary shares or owning shares with an aggregate nominal value of at least €500,000 may request the addition of one or several items to the agenda of any shareholders' meeting. Shareholders' meetings may be summoned either via publication in the German Federal Gazette (*Bundesanzeiger*) or via mail or email, in each case generally at least 36 days before the meeting.

Shareholders may participate and vote in the shareholders' meeting if they are registered as a shareholder with the Company's share register. A shareholder who wishes to attend the shareholders' meeting—either in person or by proxy, which may also be appointed by us (*Stimmrechtsvertreter*)—must register for the meeting, which registration must occur no later than six days before the meeting (or at a later date, if so determined by our Management Board).

Each share carries one vote at a shareholders' meeting. Resolutions are, in accordance with our Articles of Association (*Satzung*), generally taken by simple majority of the votes cast. However, under applicable German and European law, a number of resolutions must be passed by either a three-quarter majority of the votes cast or a three-quarter majority of the share capital represented at the meeting. The fact that in these cases the quorum is determined in relation to the share capital or shares present (as opposed to, for example, all shares eligible to vote) means that holders of a minority of our shares could potentially control the outcome of resolutions.

Claims against Directors and Shareholders' Derivative Actions

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its management board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board. This concerns, in particular, claims against members of the Management Board or the Supervisory Board.

However, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so. Further, the Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims

against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can also request that a representative pursue the claim on behalf of the company. The court may appoint such a representative upon the request of shareholders holding at least 10% of the company's share capital or a participation of at least €1,000,000 in the share capital.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least 1% of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) must comply with special claim approval procedures conducted before a competent court which will allow the pertinent request only if there are circumstances justifying the assumption that damage has been afflicted on the company by improper conduct or a gross breach of the law or the articles of association.

Dividend Rights

Under German law, distributions of dividends on shares for a given fiscal year are generally determined by a process in which the management board and supervisory board submit a proposal to the company's annual general shareholders' meeting held in the subsequent fiscal year and such annual general shareholders' meeting adopts a resolution.

German law provides that a resolution concerning dividends and distribution thereof may be adopted only if the company's unconsolidated financial statements prepared in accordance with German law show net retained profits. In determining the profit available for distribution, the result for the relevant year must be adjusted for profits and losses brought forward from the previous year and for withdrawals from or transfers to reserves. Certain reserves are required by law and must be deducted when calculating the profit available for distribution.

Shareholders generally participate in profit distributions in proportion to the number of shares they hold. Dividends on shares resolved by the general shareholders' meeting are paid annually, shortly after the general shareholders' meeting, in compliance with the rules of the respective clearing system. Dividend payment claims are subject to a three-year statute of limitation in the company's favor.

Authorization to Purchase and Sell Our Own Shares

We may not purchase our own shares unless authorized by the shareholders' meeting or in other very limited circumstances as set out in the German Stock Corporation Act. The Company's shareholders' meeting held on August 19, 2019 authorized the Management Board until August 18, 2024, provided it complies with the legal requirement of equal treatment, to acquire treasury shares up to a total of 10% of the Company's share capital at the time of the relevant resolution or at the time the authorization is exercised. These shares held by the Company (including shares attributable to it pursuant to the AktG) must never exceed 10% of the share capital. The shares may be purchased (i) through the stock exchange, (ii) by means of a public offer directed to all shareholders of the Company, (iii) by means of a public invitation to the shareholders to make a sales offer or (iv) from the Bill & Melinda Gates Foundation under very limited circumstances as specified in the authorization. Such shares may not be purchased for trading purposes. The Management Board is authorized to use the shares only as specified in the authorization.

Squeeze-Out of Minority Shareholders

Under German law, the shareholders' meeting of a stock corporation may resolve, upon request of a shareholder that holds at least 95% of the share capital, that the shares held by any remaining minority shareholders be transferred to the majority shareholder against payment of "adequate cash compensation" (*Ausschluss von Minderheitsaktionären*). This amount must take into account the full value of the company at the time of the resolution, which is generally determined using the future earnings value method (*Ertragswertmethode*).

A squeeze-out in the context of a merger (*umwandlungsrechtlicher Squeeze-Out*) only requires a majority shareholder to hold at least 90% of the share capital.

Liquidation Rights

Apart from liquidation, e.g., as a result of insolvency proceedings, we may be liquidated with a vote of the holders of at least three-quarters of the share capital represented at the shareholders' meeting at which such a vote is taken. If we are liquidated, any assets remaining after all of our liabilities have been paid off would be distributed among our shareholders in proportion to their holdings in accordance with German statutory law. The German Stock Corporation Act provides certain protections for creditors, which must be observed in the event of liquidation.

C. Material Contracts

Except as otherwise disclosed in this Annual Report (including the exhibits thereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of our business.

D. Exchange Controls

There are currently no legal restrictions in the Federal Republic of Germany on international capital movements and foreign exchange transactions, except in limited embargo circumstances (*Teilembargo*) relating to certain areas, entities or persons as a result of applicable resolutions adopted by the United Nations and the European Union. Restrictions currently exist with respect to, among others, Belarus, Congo, Egypt, Eritrea, Guinea, Guinea-Bissau, Iran, Iraq, Lebanon, Libya, North Korea, Somalia, South Sudan, Sudan, Syria, Tunisia and Zimbabwe.

For statistical purposes, there are, however, limited notification requirements regarding transactions involving cross-border monetary transfers. With some exceptions, every corporation or individual residing in the Federal Republic of Germany must report to the German Central Bank (*Deutsche Bundesbank*) (i) any payment received from, or made to, a non-resident corporation or individual that exceeds €12,500 (or the equivalent in a foreign currency) and (ii) (with the exception of individuals residing in the Federal Republic of Germany) in case the sum of claims against, or liabilities payable to, non-resident corporations or individuals exceeds €5,000,000 (or the equivalent in a foreign currency) at the end of any calendar month. Payments include cash payments made by means of direct debit, checks and bills, remittances denominated in euros and other currencies made through financial institutions, as well as netting and clearing arrangements.

E. Taxation

German Taxation

The following discussion addresses certain German tax consequences of acquiring, owning or disposing of the ADSs. With the exception of "—Taxation of Holders Tax Resident in Germany" below, which provides an overview of dividend taxation and of capital gains taxation with respect to holders that are residents of Germany, this discussion applies only to U.S. treaty beneficiaries (defined below) that acquire the ADSs representing our ordinary shares.

This discussion is based on domestic German tax laws, including, but not limited to, circulars issued by German tax authorities, which, e.g., are not binding on the German courts, and the Treaty (defined below). It is based upon tax laws in effect at the time of filing of this report. These laws are subject to change, possibly with retroactive effect. For example, certain member states of the European Union are considering introducing a financial transaction tax (*Finanztransaktionssteuer*) which, if introduced, may also be applicable on sales and/or transfer of ADSs. In addition, in Germany, for example, there are currently ongoing discussions on an increase of the top tax rate, which may also have an effect on the German tax consequences of acquiring, owning and disposing of the ADSs. There is no assurance that German tax authorities will not challenge one or more of the tax consequences described in this section.

In addition, this discussion is based upon the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms. It does not purport to be a comprehensive or exhaustive description of all German tax considerations that may be of relevance in the context of acquiring, owning and disposing of ADSs.

The tax information presented in this report is not a substitute for tax advice. Prospective holders of ADSs should consult their own tax advisors regarding the German tax consequences of the purchase, ownership, disposition, donation or inheritance of ADSs in light of their particular circumstances, including the effect of any state, local, or other foreign or

domestic laws or changes in tax law or interpretation. The same applies with respect to the rules governing the refund of any German dividend withholding tax (*Kapitalertragsteuer*) withheld. Only an individual tax consultation can appropriately account for the particular tax situation of each investor.

General

Based on the circular issued by the German Federal Ministry of Finance (*BMF-Schreiben*), dated May 24, 2013, reference number IV C 1-S2204/12/10003, as amended by the circular dated December 18, 2018 (reference number IV C 1 – S 2204/12/10003), in respect of the taxation of American Depositary Receipts, or ADRs, on domestic shares, or the ADR Tax Circular, for German tax purposes, the ADSs should, in light of the ADR Tax Circular, represent a beneficial ownership interest in the underlying shares of BioNTech and qualify as ADRs for the purpose of the ADR Tax Circular. If the ADSs qualify as ADRs under the ADR Tax Circular, dividends would accordingly be attributable to holders of the ADSs for German tax purposes, and not to the legal owner of the ordinary shares (*i.e.*, the financial institution on behalf of which the ordinary shares are stored at a domestic depository for the ADS holders). Furthermore, holders of the ADSs should be treated as beneficial owners of the capital of BioNTech with respect to capital gains (see below in section "—German Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs"). However, investors should note that circulars published by the German tax authorities (including the ADR Tax Circular) are not, e.g., binding on German courts, including German tax courts, and it is unclear whether a German court would follow the ADR Tax Circular in determining the German tax treatment of the ADSs. For the purpose of this German tax section, it is assumed that the ADSs qualify as ADRs within the meaning of the ADR Tax Circular.

Taxation of Holders Not Tax Resident in Germany

The following discussion describes selected German tax consequences of acquiring the ADSs, owning the ADSs and disposing of the ADSs to a holder that is a U.S. treaty beneficiary. For purposes of this discussion, a "U.S. treaty beneficiary" is a resident of the United States for purposes of the Convention between the Federal Republic of Germany and United States of America for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and Capital and Certain Other Taxes of 1989, as amended by the Protocol as of June 4, 2008 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung und zur Verhinderung der Steuerverkürzung auf dem Gebiet der Steuern vom Einkommen und vom Vermögen und einiger anderer Steuern in der Fassung vom 4. Juni 2008*), hereinafter referred to as the "Treaty," who is eligible for relevant benefits under the Treaty.

A holder will be a U.S. treaty beneficiary entitled to full Treaty benefits in respect of the ADSs if it is, inter alia:

- the beneficial owner of the ADSs (and the dividends paid with respect thereto);
- a U.S. tax resident corporation or individual;
- not also a resident of Germany for German tax purposes; and
- not subject to the limitation on benefits (i.e., anti-treaty shopping) article of the Treaty that applies in limited circumstances.

Special rules apply to pension funds and certain other tax-exempt investors.

This discussion does not address the treatment of ADSs that are (i) held in connection with a permanent establishment or fixed base through which a U.S. treaty beneficiary carries on business or performs personal services in Germany or (ii) part of business assets for which a permanent representative in Germany has been appointed.

ssed on the purchase, sale or other transfer of ADSs. Provided that certain requirements are met, an entrepreneur may, however, opt for value-added tax on transactions that are otherwise tax-exempt. Net wealth tax (*Vermögensteuer*) is not imposed currently in Germany.

General Rules for the Taxation of Holders Not Tax Resident in Germany

Non-German resident holders of ADSs are subject to German taxation with respect to German source income (*beschränkte Steuerpflicht*). According to the ADR Tax Circular, income from the shares should be attributed to the holder of the ADSs for German tax purposes. As a consequence, income from the ADSs should be treated as German source income.

German Withholding Taxation of Dividends of the U.S. Treaty Beneficiaries of the ADSs

Generally, the full amount of a dividend distributed by BioNTech to a non-German resident holder, which does not maintain a permanent establishment or other taxable presence in Germany, is subject to (final) German withholding tax at an aggregate rate of 26.375% (that amount consists of 25% on dividends distributed plus solidarity surcharge of 5.5% on the amount of the withholding tax). The basis for the withholding tax is generally the dividend approved for distribution by our general shareholder's meeting. German withholding tax is withheld and remitted to the German tax authorities by (i) the disbursing agent (*i.e.*, the German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act (*Kreditwesengesetz*) and in each case including a German branch of a foreign enterprise, but excluding a foreign branch of a German enterprise)) that holds or administers the underlying shares in custody and (a) disburses or credits the dividend income from the underlying shares, (b) disburses or credits the dividend income from the underlying shares on delivery of the dividend coupons or (c) disburses such dividend income to a foreign agent; or (ii) the central securities depository (*Wertpapiersammelbank*) in terms of the German Depositary Act (*Depotgesetz*) holding the underlying shares in a collective deposit, if such central securities depository disburses the dividend income from the underlying shares to a foreign agent, regardless of whether a holder must report the dividend for tax purposes and regardless of whether or not a holder is a resident of Germany. Dividend payments, to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), subject to certain prerequisites, do not form part of the taxable dividend income but should lower the holder's acquisition costs for the ADSs.

Pursuant to the Treaty, the German withholding tax may generally not exceed (i) 15% of the gross amount of the dividends received by a U.S. treaty beneficiary other than a company holding ADSs which represent 10% or more of the voting shares in BioNTech, and (ii) 5% of the gross amount of the dividends received by a U.S. treaty beneficiary that is a company holding ADSs which represent 10% or more of the voting shares in BioNTech. The excess of the total withholding tax, including the solidarity surcharge, over the maximum rate of withholding tax permitted by the Treaty is refunded to U.S. treaty beneficiaries upon application. For example, for a declared dividend of 100, a U.S. treaty beneficiary initially receives 73.625 (100 minus the 26.375% withholding tax including solidarity surcharge). A U.S. treaty beneficiary other than a company holding ADSs which represent 10% or more of the voting shares in BioNTech is entitled to a partial refund from the German tax authorities in the amount of 11.375% of the gross dividend (of 100). As a result, the U.S. treaty beneficiary ultimately receives a total of 85 (85% of the declared dividend) following the refund of the excess withholding. However, it should be noted that there is uncertainty as to how the German tax authorities will apply the refund process to dividends on the ADSs with respect to non-German resident holders. Further, such refund is subject to the German anti-avoidance treaty shopping rule (as described below in "—Withholding Tax Refund for U.S. Treaty Beneficiaries").

German Withholding Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs

The capital gains from the disposition of the ADSs realized by a non-German resident holder, which does not maintain a permanent establishment or other taxable presence in Germany, would be treated as German source income and be subject to German tax if the ADSs qualify as a Qualifying Participation. A Qualifying Participation exists if a holder at any time during the five years preceding the disposition, directly or indirectly, owned at least 1% of BioNTech's share capital, irrespective of whether through the ADSs or shares of BioNTech. If such holder had acquired the ADSs without consideration, the previous owner's holding period and quota would be taken into account.

Pursuant to the Treaty, capital gains from the disposal of a Qualifying Participation realized by a U.S. treaty beneficiary are, however, generally exempt from German taxation. Pursuant to the Treaty, U.S. treaty beneficiaries are not subject to German tax in relation to capital gains from the disposal of a Qualifying Participation even under the circumstances described in the preceding paragraph and therefore should not be subject to German taxation on capital gains from the disposition of the ADSs.

German statutory law requires the disbursing agent to levy withholding tax on capital gains from the sale of ADSs or other securities held in a custodial account in Germany. With regard to the German taxation of capital gains, disbursing agent means a German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act and, in each case including a German branch if a foreign enterprise, but excluding a foreign branch of a German enterprise) that holds the ADSs in custody or administers the ADSs for the investor or conducts sales or other dispositions and disburses or credits the income from the ADSs to the holder of the ADSs. The German statutory law does not explicitly condition the obligation to withhold taxes on capital gains being subject to

taxation in Germany under German statutory law or on an applicable income tax treaty permitting Germany to tax such capital gains.

However, a circular issued by the German Federal Ministry of Finance, dated January 18, 2016, reference number IV C 1-S2252/08/10004 :017, as most recently amended by circular dated September 16, 2019, reference number IV C 1-S2252/08/10004 :027, provides that taxes need not be withheld when the holder of the custody account is not a resident of Germany for tax purposes and the income is not subject to German taxation. The circular further states that there is no obligation to withhold such tax even if the non-resident holder owns at least 1% of the share capital of a German corporation. While circulars issued by the German Federal Ministry of Finance are generally only to be adhered to by the German tax authorities but are, for example, not binding on the German courts, in practice, the disbursing agents nevertheless typically rely on guidance contained in such circulars. Therefore, a disbursing agent would only withhold tax at 26.375% on capital gains derived by a U.S. treaty beneficiary from the sale of ADSs held in a custodial account in Germany in the event that the disbursing agent did not follow the abovementioned guidance. In this case, the U.S. treaty beneficiary may be entitled to claim a refund of the withholding tax from the German tax authorities under the Treaty, as described below in "—Withholding Tax Refund for U.S. Treaty Beneficiaries." A refund of taxes withheld on capital gains from the disposition of the ADSs which do not qualify as Qualifying Participations may also be claimed based on German statutory domestic law.

Withholding Tax Refund for U.S. Treaty Beneficiaries

U.S. treaty beneficiaries are generally eligible for treaty benefits under the Treaty, as described above in "—Taxation of Holders Not Tax Resident in Germany." Accordingly, U.S. treaty beneficiaries are in general entitled to claim a refund of (i) the portion of the otherwise applicable 26.375% German withholding tax (*Kapitalertragsteuer*) on dividends that exceeds the applicable Treaty rate and (ii) the full amount of German withholding tax (*Kapitalertragsteuer*) on capital gains from the disposition of ADSs. The application for such claim is generally to be filed with the Federal Central Office of Taxation (*Bundeszentralamt für Steuern*) within four years after the end of the calendar year in which the capital gains or dividends have been received (*bezogen*).

However, in respect of dividends, the refund described in the preceding paragraph is only possible if, due to special rules on the restriction of withholding tax credit, the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk by more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, then for a holder not being tax-resident in Germany who applied for a full or partial refund of the withholding tax pursuant to a double taxation treaty, no refund is available. This restriction generally does only apply if (a) the German tax underlying the refund application is below a tax rate of 15% based on the gross amount of the dividends and (b) the holder does not directly own 10% or more of the shares of BioNTech and is subject to income taxes in its state of residence, without being tax-exempt. The restriction of the withholding tax credit does not apply if the holder has beneficially owned the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

In general, as previously discussed, investors should note that it is unclear how the German tax administration will apply the refund process to dividends on the ADSs. Further, such refund is subject to the German anti treaty shopping rule. Generally, this rule requires that the U.S. treaty beneficiary (in case it is a non-German resident company) maintains its own administrative substance and conducts its own business activities. In particular, a foreign company has no right to a full or partial refund to the extent persons holding ownership interests in BioNTech would not be entitled to the refund if they derived the income directly and the gross income realized by the foreign company is not caused by the business activities of the foreign company, and there are either no economic or other considerable reasons for the interposition of the foreign company, or the foreign company does not participate in general commerce by means of a business organization with resources appropriate to its business purpose. However, this shall not apply if the foreign company's principal class of stock is regularly traded in substantial volume on a recognized stock exchange, or if the foreign company is subject to the provisions of the German Investment Tax Act (*Investmentsteuergesetz*). Whether or not and to which extent the anti-treaty shopping rule applies to the ADSs has to be analyzed on a case by case basis taking into account all relevant tests. In addition, the interpretation of these tests is disputed and to date no published decisions of the German Federal Finance Court exist in this regard.

Due to the legal structure of the ADSs, only limited guidance from the German tax authorities exists on the practical application of the refund process with respect to the ADSs and the respective limitations. Recently, the German tax authorities have indicated that for ADR programs (which are considered comparable to ADS programs) a collective tax certificate in connection with a withholding of tax amounts may no longer be issued by the domestic depositary of the shares upon request of the foreign depositary agents. Rather, individual tax certificates need to be issued which might delay a potential refund procedure. Moreover, the simplified refund procedure based on electronic data exchange (*Datenträgerverfahren*) for claims for reimbursement based on ADRs has been suspended temporarily by the tax authorities.

Taxation of Holders Tax Resident in Germany

This subsection provides an overview of dividend taxation and of capital gains taxation with regard to the general principles applicable to ADS holders that are tax resident in Germany. A holder is a German tax resident if, in case of an individual, he or she maintains a domicile (*Wohnsitz*) or a usual residence (*gewöhnlicher Aufenthalt*) in Germany or if, in case of a corporation, it has its place of management (*Geschäftsleitung*) or registered seat (*Sitz*) in Germany.

The German dividend and capital gains taxation rules applicable to German tax residents require a distinction between ADSs held as private assets (*Privatvermögen*) and ADSs held as business assets (*Betriebsvermögen*).

ADSs as Private Assets (Privatvermögen)

If the ADSs are held as private assets by a German tax resident, dividends and capital gains (other than capital gains from the disposition of a Qualifying Participation) are taxed as investment income and are principally subject to 25% German flat income tax on capital income (*Abgeltungsteuer*) (plus a 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon, resulting in an aggregate rate of 26.375%), which is levied in the form of withholding tax (*Kapitalertragsteuer*). In other words, once deducted, the holder's income tax liability on the dividends will be settled. Dividend payments to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), subject to certain prerequisites, do not form part of the taxable dividend income but should lower the holder's acquisition costs for the ADSs.

Holders of ADSs may apply to have their capital investment income assessed in accordance with the general rules and with an individual's personal income tax rate if this would result in a lower tax burden in which case actually incurred expenses are not deductible. The holder would be taxed on gross personal investment income (including dividends or gains with respect to ADSs), less the saver's allowance of €801 for an individual or €1,602 for a married couple and a registered civil union (*eingetragene Lebenspartnerschaft*) filing taxes jointly. The deduction of expenses related to the investment income (including dividends or gains with respect to ADSs) is generally not possible for private investors.

Losses resulting from the disposal of ADSs can only be offset against capital gains from the sale of any shares (*Aktien*) and other ADSs. If, however, a holder holds a Qualifying Participation, 60% of any capital gains resulting from the sale and transfer are taxable at the holder's personal income tax rate (plus 5.5% solidarity surcharge thereon). Conversely, 60% of any capital losses are recognized for tax purposes.

Since 2021, the basis for the calculation of the solidarity surcharge (*Solidaritätszuschlag*) has been reduced for certain individual persons being subject to tax assessments (other than withholding taxes), and in certain cases, the solidarity surcharge has been abolished. However, the abolition or reduction of the solidarity surcharge is not applicable to corporations. In addition, the abolition or reduction of the solidarity surcharge will not affect withholding taxes. Solidarity surcharge will still be levied at 5.5% on the full withholding tax amount and withheld accordingly. There will not be any separate refund of such withheld solidarity surcharge (regardless of the aforementioned exemption limits) in case the withholding tax cannot be refunded either.

Church tax generally has to be withheld, if applicable, based on an automatic data access procedure, unless the holder of ADSs has filed a blocking notice (*Sperrvermerk*) with the Federal Central Tax Office. Where church tax is not levied by way of withholding, it is determined by means of income tax assessment.

ADSs as Business Assets (Betriebsvermögen)

In case the ADSs are held as business assets, the taxation depends on the legal form of the holder (*i.e.*, whether the holder is a corporation or an individual).

Irrespective of the legal form of the holder, dividends are subject to the aggregate withholding tax rate of 26.375%. The withholding tax is generally creditable against the respective holder's corporate income tax or income tax liability. Due to special rules on the restriction of withholding tax credits in respect of dividends, a full withholding tax credit requires that the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days occurring within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk for more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, three-fifths of the withholding tax imposed on the dividends must not be credited against the holder's corporate income tax or income tax liability, but may, upon application, be deducted from the holder's tax base for the relevant tax assessment period. A holder that is generally subject to German income tax or corporate income tax and that has received gross dividends without any deduction of withholding tax due to a tax exemption without qualifying for a full tax credit under the aforementioned requirements has to notify the competent local tax office accordingly, has to file withholding tax returns for a withholding tax of 15% in accordance with statutory formal requirements and has to make a payment in the amount of the omitted withholding tax deduction. The special rules on the restriction of withholding tax credit (and the corresponding notification and payment obligations) do not apply to a holder whose overall dividend earnings within an assessment period do not exceed €20,000 or that has been the beneficial owner of the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

To the extent the amount withheld exceeds the income tax liability, the withholding tax will be refunded, provided that certain requirements are met (including the aforementioned requirements).

Special rules apply to credit institutions (*Kreditinstitute*), financial services institutions (*Finanzdienstleistungsinstitute*), financial enterprises (*Finanzunternehmen*), life insurance and health insurance companies, and pension funds.

In principle, dividends that a corporation receives from German or foreign corporations are subject to corporate income tax (and solidarity surcharge thereon) at a rate of 15.825% and also subject to trade tax of between 7.0% and 19.0% depending on the multiplier applied by the relevant municipality. However, with regard to holders in the legal form of a corporation, capital gains are in general effectively 95% tax exempt from corporate income tax (including solidarity surcharge). Dividends are also generally 95% tax exempt from corporate income tax (including solidarity surcharge), inter alia, if the holder held at least 10% of the registered share capital (*Grundkapital oder Stammkapital*) of BioNTech at the beginning of the calendar year, or Qualifying Dividends. Five percent of the capital gains and five percent of the Qualifying Dividends are treated as non-deductible business expenses, respectively, and, as such, are subject to corporate income tax (including solidarity surcharge); actual business expenses incurred to generate dividends may be deducted. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the determination of whether a dividend is a Qualifying Dividend. Participations in the share capital of BioNTech held through a partnership, including co-entrepreneurships (*Mitunternehmerschaften*), are attributable to the respective partner only on a pro rata basis at the ratio of its entitlement to the profits of the partnership.

Capital gains and dividend income of a German tax resident corporation are generally subject to German trade tax of between 7.0% and 19.0% depending on the multiplier applied by the relevant municipality. The aforementioned 95% exemption for capital gains generally applies also for trade tax purposes. However, the amount of any dividends after deducting business expenses related to the dividends is not subject to trade tax if the corporation held at least 15% of BioNTech's registered share capital at the beginning of the relevant tax assessment period. In this case, the aforementioned exemption of 95% of the dividend income also applies for trade tax purposes. Losses from the sale of ADSs are generally not tax deductible for corporate income tax and trade tax purposes.

With regard to individuals holding ADSs as business assets, 60% of dividends and capital gains are taxed at the individual's personal income tax rate (plus 5.5% solidarity surcharge thereon). Correspondingly, only 60% of business expenses related to the dividends and capital gains as well as losses from the sale of ADSs are principally deductible for income tax purposes. Since 2021, the basis for the calculation of the solidarity surcharge (*Solidaritätszuschlag*) has been reduced for certain individual persons being subject to tax assessments (other than withholding taxes), and in certain cases, the solidarity surcharge has been abolished, subject to the limitations described above in "—ADSs as Private Assets (*Privatvermögen*)". The dividend income and 60% of the capital gains are generally subject to trade tax, which is fully or

partly creditable against the individual's personal income tax by a lump-sum method. Dividends (after deduction of business expenses economically related thereto) are exempt from trade tax if the holder held at least 15% of BioNTech's registered share capital at the beginning of the relevant tax assessment period.

German Inheritance and Gift Tax (Erbschaft- und Schenkungsteuer)

The transfer of ADSs to another person by inheritance or gift generally should be subject to German inheritance and gift tax only if:

(i) the decedent or donor or heir, beneficiary or other transferee (a) maintained his or her domicile or a usual residence in Germany, (b) had its place of management or registered office in Germany at the time of the transfer, (c) is a German citizen who has spent no more than five consecutive years outside of Germany without maintaining a domicile in Germany or (d) is a German citizen who serves for a German entity established under public law and is remunerated for his or her service from German public funds (including family members who form part of such person's household, if they are German citizens) and is only subject to estate or inheritance tax in his or her country of domicile or usual residence with respect to assets located in such country (special rules apply to certain former German citizens who neither maintain a domicile nor have their usual residence in Germany);

(ii) at the time of the transfer, the ADSs are held by the decedent or donor as business assets forming part of a permanent establishment in Germany or for which a permanent representative in Germany has been appointed; or

(iii) the ADSs subject to such transfer form part of a portfolio that represents at the time of the transfer 10% or more of the registered share capital of BioNTech and that has been held directly or indirectly by the decedent or donor, either alone or together with related persons.

The Agreement between the Federal Republic of Germany and the United States of America for the avoidance of double taxation with respect to taxes on inheritances and gifts as of December 21, 2000 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung auf dem Gebiet der Nachlass-, Erbschaft- und Schenkungssteuern in der Fassung vom 21. Dezember 2000*), hereinafter referred to as the "United States-Germany Inheritance and Gifts Tax Treaty," provides that the German inheritance tax or gift tax can, with certain restrictions, only be levied in the cases of (i) and (ii) above. Special provisions apply to certain German citizens living outside of Germany and former German citizens.

Other Taxes

No German transfer tax, value-added tax, stamp duty or similar taxes are assesessed on dividend payments.

Material United States Federal Income Tax Considerations

The following discussion describes material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. Holder (as defined below) that acquires our ADSs and holds them as a capital asset. This discussion is based on the tax laws of the United States, including the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated or proposed thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof. These tax laws are subject to change, possibly with retroactive effect, and subject to differing interpretations that could affect the tax consequences described herein. This section does not address the treatment of a non-U.S. holder, nor does it address the tax treatment under the laws of any state, local or foreign taxing jurisdiction.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ADSs that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a domestic corporation (or other entity taxable as a corporation);
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

- a trust if (i) a court within the United States is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) a valid election under the Treasury regulations is in effect for the trust to be treated as a U.S. person.

This discussion does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders in light of their particular circumstances or status (including, for example, banks and other financial institutions, insurance companies, broker and dealers in securities or currencies, traders that have elected to mark securities to market, regulated investment companies, real estate investment trusts, partnerships or other pass- through entities, corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, pension plans, persons that hold our shares as part of a straddle, hedge or other integrated investment, persons subject to alternative minimum tax or whose "functional currency" is not the U.S. dollar).

If a partnership (including any entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our ADSs, the tax treatment of a person treated as a partner in the partnership for U.S. federal income tax purposes generally will depend on the status of the partner and the activities of the partnership. Partnerships (and other entities or arrangements so treated for U.S. federal income tax purposes) and their partners should consult their own tax advisors.

In general, and taking into account the earlier assumptions, for U.S. federal income and German tax purposes, a holder of ADSs will be treated as the owner of the shares represented by those ADSs. Exchanges of shares for ADSs, and ADSs for shares, generally will not be subject to U.S. federal income or to German tax.

This discussion addresses only U.S. Holders and does not discuss any tax considerations other than U.S. federal income tax considerations. Prospective investors are urged to consult their own tax advisors regarding the U.S. federal, state and local, and foreign tax consequences of the purchase, ownership, and disposition of ADSs.

Dividends

Under the U.S. federal income tax laws, and subject to the passive foreign investment company, or PFIC, rules discussed below, the gross amount of any dividend we pay out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) is includible in income for a U.S. Holder and subject to U.S. federal income taxation. Dividends paid to a noncorporate U.S. Holder that constitute qualified dividend income will be taxable at a preferential tax rate applicable to long-term capital gains, provided that the U.S. Holder holds the ADSs for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and meets other holding period requirements. Dividends we pay with respect to the ADSs generally will be qualified dividend income.

A U.S. Holder must include any German tax withheld as part of the gross dividend payment, as described above under "—German Taxation—General Rules for the Taxation of Holders Not Tax Resident in Germany," even though the holder does not in fact receive it. The dividend is taxable to the holder when the depositary receives the dividend, actually or constructively. Because we are not a U.S. corporation, the dividend will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. The amount of the dividend distribution includible in U.S. Holder's income will be the U.S. dollar value of the Euro payments made, determined at the spot Euro/U.S. dollar rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is included in income to the date the payment is converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

To the extent a distribution with respect to ADSs exceeds our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, the distribution will be treated, first, as a tax-free return of the U.S. Holder's investment, up to the holder's adjusted tax basis in its ADSs, and, thereafter, as capital gain, which is subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition."

Subject to certain limitations, the German tax withheld in accordance with the Treaty and paid over to the German taxing authority will be creditable or deductible against a U.S. Holder's U.S. federal income tax liability. To the extent a refund of the tax withheld is available to a U.S. Holder under German law or under the Treaty, the amount of tax withheld

that is refundable will not be eligible for credit against a U.S. Holder's U.S. federal income tax liability. See "—German Taxation—Withholding Tax Refund for U.S. Treaty Beneficiaries" above for the procedures for obtaining a tax refund.

Gain On Sale, Exchange or Other Taxable Disposition

Subject to the PFIC rules described below under "—Passive Foreign Investment Company Considerations", a U.S. Holder that sells, exchanges or otherwise disposes of ADSs in a taxable disposition generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference between the U.S. dollar value of the amount realized and the holder's tax basis, determined in U.S. dollars, in the ADSs. Gain or loss recognized on such a sale, exchange or other disposition of ADSs generally will be long-term capital gain if the U.S. Holder's holding period in the ADSs exceeds one year. Long-term capital gains of non-corporate U.S. Holders are taxed generally at preferential rates. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes. A U.S. Holder's ability to deduct capital losses is subject to limitations.

Passive Foreign Investment Company Considerations

We do not believe that we should be treated as, and do not expect to become, a PFIC. Because the determination of our PFIC status is made annually based on the factual tests described below, however, we cannot provide any assurances regarding our PFIC status for the current or future taxable years or that the IRS will agree with our conclusion regarding our PFIC status.

If we were classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules with respect to distributions on and sales, exchanges and other dispositions of the ADSs. We will be treated as a PFIC for any taxable year in which at least 75% of our gross income is "passive income" or at least 50% of our gross assets during the taxable year (based on the average of the fair market values of the assets determined at the end of each quarterly period) are assets that produce or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions, and gains from assets that produce passive income. However, rents and royalties received from unrelated parties in connection with the active conduct of a trade or business are not considered passive income for purposes of the PFIC test. In determining whether we are a PFIC, a pro rata portion of the income and assets of each corporation in which we own, directly or indirectly, at least a 25% interest (by value) is taken into account.

If we were a PFIC with respect to a U.S. Holder, then unless such U.S. Holder makes one of the elections described below, a special tax regime would apply to the U.S. Holder with respect to (i) any "excess distribution" (generally, aggregate distributions in any year that are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or the holder's holding period for the ADSs) and (ii) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over the U.S. Holder's holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. Holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. If we were determined to be a PFIC, this tax treatment for U.S. Holders would apply also to indirect distributions and gains deemed realized by U.S. Holders in respect of stock of any of our subsidiaries determined to be PFICs. In addition, dividend distributions would not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "—Taxation of Dividends."

A U.S. Holder that holds the ADSs at any time during a taxable year in which we are classified as a PFIC generally will continue to treat such ADSs as ADSs in a PFIC, even if we no longer satisfy the income and asset tests described above, unless the U.S. Holder elects to recognize gain, which will be taxed under the excess distribution rules as if such ADSs had been sold on the last day of the last taxable year for which we were a PFIC.

Certain elections by a U.S. Holder would alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs, as described below.

If we were a PFIC, the rules above would not apply to a U.S. Holder that makes an election to treat ADSs as stock of a "qualified electing fund" or QEF. However, we do not expect that a U.S. Holder would be able to make this election because we do not intend to provide to U.S. Holders the required information to make a valid QEF election.

If we were a PFIC, the rules above also would not apply to a U.S. Holder that makes a "mark-to-market" election with respect to the ADSs, but this election will be available with respect to the ADSs only if they meet certain minimum trading requirements to be considered "marketable stock" for purposes of the PFIC rules. Generally, shares of ADSs will be treated as marketable stock if they are "regularly traded" on a "qualified exchange" within the meaning of applicable U.S. Treasury Regulations. ADSs generally will be considered regularly traded during any calendar year during which they are traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be marketable stock as long as they remain listed on the Nasdaq Global Select Market and are traded regularly.

A U.S. Holder that makes a valid mark-to-market election for the first tax year in which the holder holds (or is deemed to hold) ADSs and for which we are a PFIC will be required to include each year an amount equal to the excess, if any, of the fair market value of such ADSs the holder owns as of the close of the taxable year over the holder's adjusted tax basis in such ADSs. The U.S. Holder will be entitled to a deduction for the excess, if any, of the holder's adjusted tax basis in the ADSs over the fair market value of such ADSs as of the close of the taxable year, but only to the extent of any net mark-to-market gains with respect to such ADSs included by the U.S. Holder under the election for prior taxable years. The U.S. Holder's basis in such ADSs will be adjusted to reflect the amounts included or deducted pursuant to the election. Amounts included in income pursuant to a mark-to-market election, as well as gain on the sale, exchange or other taxable disposition of such ADSs, will be treated as ordinary income. The deductible portion of any mark-to-market loss, as well as loss on a sale, exchange or other disposition of ADSs to the extent that the amount of such loss does not exceed net mark-to-market gains previously included in income, will be treated as ordinary loss.

The mark-to-market election applies to the taxable year for which the election is made and all subsequent taxable years, unless the shares cease to be treated as marketable stock for purposes of the PFIC rules or the IRS consents to its revocation. The excess distribution rules described above generally will not apply to a U.S. Holder for tax years for which a mark-to-market election is in effect. However, if we were a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above would apply to any mark-to-market gain recognized in the year the election is made.

A U.S. Holder of PFIC shares must generally file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund). The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

U.S. Holders are urged to consult their tax advisors as to our status as a PFIC, and the tax consequences to them if we were a PFIC, including the reporting requirements and the desirability of making, and the availability of, a QEF election or a mark-to-market election with respect to the ADSs.

Medicare Tax

Non-corporate U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. A U.S. person that is an individual, estate or trust is encouraged to consult its tax advisors regarding the applicability of this Medicare tax to its income and gains in respect of any investment in ADSs.

Information Reporting with Respect to Foreign Financial Assets

Individual U.S. Holders may be subject to certain reporting obligations on IRS Form 8938 (Statement of Specified Foreign Financial Assets) with respect to the ADSs for any taxable year during which the U.S. Holder's aggregate value of these and certain other "specified foreign financial assets" exceed a threshold amount that varies with the filing status of the individual. This reporting obligation also applies to domestic entities formed or availed of to hold, directly or indirectly, specified foreign financial assets, including the ADSs. Significant penalties can apply if U.S. Holders are required to make this disclosure and fail to do so.

U.S. Holders who acquire ADSs for cash may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the U.S. Holder owns directly or indirectly (or by attribution) at least 10% of our total voting power or value or (ii) the amount of cash transferred to us in exchange for ADSs, when aggregated with all related transfers under applicable regulations, exceeds $100,000. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement.

Information Reporting and Backup Withholding

In general, information reporting, on IRS Form 1099, will apply to dividends in respect of ADSs and the proceeds from the sale, exchange or redemption of ADSs that are paid to a holder of ADSs within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient such as a corporation. Backup withholding (currently at a 24% rate) may apply to such payments if a holder of ADSs fails to provide a taxpayer identification number (generally on an IRS Form W-9) or certification of other exempt status or fails to report in full dividend and interest income.

Backup withholding is not an additional tax. A U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the U.S. Holder's income tax liability by filing a refund claim with the IRS.

F. Dividends and Paying Agents

We will propose a special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which corresponds to an aggregate of approximately €486.0 million, based on the shares outstanding as of March 30, 2022, pending approval at our Annual General Meeting to be held in June 2022 which we expect to serve as the record date for the dividend.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We also make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is www.biontech.de. The information contained on our website is not incorporated by reference in this Annual Report and our website address is included in this Annual Report as an inactive textual reference only.

Statements contained in this Annual Report regarding the contents of any contract or other document are not necessarily complete, and, where the contract or other document is an exhibit to the Annual Report, each of these statements is qualified in all respects by the provisions of the actual contract or other documents.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various risks in relation to financial instruments, including currency risk. Our risk management is coordinated by our Management Board. We do not engage in the trading of financial assets for speculative purposes. The most significant financial risks to which we are exposed include the risks discussed below.

Foreign Currency Risk

We publish our consolidated financial statements in Euro. Revenue and expenses incurred in U.S. dollars will be translated into Euro when they are reported in our consolidated financial statements. We are subject to currency risk, as our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are exposed to exchange rate fluctuations between these currencies. Cash inflows denominated in U.S. dollar mainly result from generating proceeds under our collaboration agreements which significantly increased in the past year. Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Consequently, we have progressed from earning revenues primarily from research and development to earning revenues from commercial sales. Our commercial revenues are primarily collaboration revenues from earnings based on our partners' gross profit, which is shared under the respective collaboration agreements and represents payments we receive in U.S. dollar. Cash outflows dominated in U.S. dollar mainly result from amounts spent on research and development activities as well as expanding our global footprint further. Especially when funds are required in Euros, we are exposed to foreign currency exchange risks. With the aim of preserving capital, surplus liquidity is invested carefully for example into foreign currency investments. Exchange rate fluctuations can reduce the value of our financial positions. We limit the effects of the identified risks by means of a coordinated and consistently implemented risk strategy. Besides applying natural hedging relationships where possible, a matter of principle, foreign exchange forward contracts are concluded as instruments to mitigate foreign currency exchange risk associated with foreign currency-denominated payments.

For further disclosures relating to foreign exchange forward contracts, see Note 12 to our consolidated financial statements included elsewhere in this Annual Report.

Notwithstanding our efforts to mitigate some foreign currency exchange risks, there can be no assurance that our hedging activities will adequately protect us against the risks associated with foreign currency fluctuations. We believe the counterparties to our foreign currency forward contracts are creditworthy multinational commercial banks. While we believe the risk of counterparty nonperformance is not material, a sustained decline in the financial stability of financial institutions as a result of disruption in the financial markets could affect our ability to secure creditworthy counterparties for our foreign currency hedging programs.Therefore, developments on the financial markets are continuously monitored to enable us to respond to exceptional events at short notice.

As a result, any substantial future appreciation or decline of the U.S. dollar against the Euro could have a material effect on our revenue and profitability. As an example, if the U.S. dollar weakens by 5% against the Euro, financial assets and liabilities denominated in U.S. dollar as of December 31, 2021 would have an effect of €364.3 million on our profit before tax.

For additional information about our quantitative and qualitative market risks, see Note 12 to the consolidated financial statements.

Item 12. Description of Securities Other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	*For:*
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to an ADS holder had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when an ADS holder deposits or withdraws shares
Expenses of the depositary	Cable and facsimile transmissions (when expressly provided in the deposit agreement)
	Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by, or affiliated with, the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary

makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

ADS holders will be responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register any transfer of ADS holders ADSs or allow him or her to withdraw the deposited securities represented by his or her ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by his or her ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, if appropriate, it will reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

Item 15. Controls and Procedures

Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, management, including our Chief Executive Officer (CEO) and our Chief Financial Officer (CFO), has performed an evaluation of the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosures.

Based on the foregoing, our CEO and CFO have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in by the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Our internal control over financial reporting is a process designed by or under the supervision of the Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with International Financial Reporting Standards as issued by the IASB.

No system of internal control over financial reporting, including one determined to be effective, may prevent or detect all misstatements. It can provide only reasonable assurance regarding financial statement preparation and presentation. Also, projections of the results of any evaluation of the effectiveness of internal control over financial reporting into future periods are subject to inherent risk. The relevant controls may become inadequate due to changes in circumstances or the degree of compliance with the underlying policies or procedures may deteriorate.

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2021. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control - Integrated Framework (2013)".

Based on this assessment, our management has determined that the Company's internal control over financial reporting as of December 31, 2021 is effective.

Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, an independent registered public accounting firm. Their report is included on page F-2. Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft is a member of the Chamber of Public Accountants (*Wirtschaftsprüferkammer*), Berlin, Germany.

Changes in Control over Financial Reporting

There were no changes to our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934) that occurred during the period covered by this form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our Audit Committee consists of Dr. Ulrich Wandschneider, Michael Motschmann and Prof. Christoph Huber. Dr. Ulrich Wandschneider is the chair of the Audit Committee. All members of the Audit Committee qualify as "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that Dr. Ulrich Wandschneider qualifies as an "audit committee financial expert" as that term is defined under the Exchange Act.

Item 16B. Code of Ethics

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees. The full text of the Code of Conduct is available on our website at https://www.biontech.de. The information and other content appearing on our website are not part of this Annual Report and our website address is included in this Annual Report as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

Item 16C. Principal Accountant Fees and Services

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, or EY, has served as our independent registered public accounting firm for the years ended December 31, 2021, December 31, 2020, December 31, 2019 and December 31, 2018 for which audited financial statements appear in this Annual Report.

The following table sets out the aggregate fees for professional audit services and other services rendered by EY in the periods indicated:

	Years ended December 31,	
(in millions)	**2021**	**2020**
Audit fees	€1.9	€1.4
Audit-related fees	0.7	0.4
Tax fees	0.5	0.3
All other fees	0.1	0.4
Total fees for professional audit services and other services	**€3.2**	**€2.5**

In the year ended December 31, 2021, audit fees related to the audit of the financial statements as set out in this Annual Report, certain procedures on our quarterly results as prework for this Annual Report and professional services related to our statutory and regulatory filings for our subsidiaries. In the year ended December 31, 2020, audit fees relate to the audit of the financial statements as set out in this Annual Report, certain procedures on our quarterly results, fees for testing our internal controls over financial reporting during the six months ended December 31, 2020 and services related to our statutory and regulatory filings for our subsidiaries.

In the year ended December 31, 2021, 2021, audit-related fees were billed for reviews and testing on internal controls, professional services, quarterly reviews as well as services around our at-the-market offering program. In the year ended December 31, 2020, audit-related fees billed for assurance and related services are related mainly to the issuance of comfort letters in connection with our financing transactions.

In the year ended December 31, 2021, tax service fees were billed for services in conjunction with transactions, especially with our financing and deal transactions. In the year ended December 31, 2020, tax service fees billed for services in conjunction with transactions, especially with our financing and deal transactions

Other fees comprised fees for services around grant applications for our COVID-19 vaccine program throughout the year ended December 31, 2021, reviews of internal control systems at one of our subsidiaries and accounting assessments of different accounting topics. In the year ended December 31, 2020, the other fees comprised fees for testing the implementation of our internal controls over financial reporting during the six months ended June 30, 2020.

The Audit Committee evaluates the qualifications, independence and performance of the independent auditor as well as pre-approves and reviews the audit and non-audit services to be performed by the independent auditor. The external audit plan and fees for professional audit services and other services rendered by EY for the years ended December 31, 2021 and 2020 were approved by the Audit Committee. The Audit Committee monitors compliance with the German and U.S. rules on non-audit services provided by an independent registered public accounting firm.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Please see "Board Practices—Supervisory Board Practices—Audit Committee" in Item 6C in this Annual Report for the information required by this Item 16D.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We expect our Management Board and Supervisory Board to authorize a share repurchase program of ADSs, pursuant to which we may repurchase ADSs in the amount of up to $1.5 billion over the next two years. We expect to use all or a portion of the ADSs we repurchase and hold in treasury to satisfy upcoming settlement obligations under our share-based payment arrangements.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

German Corporate Governance Code

The German Corporate Governance Code, or the Corporate Governance Code, was originally published by the German Federal Ministry of Justice (*Bundesministerium der Justiz*) in 2002. The version currently in effect, dated December 16, 2019, was published in the German Federal Gazette (*Bundesanzeiger*) on March 20, 2020. The Corporate Governance Code contains recommendations (*Empfehlungen*) and suggestions (*Anregungen*) relating to the management and supervision of German companies that are listed on a stock exchange. It follows internationally and nationally recognized standards for good and responsible corporate governance. The purpose of the Corporate Governance Code is to make the German system of corporate governance transparent for investors. The Corporate Governance Code includes corporate governance recommendations and suggestions with respect to shareholders and shareholders' meetings, the management and supervisory boards, transparency, accounting policies and auditing.

There is no obligation to comply with the recommendations or suggestions of the Corporate Governance Code. The German Stock Corporation Act (*Aktiengesetz*) requires only that the management board and supervisory board of a German company listed on a trading facility (such as a stock exchange) which is regulated and supervised by government authorities issue an annual declaration that either (i) states that the company has complied with the recommendations of the Corporate Governance Code or (ii) lists the recommendations that the company has not complied with and explains its reasons for deviating from the recommendations of the Corporate Governance Code (*Entsprechenserklärung*). In addition, a listed company is also required to state in this annual declaration whether it intends to comply with the recommendations or list the recommendations it does not plan to comply with in the future. These declarations must be made accessible to shareholders at all times. If the company changes its policy on certain recommendations between such annual declarations, it must disclose this fact and explain its reasons for deviating from the recommendations. Non-compliance with suggestions contained in the Corporate Governance Code need not be disclosed.

Our Management Board and Supervisory Board comply with the Corporate Governance Code except for such provisions which are listed explicitly in the annual declaration and for which they provide an explanation of non-compliance.

Differences in Corporate Law

The applicable provisions of the SE Regulation in conjunction with the German Stock Corporation Act as applied to a European stock corporation that has its legal seat in Germany differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the SE Regulation in conjunction with the German Stock Corporation Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and European and German law.

	European Union/Federal Republic of Germany	***Delaware***
Board System	A European stock corporation may choose to have a two-tier board structure composed of the Management Board (*Vorstand*) and the Supervisory Board (*Aufsichtsrat*). We have chosen this structure. The Management Board is responsible for running the company's affairs and representing the company in dealings with third parties. The Supervisory Board of a European stock corporation under German law has a control and supervisory function. The Supervisory Board does not actively manage the company but certain Management Board actions require the approval of the Supervisory Board.	Under Delaware law, a corporation has a unitary board structure, and it is the responsibility of the board of directors to appoint and oversee the management of the corporation on behalf of and in the best interests of the stockholders of the corporation. Management is responsible for running the corporation and overseeing its day-to-day operations.

Appointment and Number of Directors	Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million generally must have at least two members on its Management Board and the number of members shall be determined by or in the manner provided in the company's articles of association. The Supervisory Board must consist of at least three but—depending on the share capital—no more than 21 Supervisory Board members, whereby the number of Supervisory Board members must be divisible by three if this is necessary for the fulfilment of co-determination requirements. The articles of association of the company must specify if the Supervisory Board has more than three members. Supervisory Board members are either appointed by the shareholders' meeting or delegated by one or more individual shareholders if so provided for in the company's articles of association. If the Supervisory Board consists of fewer members than is required to meet the quorum for resolutions (either statutory or pursuant to the company's articles of association), a competent court may appoint additional members as needed to meet the quorum. The provisions of German law in relation to employees' co-determination do not apply to the Company.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.

Removal of Directors	Members of the Management Board of a European stock corporation are appointed by the Supervisory Board for a maximum period of six years with an opportunity to be reelected. The articles of association may provide for a shorter term, which in our case is up to five years. The members of the Management Board may be reelected, even repeatedly. The Supervisory Board may remove a member of the Management Board prior to the expiration of his or her term only for cause, such as gross breach of duties (*grobe Pflichtverletzung*), the inability to manage the business properly (*Unfähigkeit zur ordnungsgemäßen Pflichtausübung*) or a vote of no-confidence during the shareholders' meeting (*Vertrauensentzug*). The shareholders themselves are not entitled to appoint or dismiss the members of the Management Board. Under European law, a member of the Supervisory Board of a company may be elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a period up to the end of the general meeting deciding on the discharge for the fourth financial year after the election. Reelection, including repeated reelection, is permissible. Members of the Supervisory Board may be removed with or without cause by way of a general meeting resolution, with the applicable majority requirement depending on the relevant company's articles of association.	Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause; or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Vacancies on the Board of Directors	Under the law, vacant positions on the Management Board are filled by the Supervisory Board in accordance with the general rules of appointment, which provide that vacancies are filled by the simple majority of votes of Supervisory Board members present or represented by proxy at the vote (with, under certain circumstances, the chairman having a casting vote), unless otherwise provided by the company's articles of association. In case of emergencies, a vacant position on the Management Board may be filled by an individual appointed by the court. Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment.	Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (i) otherwise provided in the certificate of incorporation or by-laws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.
Annual General Meeting	A European stock corporation, which is governed by German law, must hold an annual shareholders' meeting within six months of the end of its fiscal year. The annual shareholders' meeting must be held at a location determined by the articles of association. If the articles of association do not provide for a specific location, the shareholders' meeting shall be held at the company's seat or, if applicable, at the venue (in Germany) where its shares are listed.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under the law, extraordinary shareholders' meetings, in addition to the annual shareholders' meetings, may be called either by the Management Board, or the Supervisory Board. Shareholders holding at least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, a competent court may order that the meeting be convened or authorize the shareholders or their representative to convene the meeting themselves.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

Notice of General Meetings	Under applicable European and German law, unless a longer period is otherwise provided for in the articles of association or applies because of registration requirements stipulated in the articles of association, the shareholders must be given at least 30 days' advance notice of the shareholders' meeting. Such notices must at least specify the name of the company, the statutory seat of the company, and the location, date and time of the shareholders' meeting. In addition, the invitation must contain the agenda items as well as the Management Board's and the Supervisory Board's voting proposal for each agenda item and, depending on the circumstances, certain further information. If all shareholders entitled to attend the shareholders' meeting are present or represented and do not object to the meeting being held, the formalities of calling and holding of a shareholders' meeting do not apply.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.
Proxy	A shareholder may designate another person to attend, speak and vote at a shareholders' meeting of the company on such shareholder's behalf by proxy. With respect to Management Board meetings, a Management Board member may transmit its (written or verbal) vote via another Management Board member. With respect to Supervisory Board meetings, a Supervisory Board member may participate in voting by issuing a written vote to another Supervisory Board member or any third party entitled to attend the Supervisory Board meeting.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Preemptive Rights	Under the law applicable to European stock corporations governed by German law, existing shareholders have a statutory subscription right for any additional issue of shares or any security convertible into shares pro rata to the nominal value of their respective holdings in the company, unless (i) shareholders representing three-quarters of the registered share capital present at the shareholders' meeting have resolved upon the whole or partial exclusion of the subscription right and (ii) there exists good and objective cause for such exclusion. No separate resolution on the exclusion of subscription rights is required if all shareholders waive their statutory subscription rights.	Under Delaware law, stockholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.
Authority to Allot	Under applicable European and German law, the Management Board may not allot shares, grant rights to subscribe for or to convert any security into shares unless a shareholder resolution to that effect has been passed at the company's shareholders' meeting granting the Management Board with such authority—subject to the approval of the Supervisory Board—in each case in accordance with the provisions of the German Stock Corporation Act.	Under Delaware law, if the corporation's certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.

Liability of Directors and Officers	Under German law, any provision, whether contained in the company's articles of association or any contract or otherwise, that purports to exempt a Management or Supervisory Board member from any liability that would otherwise attach to such board member in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void. Under German law, members of both the Management Board and members of the Supervisory Board are liable to the company, and in certain cases to third parties or shareholders, for any damage caused to them due to a breach of such member's duty of care. Apart from insolvency or special circumstances, only the company has the right to claim damages from members of either board. The company may waive claims for damages against a negligent Management or Supervisory Board member only after the expiry of three years.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: • any breach of the director's duty of loyalty to the corporation or its stockholders; • acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; • intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or • any transaction from which the director derives an improper personal benefit.
Voting Rights	Under the relevant European and German law, each share, except for statutory non-voting preferred shares (*nicht stimmberechtigte Vorzugsaktien*), entitles its holder to vote at the shareholders' meeting with, in the case of no-par value shares, each share conferring one vote. While German law does not provide for a minimum attendance quorum for shareholders' meetings, the company's articles of association may so provide. In general, resolutions adopted at a shareholders' meeting may be passed by a simple majority of votes cast, unless a higher majority is required by law or under the company's articles of association.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

Shareholder Vote on Certain Transactions	Under applicable European and German law, certain shareholders' resolutions of fundamental importance require the vote of at least three-quarters of the share capital present or represented in the voting at the time of adoption of the resolution. Resolutions of fundamental importance include, in particular, capital increases with exclusion of subscription rights, capital decreases, the creation of authorized or conditional share capital, the dissolution of a company, a merger into or with another company, split-offs and split-ups, the conclusion of inter-company agreements (*Unternehmensverträge*), in particular domination agreements (*Beherrschungsverträge*) and profit and loss transfer agreements (*Ergebnisabführungsverträge*).	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: • the approval of the board of directors; and • approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

Standard of Conduct for Directors		
	Under applicable European and German law, both Management and Supervisory Board members must conduct their affairs with "the care and diligence of a prudent business man" and act in the best interest of the company. The scope of the fiduciary duties of Management and Supervisory Board members is generally determined by European and German legislation and by the courts. Statutory and fiduciary duties of members of the Management Board to the company include, among others: • to act in accordance with the law, the company's articles of association and the rules of procedure for the Management Board, if any; • to report to the Supervisory Board on a regular basis as well as on certain important occasions; • to exercise reasonable care, skill and diligence; • to maintain a proper accounting system; • to not compete, directly or indirectly, with the company without permission by the supervisory board; and • to secure that no further transactions are made in case of insolvency. Statutory and fiduciary duties of members of the Supervisory Board to the company include, among others: • to effectively supervise the Management Board's handling of the company's affairs; • to evaluate and issue a resolution on certain transactions which can only be conducted by the Management Board after approval of the Supervisory Board; • to approve the company's financial statements; • to appoint the Management Board members and to represent the company in transactions between the company and members of the Management Board; and • to approve service contracts between individual members of the Supervisory Board and the company.	Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well- informed basis and in a manner they reasonably believe to be in the best interest of the stockholders. Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Stockholder Actions

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its Management Board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board.

Additionally, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so.

The Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can request that a representative pursues the claim on behalf of the company.

If the company is unable to fulfill its third- party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least one percent of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) need(s) to pass through special claim approval procedures.

Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:

- state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiffs shares thereafter devolved on the plaintiff by operation of law; and
- either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort.

Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

Foreign Private Issuer Exemptions

As a "foreign private issuer," as defined by the SEC, although we are permitted to follow certain corporate governance practices of the Federal Republic of Germany, instead of those otherwise required under the rules of the Nasdaq Stock Market LLC, or Nasdaq, for domestic issuers, we follow the Nasdaq corporate governance rules applicable to foreign private issuers. While we voluntarily follow most Nasdaq corporate governance rules, we intend to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q and providing current reports on Form 8-K disclosing significant events within four days of their occurrence (however, we intend to furnish quarterly financial information under cover of Form 6-K);
- exemption from compliance with Regulation FD, which generally requires that when a company intentionally discloses material-non public information, it do so through a public disclosure that is broadly available to all members of the public at the same time. However, we do furnish quarterly financial information and other information on a more frequent basis under cover of Form 6-K, and intend to continue doing so. Moreover, we comply with other other securities laws, such as rule 10b-5 (rule targeting securities fraud), among others;
- exemption from Section 16 rules regarding sales of ordinary shares by insiders, which will provide less data in this regard than the data provided to shareholders of U.S. companies that are subject to the Exchange Act; and
- exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers. Although we will require board approval of any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq rules, as permitted by the foreign private issuer exemption.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer, such as we, may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625) and the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to German requirements in lieu of many of the Nasdaq corporate governance rules, we comply with the Nasdaq corporate governance rules applicable to foreign private issuers. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

The financial statements are filed as part of this Annual Report beginning on page F-1.

Item 19. Exhibits

Exhibit Number	Description
1.1*	Articles of Association of the Registrant
2.1	Form of Specimen American Depositary Receipt (included in Exhibit 2.3)

2.2	Registrant's Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
2.3	Form of Deposit Agreement among the Registrant, the depositary and holders and beneficial owners of the American Depositary Shares (incorporated herein by reference to Exhibit 1 to the Registration Statement on Form F-6 (File No. 333-233898), filed with the SEC on September 23, 2019)
2.4*	Description of Securities of the Registrant
4.1†	Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.2†	Confirmation Letter by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH dated September 15, 2016 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.3†	Supplementary Agreement for IVAC Developments to the Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH (f/k/a Eufets GmbH), JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated November 28, 2017 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.4†	License Agreement by and among the Registrant, TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, Johannes Gutenberg-Universität Mainz, Universitätsmedizin der Johannes Gutenberg-Universität and Ganymed Pharmaceuticals AG, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.5†	Framework Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated August 29, 2019 (incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.6†	Amended Patent License Agreement by and among the Registrant, the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College and Uniwersytet Warszawski, dated May 12, 2015 (incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.7†	License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 19, 2015 (incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.8†	Amendment No. 1 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2017 (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

4.9†	Amendment No. 2 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated August 4, 2017 (incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.10†	Amendment No. 3 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2018 (incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.11†	Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated November 2, 2015 (incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.12†	Amendment to Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated December 22, 2018 (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.13†	Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated September 20, 2016 (incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.14*†	First Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated June 1, 2018 (incorporated herein by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form F-1 (File No. 333-239970), filed with the SEC on July 21, 2020)
4.15*†	Second Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated December 6, 2019 (incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form F-1 (File No. 333-239970), filed with the SEC on July 21, 2020)
4.16*	Joinder and Third Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Manufacturing GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, effective as of October 1, 2020
4.17*†	Fourth Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Manufacturing GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, effective as of October 26, 2020
4.18†	Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 (incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.19*†	Second Amendment to Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, effective as of August 1, 2020
4.20†	Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 (incorporated herein by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.21*†	Second Amendment to Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, effective as of August 1, 2020
4.22†	Research Collaboration and License Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and Pfizer, Inc., dated July 20, 2018 (incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

4.23†	Collaboration and License Agreement by and between the Trustees of the University of Pennsylvania and BioNTech RNA Pharmaceuticals GmbH, dated October 9, 2018 (incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.24†	Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 14, 2013 (incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.25†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated July 5, 2014 (incorporated herein by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.26†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated June 8, 2015 (incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.27†	Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 18, 2017 (incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.30†	Lease Agreement by and among the Registrant and Wolfram Richter, dated August 17, 2011 (incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.31†	Amendment No. 1 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 17, 2012 (incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.32†	Amendment No. 2 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 1, 2013 (incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.33†	Amendment No. 3 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 6, 2013 (incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.34†	Amendment No. 4 to Lease Agreement by and among the Registrant and Wolfram Richter, dated December 10, 2013 (incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.35†	Amendment No. 5 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 29, 2016 (incorporated herein by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.36†	Amendment No. 6 to Lease Agreement by and among the Registrant and Wolfram Richter, dated October 6, 2017 (incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.37†	Lease Agreement by and among the Registrant and Wista-Management GmbH, dated April 12, 2005 (incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)

4.38†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated December 27, 2018 (incorporated herein by reference to Exhibit 10.33 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.39†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated October 24, 2019 (incorporated herein by reference to Exhibit 4.35 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2019)
4.40†	Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated June 1, 2020 (incorporated herein by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form F-1 (File No. 333-233970), filed with the SEC on July 21, 2020)
4.41†	Loan Agreement by and between BioNTech Innovative Manufacturing Services GmbH and Deutsche Bank AG dated November 21, 2017 (incorporated herein by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.42†	Loan Agreement by and between JPT Peptides Technologies GmbH and Deutsche Bank AG dated July 18, 2018 (incorporated herein by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)
4.43*†	Amended and Restated Collaboration Agreement by and between the Registrant and Pfizer Inc., dated March 17, 2020
4.44†	License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. (as successor-by-merger to Neon Therapeutics, Inc.), dated as of November 13, 2015 (incorporated herein by reference to Exhibit 10.48 to the Registrant's Registration Statement on Form F-1 (File No. 333-233970), filed with the SEC on July 21, 2020
4.45†	First Amendment to the License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. (as successor-by-merger to Neon Therapeutics, Inc.), dated as of January 18, 2018 (incorporated herein by reference to Exhibit 10.49 to the Registrant's Registration Statement on Form F-1 (File No. 333-233970), filed with the SEC on July 21, 2020
4.46†	Second Amendment to the License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. (as successor-by-merger to Neon Therapeutics, Inc.), dated as of November 14, 2018 (incorporated herein by reference to Exhibit 10.50 to the Registrant's Registration Statement on Form F-1 (File No. 333-233970), filed with the SEC on July 21, 2020
4.47†	Sales Agreement by and among the Registrant, Jefferies LLC and SVB Leerink LLC, dated November 9, 2020 (incorporated herein by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form F-3 (File No. 333-249991), filed with the SEC on November 10, 2020)
4.48*†	Advance Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated November 20, 2020
4.49*†	Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated February 17, 2021
4.50*†	Lease for Buildings H028 and H30 by and between the Pharmaserv GmbH and Novartis Manufacturing GmbH.
4.51	Lease Agreement by and between the Registrant and Tech Park 270, LLC, dated as of December 1, 2017
4.52	Amendment No. 3 to Lease Agreement by and between the Registrant and Tech Park 270, LLC, dated as of July 24, 2018

4.53	Amendment No. 4 to Lease Agreement by and between the Registrant and Tech Park 270, LLC, dated as of May 23, 2019
4.54	License Agreement by and between the Registrant and Acuitas Therapeutics, Inc., dated as of April 7, 2020
4.55	Advanced Purchase Agreement by and among the Registrant, Pfizer Inc. and European Commission, dated as of May 20, 2021
4.56	Transfer of Source Code for MyMUT Software Versions by and between the Registrant and TRON gGmbH, dated as of May 5, 2021
4.57	Amendment No. 6 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated as of June 1, 2021
4.58	Amendment to the Development Agreement by and between Registrant and Sanofi S.A., dated as of July 7, 2021
4.59	Amendment No. 6 to Lease Agreement by and between the Registrant and Tech Park 270, LLC, dated as of August 2, 2021
4.60	Side Letter No. 5 to License and Collaboration Agreement by and between Registrant and Genmab A/S, dated August 12, 2021
4.61	Amendment No. 1 to Collaboration and License Agreement by and between the Registrant and the Trustees of the University of Pennsylvania, dated as of September 8, 2021
4.62	Transfer of Source Code MyMUT Software Versions by and between the Registrant and TRON gGmbH, dated as of September 10, 2021
4.63	Amendment to Letter Agreement by and between the Registrant and Genmab A/S, dated as of December 15, 2021
4.64	Amendment No. 2 to Collaboration and License Agreement by and between the Registrant and the Trustees of the University of Pennsylvania, dated as of December 22, 2021
4.65	Lease for Areas and Rooms in Building 536 and 537 by and between the Pharmaserv GmbH and Novartis Manufacturing GmbH, dated as of January 19, 2022
8*	List of Subsidiaries of the Registrant
12.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

15.1	Consent of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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* Filed herewith.

† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on Form 20-F on its behalf.

BioNTech SE

Date: March 30, 2022

By: /s/ Prof. Ugur Sahin, M.D.

Prof. Ugur Sahin, M.D.
Chief Executive Officer

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Supervisory Boards of BioNTech SE

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of BioNTech SE (the Company) as of December 31, 2021 and 2020, the related consolidated statements of profit or loss, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with International Financial Reporting Standards as issued by the International Accounting Standard Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission "(2013 framework)," and our report dated March 30, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition from collaboration partner's COVID-19 vaccine sales

Description of the Matter

As described in more detail in Note 6 to the consolidated financial statements, the Company recognizes revenues associated with COVID-19 vaccine sales in a total amount of €18.8 billion. This includes €14.8 billion from the Company's share of its collaboration partner´s gross profit.

The Company is contractually eligible to receive a share of the collaboration partner's gross profit from vaccine sales in the collaboration partner's territories. Such gross profit share is recognized as collaboration revenue. In order to determine the gross profit share, the Company uses certain information from the collaboration partner, including vaccine sales outside of the United States and associated production costs, some of which are based on preliminary data shared by the partner and might differ once final data is available.

Auditing revenue recognition specific to the gross profit share was complex due to the significant estimation uncertainty in inputs to the calculation. Specifically, the collaboration partner's vaccine sales outside of the United States and associated manufacturing and shipping costs are partially estimated for the last month in the period based on historical information and could change based on the actual vaccine sales and costs incurred.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's controls related to revenue recognition from the collaboration partner's vaccine sales outside of the United States. For example, we tested controls over management's review of the significant assumptions used to determine the gross profit share the Company is eligible to receive.

Our audit procedures included, among others, reading the contract with the collaboration partner to understand key terms and obtaining an understanding of management's methodology and assumptions used to calculate the gross profit share. We performed a hindsight analysis to assess management's accuracy in estimating the collaboration partner's vaccine sales outside of the United States and manufacturing and shipping costs. We obtained external confirmation directly from the collaboration partner regarding vaccine sales and cost inputs used to estimate the profit share. We performed a sensitivity analysis of the significant assumptions to evaluate the change in the gross profit share resulting from changing the assumptions, as well as an analysis of previous estimation compared to the actual payments obtained to date. We tested the completeness and accuracy of the Company's gross profit share calculation. We evaluated the Company's related disclosures in the consolidated financial statements.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2018

Cologne, Germany

March 30, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Supervisory Board of BioNTech SE

Opinion on Internal Control Over Financial Reporting

We have audited BioNTech SE's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission "(2013 framework)," (the COSO criteria). In our opinion, BioNTech SE (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2021 and 2020, the related consolidated statements of profit or loss, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated March 30, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Cologne, Germany

March 30, 2022

Consolidated Statements of Profit or Loss

(in millions, except per share data)	Note	Years ended December 31, 2021	2020	2019
Revenues				
Research & development revenues	6	€102.7	€178.8	€84.4
Commercial revenues	6	18,874.0	303.5	24.2
Total revenues		**€18,976.7**	**€482.3**	**€108.6**
Cost of sales	7.1	(2,911.5)	(59.3)	(17.4)
Research and development expenses	7.2	(949.2)	(645.0)	(226.5)
Sales and marketing expenses	7.3	(50.4)	(14.5)	(2.7)
General and administrative expenses	7.4	(285.8)	(94.0)	(45.5)
Other operating expenses	7.5	(94.4)	(2.4)	(0.7)
Other operating income	7.6	598.4	250.5	2.7
Operating income / (loss)		**€15,283.8**	**€(82.4)**	**€(181.5)**
Finance income	7.7	67.7	1.6	4.1
Finance expenses[1]	7.8	(305.1)	(65.0)	(2.0)
Profit / (loss) before tax		**€15,046.4**	**€(145.8)**	**€(179.4)**
Income taxes	8	(4,753.9)	161.0	0.2
Profit / (loss) for the period		**€10,292.5**	**€15.2**	**€(179.2)**
Attributable to:				
Equity holders of the parent		10,292.5	15.2	(179.1)
Non-controlling interests		—	—	(0.1)
Profit / (loss) for the period		**€10,292.5**	**€15.2**	**€(179.2)**
Earnings per share[2]				
Basic profit / (loss) for the period per share		€42.18	€0.06	€(0.85)
Diluted profit / (loss) for the period per share		€39.63	€0.06	€(0.85)

(1) Finance expenses disclosed separately in prior periods have been condensed. Please refer to Note 7.8 for further details on finance expenses.

(2) Capital increase due to 1:18 share split occurred on September 18, 2019. Retroactive effect is reflected in number of shares which relate to the period before the share split.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Comprehensive Income / (Loss)

(in millions)	Note	Years ended December 31, 2021	2020	2019
Profit / (loss) for the period		**€10,292.5**	**€15.2**	**€(179.2)**
Other comprehensive income / (loss)				
Other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods, net of tax				
Exchange differences on translation of foreign operations		8.4	(11.1)	0.1
Net other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods		**€8.4**	**€(11.1)**	**€0.1**
Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods, net of tax				
Remeasurement income / (loss) on defined benefit plans		0.3	(0.3)	—
Net other comprehensive income / (loss) that will not be reclassified to profit or loss in subsequent periods		**€0.3**	**€(0.3)**	**€—**
Other comprehensive income / (loss) for the period, net of tax		**€8.7**	**€(11.4)**	**€0.1**
Comprehensive income / (loss) for the period, net of tax		**€10,301.2**	**€3.8**	**€(179.1)**
Attributable to:				
Equity holders of the parent		10,301.2	3.8	(179.0)
Non-controlling interests		—	—	(0.1)
Comprehensive income / (loss) for the period, net of tax		**€10,301.2**	**€3.8**	**€(179.1)**

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Financial Position

(in millions)		December 31, 2021	December 31, 2020
Assets	**Note**		
Non-current assets			
Intangible assets	11	€202.4	€163.5
Property, plant and equipment	10	322.5	227.0
Right-of-use assets	20	197.9	99.0
Other financial assets	12	21.3	—
Other assets	14	0.8	1.0
Deferred expenses	15	13.6	—
Deferred tax assets	8	—	161.2
Total non-current assets		**€758.5**	**€651.7**
Current assets			
Inventories	13	502.5	64.1
Trade and other receivables	12	12,381.7	165.5
Other financial assets	12	381.6	137.2
Other assets	14	64.9	61.0
Income tax assets	8	0.4	0.9
Deferred expenses	15	48.5	28.0
Cash and cash equivalents	12	1,692.7	1,210.2
Total current assets		**€15,072.3**	**€1,666.9**
Total assets		**€15,830.8**	**€2,318.6**
Equity and liabilities			
Equity			
Share capital	16	246.3	246.3
Capital reserve	16	1,674.4	1,514.5
Treasury shares	16	(3.8)	(4.8)
Retained earnings / (accumulated losses)		9,882.9	(409.6)
Other reserves	17	93.9	25.4
Total equity		**€11,893.7**	**€1,371.8**
Non-current liabilities			
Loans and borrowings	12	171.6	231.0
Other financial liabilities	12	6.1	31.5
Income tax liabilities	8	4.4	—
Provisions	18	184.9	5.5
Contract liabilities	6	9.0	71.9
Other liabilities	19	12.8	0.7
Deferred tax liabilities	8	66.7	0.2
Total non-current liabilities		**€455.5**	**€340.8**
Current liabilities			
Loans and borrowings	12	129.9	9.1
Trade payables	12	160.0	102.3
Other financial liabilities	12	1,190.4	74.1
Government grants	7.5	3.0	92.0
Refund liabilities	6	90.0	—
Income tax liabilities	8	1,568.9	—
Provisions	18	110.2	0.9
Contract liabilities	6	186.1	299.6
Other liabilities	19	43.1	28.0
Total current liabilities		**€3,481.6**	**€606.0**
Total liabilities		**€3,937.1**	**€946.8**
Total equity and liabilities		**€15,830.8**	**€2,318.6**

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Changes in Stockholders' Equity

(in millions)	Note	Equity attributable to equity holders of the parent							
		Share capital[1]	Capital reserve[1]	Treasury shares[1]	Retained earnings / (accumulated losses)	Other reserves [2]	Total	Non-controlling interest	Total equity
As of January 1, 2019		**€193.3**	**€344.1**	**€—**	**€(245.7)**	**€(25.5)**	**€266.2**	**€0.8**	**€267.0**
Loss for the period		—	—	—	(179.1)	—	(179.1)	(0.1)	**€(179.2)**
Other comprehensive income		—	—	—	—	0.1	0.1	—	**€0.1**
Total comprehensive profit / (loss)		**€—**	**€—**	**€—**	**€(179.1)**	**€0.1**	**€(179.0)**	**€(0.1)**	**€(179.1)**
Issuance of share capital		8.1	41.8	—	—	—	49.9	—	**€49.9**
Capital increase Series B	16	18.0	186.4	(5.5)	—	—	198.9	—	**€198.9**
Capital increase initial public offering (referred to as IPO)	16	10.5	132.7	—	—	—	143.2	—	**€143.2**
Acquisition of non-controlling interest	16	2.4	(1.7)	—	—	—	0.7	(0.7)	**€—**
Transaction costs	16	—	(16.6)	—	—	—	(16.6)	—	**€(16.6)**
Share-based payments	17	—	—	—	—	30.2	30.2	—	**€30.2**
As of December 31, 2019		**€232.3**	**€686.7**	**€(5.5)**	**€(424.8)**	**€4.8**	**€493.5**	**€—**	**€493.5**
Profit for the period		—	—	—	15.2	—	15.2	—	**€15.2**
Other comprehensive loss		—	—	—	—	(11.4)	(11.4)	—	**€(11.4)**
Total comprehensive profit / (loss)		**—**	**—**	**—**	**15.2**	**(11.4)**	**3.8**	**—**	**€3.8**
Issuance of share capital and treasury shares	16	14.0	861.0	0.7	—	—	875.7	—	**€875.7**
Transaction costs	16	—	(33.2)	—	—	—	(33.2)	—	**€(33.2)**
Share-based payments	17	—	—	—	—	32.0	32.0	—	**€32.0**
As of December 31, 2020		**€246.3**	**€1,514.5**	**€(4.8)**	**€(409.6)**	**€25.4**	**€1,371.8**	**€—**	**€1,371.8**
Profit for the period		—	—	—	10,292.5	—	10,292.5	—	**€10,292.5**
Other comprehensive income		—	—	—	—	8.7	8.7	—	**€8.7**
Total comprehensive income		**€—**	**€—**	**€—**	**€10,292.5**	**€8.7**	**€10,301.2**	€—	**€10,301.2**
Issuance of treasury shares	16	—	162.6	1.0	—	—	163.6	—	**€163.6**
Transaction costs	16	—	(2.7)	—	—	—	(2.7)	—	**€(2.7)**
Share-based payments	17	—	—	—	—	59.8	59.8	—	**€59.8**
As of December 31, 2021		**€246.3**	**€1,674.4**	**€(3.8)**	**€9,882.9**	**€93.9**	**€11,893.7**	**€—**	**€11,893.7**

(1) Capital increase due to 1:18 share split occurred on September 18, 2019. Retroactive effect is reflected in number of shares which relate to the period before the share split.

(2) Includes foreign currency translation reserve which was presented separately in prior periods.

Consolidated Statements of Cash Flows

(in millions)	Years ended December 31, 2021	2020	2019
Operating activities			
Profit / (loss) for the period	€10,292.5	€15.2	€(179.2)
Income taxes	4,753.9	(161.0)	(0.2)
Profit / (loss) before tax	**€15,046.4**	**€(145.8)**	**€(179.4)**
Adjustments to reconcile profit / (loss) before tax to net cash flows:			
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	75.2	38.7	33.9
Share-based payment expense	80.5	32.1	30.2
Net foreign exchange differences	(387.5)	41.3	0.1
Gain on disposal of property, plant and equipment	4.6	0.6	0.5
Finance income	(1.5)	(1.6)	(1.8)
Finance expense	305.2	22.3	2.0
Movements in government grants	(89.0)	92.0	—
Other non-cash income	(2.2)	1.7	—
Net loss on derivative instruments at fair value through profit or loss	57.3	—	—
Working capital adjustments:			
Decrease / (Increase) in trade and other receivables, contract assets and other assets	(11,808.1)	(247.9)	2.9
Increase in inventories	(438.4)	(49.8)	(5.8)
(Decrease) / Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	1,516.1	204.6	(80.6)
Interest received	1.2	1.4	1.3
Interest paid	(12.2)	(3.6)	(2.0)
Income tax received / (paid), net	(3,457.9)	0.5	0.2
Net cash flows from / (used in) operating activities	**€889.7**	**€(13.5)**	**€(198.5)**
Investing activities			
Purchase of property, plant and equipment	(127.5)	(66.0)	(38.6)
Proceeds from sale of property, plant and equipment	3.4	1.2	—
Purchase of intangibles assets and right-of-use assets	(26.5)	(19.4)	(32.5)
Acquisition of subsidiaries and businesses, net of cash acquired	(20.8)	(60.6)	(6.1)
Investment into equity instruments designated at fair value through OCI	(19.5)	—	—
Investment into cash deposit with an original term of six months	(375.2)	—	—
Net cash flows used in investing activities	**€(566.1)**	**€(144.8)**	**€(77.2)**
Financing activities			
Proceeds from issuance of share capital and treasury shares, net of costs	160.9	753.0	375.4
Proceeds from loans and borrowings	—	156.0	11.0
Repayment of loans and borrowings	(52.6)	(1.6)	—
Payments related to lease liabilities	(14.1)	(12.7)	(3.1)
Net cash flows from / (used in) financing activities	**€94.2**	**€894.7**	**€383.3**
Net increase / (decrease) in cash and cash equivalents	417.8	736.4	107.6
Change in cash and cash equivalents resulting from exchange rate differences	64.7	(45.3)	—
Cash and cash equivalents at the beginning of the period	1,210.2	519.1	411.5
Cash and cash equivalents at December 31	**€1,692.7**	**€1,210.2**	**€519.1**

The accompanying notes form an integral part of these consolidated financial statements.

1 Corporate Information

BioNTech SE is a limited company incorporated and domiciled in Germany. American Depositary Shares (ADS) representing BioNTech SE's ordinary shares have been publicly traded on Nasdaq Global Select Market since October 10, 2019. The registered office is located in Mainz, Germany (An der Goldgrube 12, 55131 Mainz). BioNTech SE is registered in the commercial register B of the Mainz Local Court under the number HRB 48720. The accompanying International Financial Reporting Standards (IFRS) consolidated financial statements present the financial position and the results of operation of BioNTech SE and its subsidiaries, hereinafter also referred to as "BioNTech," the "Group," "we" or "us".

During the year ended December 31, 2021, the following changes to the Group structure occurred:

- In March 2021, BioNTech Turkey Tıbbi Ürünler Ve Klinik Araştirma Ticaret Anonim Şirketi, which translates into English as BioNTech Turkey Pharmaceutical Products and Clinical Trials Trading JSC, Istanbul, Turkey, was founded and is a wholly owned consolidated subsidiary of BioNTech SE.
- In June 2021, BioNTech Austria Beteiligungen GmbH, Vienna, Austria, was liquidated.
- In June 2021, the merger agreement between BioNTech RNA Pharmaceuticals GmbH, Mainz, Germany, and BioNTech SE was registered within the commercial register *(Handelsregister)* of BioNTech SE under BioNTech RNA Pharmaceuticals GmbH was effectively merged onto BioNTech SE.
- In July 2021, BioNTech (Shanghai) Pharmaceuticals Co. Ltd., Shanghai, China, was founded and is a wholly owned subsidiary of BioNTech Pharmaceuticals Asia Pacific Pte. Ltd., a wholly owned consolidated subsidiary of BioNTech SE.
- In September 2021, BioNTech Services Marburg GmbH, Marburg, Germany, was founded and is a wholly owned consolidated subsidiary of BioNTech SE. In December 2021, the entity was renamed to BioNTech Innovation and Services Marburg GmbH.
- In October 2021, BioNTech SE acquired PhagoMed Biopharma GmbH, Vienna, Austria (subsequently renamed to BioNTech R&D (Austria) GmbH).
- In October 2021, BioNTech Real Estate an der Goldgrube 12 GmbH & Co. KG, Holzkirchen, Germany, was founded and is wholly owned by its limited partner BioNTech Real Estate Holding GmbH, a wholly owned consolidated subsidiary of BioNTech SE.
- In November 2021, BioNTech Innovation GmbH i.G. (in establishment), Mainz, Germany, was founded and is a wholly owned consolidated subsidiary of BioNTech SE.

All entities listed above are included in our consolidated financial statements.

During the year ended December 31, 2020, two entities were acquired: Neon Therapeutics, Inc. (subsequently renamed BioNTech US Inc.) and Novartis Manufacturing GmbH (subsequently renamed BioNTech Manufacturing Marburg GmbH). Additionally, BioNTech UK Limited., BioNTech Pharmaceuticals Asia Pacific Pte. Ltd, BioNTech Real Estate Haus Vier GmbH & Co. KG, BioNTech Real Estate An der Goldgrube GmbH & Co. KG and BioNTech Real Estate Adam Opel Straße GmbH & Co. KG were established.

Information on the Group's structure is provided in Note 4.

Our consolidated financial statements for the year ended December 31, 2021, were authorized for issue in accordance with a resolution of the Supervisory Board on March 30, 2022.

2 Significant Accounting Policies

2.1 Basis of Preparation

General

The consolidated financial statements have been prepared on a going concern basis in accordance with the IFRS as issued by the International Accounting Standards Board (IASB).

We prepare and publish our consolidated financial statements in Euros and round numbers to thousands or millions of Euros, respectively. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them and figures presented in the explanatory notes may not add up to the rounded arithmetic aggregations. Rounding applied may differ from rounding published in different units in the previous years.

Segment Information

Decisions with respect to business operations and resource allocations are made by our Management Board, as the chief operating decision maker (CODM) based on BioNTech as a whole. Accordingly, we operate and make decisions as a single operating segment, which is also our reporting segment.

2.2 Basis of Consolidation

The consolidated financial statements comprise the financial statements of BioNTech SE and its controlled investees (subsidiaries).

The Group controls an investee if, and only if, the Group has

- power over the investee (*i.e.*, existing rights that give it the current ability to direct the relevant activities of the investee);
- exposure, or rights, to variable returns from its involvement with the investee; and
- the ability to use its power over the investee to affect its returns.

Generally, there is a presumption that a majority of voting rights results in control.

Whether an investee is controlled is re-assessed if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when control is obtained over the subsidiary and ceases when control of the subsidiary is lost.

The profit / (loss) and each component of other comprehensive income / (loss) for the period are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the consolidated financial statements of subsidiaries to bring their accounting policies in line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If control over a subsidiary is lost, the related assets (including goodwill), liabilities, non-controlling interests and other components of equity are derecognized, while any resultant gain or loss is recognized in the consolidated statements of profit or loss. Any investment retained is recognized at fair value.

2.3 Summary of Significant Accounting Policies

2.3.1 Business Combinations and Goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, which is measured at acquisition date fair value, and the amount of any non-controlling interests in the acquiree.

Goodwill is initially measured at cost as the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held over the net identifiable assets acquired and liabilities assumed.

After initial recognition, goodwill is tested at least annually or when there is an indication for impairment. See Note 2.3.13. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units.

Where goodwill has been allocated to a cash-generating unit (CGU) and part of the operation within that unit is disposed of, the goodwill associated with the disposed operation is included in the carrying amount of the operation when determining the gain or loss on disposal. Goodwill disposed in these circumstances is measured based on the relative values of the disposed operation and the portion of the cash-generating unit retained.

2.3.2 Current versus Non-Current Classifications

Assets and liabilities in the consolidated statements of financial position are presented based on current or non-current classification.

An asset is current when it is either: (i) expected to be realized or intended to be sold or consumed in the normal operating cycle, (ii) held primarily for the purpose of trading, (iii) expected to be realized within twelve months after the reporting period or (iv) cash or cash equivalents, unless it is restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period. All other assets are classified as non-current.

A liability is current when it is either: (i) expected to be settled in the normal operating cycle, (ii) held primarily for the purpose of trading, (iii) due to be settled within twelve months after the reporting period, or (iv) there is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period. The terms of the liability that could, at the option of the counterparty, result in its settlement by the issue of equity instruments do not affect its classification. The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities, respectively.

2.3.3 Fair Value Measurement

Fair value is a market-based measurement. For some assets and liabilities, observable market transactions or market information is available. For other assets and liabilities, observable market transactions or market information might not be available. When a price for an identical asset or liability is not observable, another valuation technique is used. To increase consistency and comparability in fair value measurements, there are three levels of the fair value hierarchy:

- Level 1 contains the use of quoted prices in active markets for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly.
- Level 3 inputs are unobservable.

Within this hierarchy, estimated values are made by management based on reasonable assumptions, including other fair value methods.

For assets and liabilities that are recognized in the financial statements at fair value on a recurring basis, we determine whether transfers have occurred between levels in the fair value hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

For the purpose of fair value disclosures, classes of assets and liabilities have been determined on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy, as explained above.

2.3.4 Revenue from Contracts with Customers

Revenue Recognition

We generate revenues from collaboration and license agreements, which contain multiple elements, including licenses to use, research, develop, manufacture and commercialize candidates and products, research and development services as well as obligations to develop and manufacture preclinical and clinical material and products. We determined that those collaboration and license agreements qualify as contracts with customers. If the grant of a license is bundled together with the rendering of services, it is assessed whether these agreements are comprised of more than one

performance obligation. A performance obligation is only accounted for as the grant of a license if the grant of a license is the sole or the predominant promise of the performance obligation.

If the consideration in an agreement includes a variable amount, we estimate the amount of consideration to which we will be entitled in exchange for transferring the goods to the customer. At contract inception, the variable consideration is estimated based on the most likely amount of consideration expected from the transaction and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. The estimated revenue is updated at each reporting date to reflect the current facts and circumstances.

If a contract with a customer contains more than one performance obligation, the transaction price is allocated to each performance obligation based on relative standalone selling prices.

For each separate performance obligation, it is evaluated whether control is transferred either at a point in time or over time. For performance obligations that are satisfied over time, revenue is recognized based on a measure of progress, which depicts the performance in transferring control to the customer. Under the terms of our licensing arrangements, we provide the licensee with a research and development license, which represents a right to access our intellectual property as it exists throughout the license period (as our intellectual property is still subject to further research). Therefore, the promise to grant a license is accounted for as a performance obligation satisfied over time as our customer simultaneously receives and consumes the benefits from our performance.

Earnings based on the collaboration partners' gross profit, which is shared under the respective collaboration agreements are recognized based on the sales-based or usage-based royalty exemption; i.e. when, or as, the underlying sales occur, which is when the performance obligation has been satisfied. As described further in Note 3, we use certain information from our collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available.

Revenue arrangements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations in order to determine the appropriate treatment for the transactions between us and the collaborator and the transactions between us and other third parties. The classification of transactions under such arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Any consideration related to activities in which we are considered the principal, which includes being in control of the good or service before such good or service is transferred to the customer, are accounted for as gross revenue. Any consideration related to activities in which we are considered the agent, are accounted for as net revenue.

Revenue from the sale of pharmaceutical and medical products (*e.g.* COVID-19 vaccine sales and other sales of peptides and retroviral vectors for clinical supply) is recognized when we transfer control of the product to the customer. Control of the product normally transfers when the customer gains physical possession and we have not retained any significant risks of ownership or future obligations with respect to the product. A receivable is recognized, as the consideration is unconditional and only the passage of time is required before payment is due. The transaction price is quoted in the relevant price lists in force at the date of customer placing the respective order for such products. In general, payments from customers are due within 30 days after invoice. However, with respect to our collaboration with Pfizer Inc., or Pfizer, a significant time span between when revenues are recognized and the payments are received exists. The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's fiscal quarter for subsidiaries outside the United States differs from ours, it creates an additional time lag between the recognition of revenues and the payment receipt.

Contract Balances

Contract Assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If we transfer goods or services to a customer before the customer pays the respective consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional.

Trade Receivables

A receivable represents our right to an amount of consideration that is unconditional (*i.e.*, only the passage of time is required before payment of the consideration is due).

Contract Liabilities

A contract liability is the obligation to transfer goods or services to a customer for which we have received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before we transfer goods or services to the customer, a contract liability is recognized when the payment is made or when the payment is due (whichever is earlier). Contract liabilities are recognized as revenue when we perform our performance obligations under the contract.

Refund Liabilities

A refund liability is a consideration which has been received but which will need to be refunded to the customer in the future as it represents an amount to which we are ultimately not entitled to under the contract. A refund liability is measured at the amount of consideration received (or receivable) for which we do not expect to be entitled (i.e., amounts not included in the transaction price). We update our estimates of refund liabilities (and the corresponding change in the transaction price) at the end of each reporting period.

2.3.5 Government Grants

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as other income on a systematic basis over the periods that the related costs, for which the grant is intended to compensate, are expensed. When the grant relates to an asset, it is recognized as deferred income within the consolidated statements of financial position. Other income is subsequently recognized in profit or loss over the useful live of the underlying asset subject to funding.

2.3.6 Taxes

Current Income Tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

In addition, current income taxes presented for the period include adjustments for uncertain tax payments or tax refunds for periods not yet finally assessed by tax authorities, excluding interest expenses and penalties on the underpayment of taxes. In the event that amounts included in the tax return are considered unlikely to be accepted by the tax authorities (uncertain tax positions), a provision for income taxes is recognized.

Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred Tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, the carry forward of unused tax credits and unused tax losses can be utilized, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year in which the asset is realized, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Recognition of Taxes

Current and deferred tax items are recognized similar to the underlying transaction either in profit or loss, other comprehensive income or directly in equity.

Current tax assets and current tax liabilities are offset if, and only if, we have a legally enforceable right to set off the recognized amounts and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously. Deferred tax assets and deferred tax liabilities are only offset when we have a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either (i) the same taxable entity or (ii) different taxable entities, which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Sales Tax

Expenses and assets are recognized net of sales tax, except when the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority.

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the consolidated statements of financial position.

2.3.7 Foreign Currencies

Our consolidated financial statements are presented in Euros, which is also our functional currency. For each entity, the Group determines the functional currency, and items included in the consolidated financial statements of such entities are measured using that functional currency. We use the direct method of consolidation and on disposal of a foreign operation, the gain or loss that is reclassified to the consolidated statements of profit or loss reflects the amount that arises from using this method.

Transactions and Balances

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

In determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which the Group initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of advance consideration.

Foreign Currency Translation

Foreign currency translation effects from the translation of operating activities include foreign exchange differences arising on operating items such as trade receivables and trade payables and are either shown as other operating income or expenses on a cumulative basis. Foreign currency translation effects presented within finance income and expenses include foreign exchange differences arising on financing items such as loans and borrowings as well as foreign exchange differences arising on cash and cash equivalents and are either shown as finance income or expenses on a cumulative basis.

Foreign Currency Translation on Consolidation

Upon consolidation, the assets and liabilities of foreign operations are translated into Euros at the rate of exchange prevailing at the reporting date and the transactions recorded in their consolidated statements of profit or loss are translated at exchange rates prevailing at the dates of the transactions.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is reclassified to profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising upon the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

2.3.8 Property, Plant and Equipment

Construction in progress is stated at cost. Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the property, plant and equipment if the recognition criteria are met. All other repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Property, plant and equipment	Useful life (years)
Buildings	10-33
Equipment, tools and installations	1-18

An item of property, plant and equipment initially recognized is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the consolidated statements of profit or loss when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year-end and adjusted prospectively, if appropriate.

2.3.9 Leases

At the inception of a contract, we assess whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. To assess whether a contract conveys the right to control the use of an identified asset, we assess whether:

- the contract involves the use of an identified asset—this may be specified explicitly or implicitly and should be physically distinct or represent substantially all of the capacity of a physically distinct asset. If the supplier has a substantive substitution right, then the asset is not identified;
- we have the right to obtain substantially all of the economic benefits from use of the asset throughout the period of use; and
- we have the right to direct the use of the asset. We possess this right when we hold the decision-making rights that are most relevant to changing how and for what purpose the asset is used. In rare cases where the decision about how and for what purpose the asset is used is predetermined, the Group has the right to direct the use of the asset if either:
    - we have the right to operate the asset; or
    - we designed the asset in a way that predetermines how and for what purpose it will be used.

At inception or on reassessment of a contract that contains a lease component, the consideration in the contract is allocated to each lease component on the basis of their relative standalone prices. However, for the leases of land and buildings in which it is a lessee, we have elected not to separate non-lease components, and instead accounts for the lease and non-lease components as a single lease component.

We recognize a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of the costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received by the Group.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset and the end of the lease term. The estimated useful lives of right-of-use assets are determined on the same basis as those of property and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the incremental borrowing interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the incremental borrowing rate is used as the discount rate.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments, including in-substance fixed payments;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as of the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that is reasonably certain to be exercised, lease payments in an optional renewal period if it is reasonably certain that the extension option is exercised, and penalties for early termination of a lease unless it is reasonably certain that the contract is not terminate early.

The lease liability is subsequently measured at amortized cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the estimate of the amount expected to be payable under a residual value guarantee, or if we change our assessment of whether we will exercise a purchase, extension or termination option. When the lease liability is remeasured, a corresponding adjustment is made to the carrying amount of the right-of-use asset or is recorded in the consolidated statements of profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

Right-of-use assets are presented separately and lease liabilities are presented in ‘‘Financial Liabilities” in the consolidated statements of financial position.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets or shorter lease term, as follows:

Right-of-use assets	Useful life or shorter lease term (years)
Buildings	2-25
Equipment, tools and installations	2-5
Production facilities	2-3
Automobiles	3-4

Short-Term Leases and Leases of Low-Value Assets

We have elected not to recognize right-of-use assets and lease liabilities for short-term leases of machinery that have a lease term of 12 months or less or leases of low-value assets. We recognize the lease payments associated with these leases as an expense in the consolidated statements of profit or loss on a straight-line basis over the lease term.

2.3.10 Intangible Assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is their fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses.

The useful lives of intangible assets are assessed as either finite or indefinite.

Intangible assets with finite lives are amortized generally on a straight-line basis over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are at least reviewed at the end of each reporting period. The amortization expense on intangible assets with finite lives is recognized in the consolidated statements of profit or loss in the expense category that is consistent with the function of the intangible assets.

A summary of the useful lives applied to the Group's intangible assets is as follows:

Intangible assets	Useful life (years)
Intellectual property rights	8-20
Licenses	3-20
Software	3-8

Intangible assets with indefinite useful lives are not amortized, but are tested for impairment at least annually, or when there is an indication for impairment, either individually or at the level of a cash-generating unit (see Note 2.3.13 for further details). The assessment of indefinite life is reviewed annually to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis.

We have classified advanced payments on intangible assets as intangible assets, which are not yet ready for use. Advanced payments on intangible assets are tested for impairment on an annual basis.

An intangible asset is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising upon derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the consolidated statements of profit or loss.

Research and Development Costs

Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, all of the following six criteria can be demonstrated:

- the technical feasibility of completing the intangible asset so that the asset will be available for use or sale;
- its intention to complete the project;
- the ability and intention to use or sell the asset;
- how the asset will generate future economic benefits;
- the availability of resources to complete the asset; and
- the ability to reliably measure the expenditure during development.

Due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, management has determined that these criteria are not met in the biotech sector until regulatory approval has been obtained. The related expenditure is reflected in the consolidated statements of profit or loss in the period in which the expenditure is incurred.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development is complete and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in cost of sales. During the period of development, the asset is tested for impairment annually.

2.3.11 Financial Instruments—Initial Recognition and Subsequent Measurement

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

i) Financial Assets

Initial Recognition and Measurement

Financial assets mainly include trade receivables, cash and cash equivalents, cash deposits with an original term of six months recognized as other financial assets as well as equity investments. Financial assets are initially measured at fair value and – depending on their classification – subsequently measured at amortized cost, fair value through other comprehensive income (OCI) or fair value through profit or loss.

Subsequent Measurement

The measurement of financial assets depends on their classification, as described below.

Trade and Other Receivables

With respect to trade receivable, we applied the practical expedient which means that they are measured at the transaction price determined under IFRS 15. Refer to the accounting policies in Note 2.3.4. Other financial assets are measured at amortized costs since they are held to collect contractual cash flows, which are solely payments of principal and interest. Gains and losses are recognized in profit or loss when the financial asset is derecognized, modified or impaired.

Financial Assets designated at Fair Value through OCI (Equity Instruments)

Upon initial recognition, we can irrevocably elect to classify equity investments as equity instruments designated at fair value through OCI when they meet the definition of equity under IAS 32 and are not held for trading. The classification is determined on an instrument-by-instrument basis. Gains and losses on these financial assets are never recycled to profit or loss. Dividends are recognized as other income in the statement of profit or loss when the right of payment has been established. Equity instruments designated at fair value through OCI are not subject to impairment assessment. We elected to irrevocably classify our non-listed equity investments under this category.

Derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (i.e., removed from the consolidated statements of financial position) when the rights to receive cash flows from the asset have expired or have been transferred in terms of fulfilling the derecognition criteria.

Impairment of Financial Assets

An allowance for expected credit losses (ECLs) is considered for all debt instruments of the Group. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all of the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

For trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. We have established a provision matrix that is based on our historical credit loss experience, which implies that expected credit losses are only recorded as far as actual historical credit losses have incurred, adjusted for forward-looking factors specific to the debtors and the economic environment and differentiates between customer groups and geographic regions.

ii) Financial Liabilities

Initial Recognition and Measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings or as payables.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

Financial liabilities include trade payables and other financial liabilities.

Subsequent Measurement

The measurement of financial liabilities depends on their classification, as described below.

Financial Liabilities at Fair Value through Profit or Loss

Financial liabilities at fair value through profit or loss include the embedded derivative, which was bifurcated from the convertible note, as host contract, and is recognized as a separate financial instrument until it is extinguished upon conversion. Furthermore, foreign exchange forward contracts not designated as hedging instruments are recognized as derivatives at fair value through profit or loss. Financial liabilities at fair value further include contingent considerations resulting from business combinations.

Gains or losses arising from fair value measurement adjustments of the embedded derivative, the derivatives not designated as hedging instruments and the contingent consideration are recognized in profit and loss within the consolidated statements of profit or loss.

Loans, Borrowings, Trade Payables and Other Financial Liabilities

After initial recognition, loans and borrowings, trade payables and other financial liabilities are subsequently measured at amortized cost using the effective interest rate (EIR) method. Gains and losses are recognized in the consolidated statements of profit or loss when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the consolidated statements of profit or loss.

This category generally applies to loans and borrowings.

Derecognition

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the

terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognized in the consolidated statements of profit or loss.

2.3.12 Inventories

Inventories are valued at the lower of cost and net realizable value.

Costs incurred in bringing each product to its present location and condition are accounted for as follows:

- raw materials and supplies: purchase cost on a first-in / first-out basis; or
- unfinished goods and finished goods: cost of direct materials and labor, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs, and a proportion of manufacturing overheads based on the normal operating capacity, but excluding borrowing costs.

Net realizable value is the estimated selling price in the ordinary course of business less estimated costs of completion and the estimated costs necessary to make the sale. Write-offs are recorded if inventories do not fulfill the specification defined by our quality standards or if its shelf-life has expired.

2.3.13 Impairment of Non-Financial Assets

At each reporting date, we assess whether there is an indication that a non-financial asset may be impaired. Goodwill is tested for impairment at least annually as of October 1. Impairment is determined for goodwill by assessing the recoverable amount of each cash generating unit (or group of CGUs) to which the goodwill relates. If any indication exists, or when annual impairment testing is performed, we estimate the asset's or CGU's recoverable amount. The recoverable amount is the higher of an asset's or CGU's fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. In case the asset is not generating independent cash inflows the impairment test is performed for the smallest group of assets that generate largely independent cash inflows from other assets (CGU). When the carrying amount of an asset or cash generating unit exceeds its recoverable amount, the asset or the non-current assets of the CGU are considered impaired and written down to their recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs of disposal, recent market transactions and our market capitalization are taken into account.

If a value in use is determined it is based on detailed budgets and forecast calculations, which are prepared separately for each of our cash generating units to which the individual assets are allocated. These budgets and forecast calculations generally cover a period of at least five years. A long-term growth rate is calculated and applied to project future cash flows after the last year of the detailed planning period.

Impairment losses are recognized in the consolidated statements of profit or loss in expense categories consistent with the function of the impaired asset.

For assets excluding goodwill, an assessment is made at each reporting date to determine whether there is an indication that previously recognized impairment losses no longer exist or have decreased. If such indication exists, the asset's or cash generating unit's recoverable amount is estimated. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the consolidated statements of profit or loss unless the asset is carried at a revalued amount, in which case, the reversal is treated as a revaluation increase.

2.3.14 Cash and Cash Equivalents

Cash and cash equivalents comprise cash at banks and on hand and short-term highly liquid deposits with an original maturity of three months or less, that are readily convertible to a known amount of cash and subject to an insignificant risk of changes in value. Deposits with an original maturity of more than three months are recognized as other financial assets.

2.3.15 Provisions

Provisions are recognized when there is a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When we expect some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain. The expense relating to a provision is presented in the consolidated statements of profit or loss net of any reimbursement.

2.3.16 Share-Based Payments

Employees (and others providing similar services) receive remuneration in the form of share-based payments, which are settled in equity instruments (equity-settled transactions) or in cash (cash-settled transactions).

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model, further details of which are given in Note 17. The cost of cash-settled transactions is determined by the fair value that is remeasured until settlement date.

These costs are recognized in cost of sales, research and development expenses, sales and marketing expenses or general and administrative expenses, together with a corresponding increase in equity (other reserves) or other liabilities, over the period in which the service is provided (the vesting period). The cumulative expense recognized for cash- and equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired. With respect to equity-settled transactions it also reflects the best estimate of the number of equity instruments that will ultimately vest.

2.4 Standards Applied for the First Time

In 2021, the following potentially relevant new and amended standards and interpretations became effective, but did not have an impact on our consolidated financial statements:

Standards / Interpretations	Date of application
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16: Interest Rate Benchmark Reform – Phase 2	January 1, 2021
Amendment to IFRS 16 Leases: Covid 19-Related Rent Concessions beyond 30 June 2021	April 1, 2021

2.5 Standard Issued but Not Yet Effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the financial statements and that might have an impact on our financial statements are disclosed below. We have not early adopted any standards and intend to adopt these new and amended standards and interpretations, if applicable, when they become effective.

Standards / Interpretations	Date of application
Amendments to IFRS 3 Business Combinations: Reference to the Conceptual Framework	January 1, 2022
Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets: Onerous Contracts – Cost of Fulfilling a Contract Amendments to IAS 37	January 1, 2022
Amendments to IAS 16 Property, Plant and Equipment: Proceeds before Intended Use	January 1, 2022
Annual Improvements to IFRS Standards 2018-2020	January 1, 2022
IFRS 17 Insurance Contracts (issued on May 18, 2017)	January 1, 2023
Amendments to IFRS 17 Insurance Contracts	January 1, 2023
Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-Current	January 1, 2023
Amendments to IAS 1 and IFRS Practice Statement 2: Disclosure of Accounting Policies	January 1, 2023
Amendments to IAS 8 Accounting policy changes: Definition of Accounting Estimates	January 1, 2023
Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023

We do not expect a significant impact of the application of any of these amendments.

3 Significant Accounting Judgments, Estimates and Assumptions

The preparation of the consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, the accompanying disclosures and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Significant accounting judgement as well as key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are described below. We based our assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Revenue from Contracts with Customers

We applied the following judgments, estimates and assumptions that significantly affect the determination of the amount and timing of revenue from contracts with customers:

Identification and Determination of Performance Obligations

We generate revenues from collaboration and license agreements, which contain multiple elements, including licenses to use, research, develop, manufacture and commercialize candidates and products, research and development services as well as obligations to develop and manufacture preclinical and clinical material and products. We determined that those collaboration and license agreements qualify as contracts with customers. At inception of each agreement, we apply judgment when determining which promises represent distinct performance obligations. If promises are not distinct, they are combined until the bundle of promised goods and services is distinct. For some agreements, this results in accounting for goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress. For these combined performance obligations, we assess which of these promises is the predominant promise to determine the nature of the performance obligation. When licenses are granted, we determined that the grant of the license is the predominant promise within the combined performance obligations. It is assessed that we grant our customers a right to access or a right to use our intellectual property due to the collaboration and license agreements.

Measurement of the Transaction Price

Our collaboration and license agreements often include variable considerations, which are contingent on the occurrence or non-occurrence of a future event *(i.e.*, reaching a certain milestone). When determining deferred revenues of a collaboration and license agreement, we need to estimate the amount of consideration to which we will be entitled in exchange for transferring the promised goods or services to our customers.

As there are usually only two possible outcomes (*i.e.*, milestone is reached or not), we have assessed that the method of the most likely amount is the best method to predict the amount of consideration to which we will be entitled. At contract inception, the most likely amount for milestone payments is estimated to be zero. We have assessed that the likelihood of achieving the respective milestone decreases depending on how far the expected date of achieving the milestone lies in the future. At each reporting date, we use judgment to determine when to include variable consideration in the transaction price, such that it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. We have concluded that future milestone payments are fully constrained at the end of the current fiscal year.

Future milestone payments would become unconstrained at the satisfaction of the milestone event, specifically a development event, a regulatory approval or achievement of a sales milestone.

Allocation of the Transaction Price to Performance Obligations and Revenue Recognition as Performance Obligations are Satisfied

We allocate the transaction price to performance obligations based on their relative standalone selling prices, which are generally based on our best estimates and interpretations of facts and circumstances of each contractual agreement and may require significant judgment to determine appropriate allocation.

Upfront payments and reimbursement for expenses are initially deferred on our consolidated statements of financial position. We assessed that no significant financing component exists within our collaboration agreements since the overall business purpose of advanced payments is to support the payment structure other than to provide a significant benefit of financing. For performance obligations in which the costs vary based on progress, an input-based measure considering cost incurred depicts most reliably the progress of the related research activities. In other cases, revenue recognition on a straight-line basis may most reliably depict our performance toward complete satisfaction. If the contractual activities progress, the achievement of development milestones will be used to measure the progress toward complete satisfaction. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net loss in the period of adjustment.

Upon successfully commercializing a pharmaceutical product, the collaboration and license agreements also provide for additional profit-sharing or tiered royalties earned when customers recognize net sales of licensed products as well as sales milestone payments. Revenue is recognized based on the sales-based or usage-based royalty exemption; *i.e.* when, or as, the underlying sales occur, which is when the performance obligation has been satisfied.

Principal-Agent Considerations

Collaboration agreements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations. Under our current collaboration agreements, the allocation of marketing and distribution rights defines territories in which the collaboration partner acts as a principal respectively. We recognize revenue net based on the collaboration partners' gross profit in territories where the partner is responsible for supply and on a gross basis when directly supplying our customers in our territories when control has been transferred. Amounts paid to collaboration partners for their share of our profits earned where we are the principal in the transaction are recorded as cost of sales.

Pfizer Agreement Characteristics

With respect to our collaboration with Pfizer, commercial revenue is recognized based on our collaboration partners' gross profit from COVID-19 vaccine sales, which is shared under the respective collaboration agreement. In determining commercial revenue pursuant to this collaboration agreement, we are reliant on our collaboration partner for detail regarding its gross profit for the period at hand. Certain of the information which our collaboration partner provides us with to identify the gross profit are, by necessity, preliminary and subject to change. This is mainly due to the fact that our

partner's financial reporting cycle differs from ours. Pfizer's subsidiaries outside the United States have a fiscal year-end of November 30; hence the Pfizer Quarter is equal to the Calendar Quarter with respect to the U.S. territory but is deferred by one month with respect to the territories outside the United States. This implies that the details on sales are required by us in advance of Pfizer closing the respective reporting periods. As a result, our determination of our share of such gross profit especially for this last month of the calendar cycle needs to be estimated for the purposes of recognizing revenues and is subject to the risk that amounts reported might vary from actual amounts reported once our collaboration partner's final financial results are available.

Pfizer's gross profit shares are calculated based on sales and include consideration of transfer prices. The latter includes manufacturing and shipping costs, which represent standard prices and include mark-ups on manufacturing costs as specified by the terms of the agreement. Manufacturing and shipping cost variances were considered as far as those have been identified. Nevertheless, those input parameters may be adjusted once actual costs are determined. The sales as reported by Pfizer for the Pfizer quarter, as well as sales preliminary reported for last month of the calendar quarter and territories outside the United States have been used to estimate license obligations in terms of royalties and sales milestones. Sales milestones and royalties are recognized as they are earned by the partners. Sales milestones are shared equally, while royalty payments are shared on the basis of revenue in the territories for which the partners are responsible. The estimated royalty fees applied to net sales reflect the license obligations to the extent currently identified from third party contractual arrangements. Changes in estimates are accounted for prospectively, when determined.

These estimated figures are likely to change prospectively in future periods as we receive final data from Pfizer. Those changes in our share of the collaboration partner's gross profit will be recognized prospectively as changes to our commercial revenues. To the extent that Pfizer does not provide such preliminary information in the future, our provisional sales figures for territories outside of the United States will be subject to a greater level of estimation and judgment.

Historically, adjustments to these estimates to reflect actual results or updated expectations, have not been material to our overall business. The adjustment to the estimated amounts as of December 31, 2020, which was recorded during the three months ended March 31, 2021 was 5% of revenues and the extent of the adjustments decreased throughout the year ended December 31, 2021 (i.e., adjustments were between 1% and 3% of revenues with respect to the first three quarters during 2021).

Pfizer's determination of manufacturing and shipping costs also affects the transfer prices that have been charged to COVID-19 vaccine supplies that it manufactures and supplies to us and may be subject to adjustment whenever manufacturing and shipping cost variances are identified. Likewise, our own cost of sales and the respective gross profit share owed to our partner may be adjusted prospectively, when changes are determined.

For the carrying amounts of the revenue recognition-related contract balances, see Note 6.

Research and Development Expenses

The nature of our business and primary focus of our activities, including development of our platforms and manufacturing technologies, generate a significant amount of research and development expenses. Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, the capitalization criteria are met. We have entered into agreements under which third parties grant licenses to us. If those licenses grant access to technologies, both parties jointly perform research or development activities and both are exposed to significant risks and rewards of the activities, costs incurred with the agreements are not treated differently from costs related to own product candidates. If the agreements grant us rights to use certain patents and technologies that meet the definition of an identifiable assets, they are treated as acquired intangible assets. Due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, management has determined that these criteria are not met before regulatory approval is achieved. The related expenditure is reflected in the consolidated statements of profit or loss in the period in which the expenditure is incurred. Sales-based milestone or royalty payments incurred under license agreements relating to self-developed intangibles after the approval date of the respective pharmaceutical product are recognized as expenses as incurred. Prior to initial regulatory approval, costs relating to production of pre-launch products are expensed as research and development expenses in the period incurred. If pre-launch products are sold, the respective product gross margin may be higher compared to the expected recurring margin as the underlying costs will not be included in cost of sales.

Business Combinations

The allocation of the purchase price for business acquisitions to the identifiable assets acquired and liabilities assumed based on their respective fair values, requires use of accounting estimates and judgment. Acquired intangible assets are valued using valuation models such as the Multi Period Excess Earnings Method under which fair values are derived from future net cash flows, which are discounted to the acquisition date using an appropriate discount factor. We have estimated fair values of assets acquired, liabilities assumed and contingent considerations based on reasonable assumptions. We continue to collect information and reevaluate these provisional estimates and assumptions in accordance with IFRS 3. Any adjustments to these provisional estimates and assumptions are recorded against goodwill provided they arise within the measurement period. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the consolidated statements of profit or loss.

For further disclosures relating to business combinations, see Note 5.

Share-Based Payments

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions. We used valuation models like a binomial or Monte-Carlo simulation model for the measurement of the cash- and equity-settled transactions' fair value considering certain assumption relating to, *e.g.*, the volatility of stock price, the determination of an appropriate risk-free interest rate, expected dividends and the probability of reaching a minimum hurdle to exercise the relevant options. For awards which were granted prior to the initial public offering, at a time where no quoted market prices existed, the valuation model assumptions included the option's underlying share price. For awards which were granted post the initial public offering, the grant date's share prices on the Nasdaq Global Select Market were included in the valuation.

For further disclosures relating to share-based payments, see Note 17.

Embedded Derivatives

Defining the fair value of the embedded derivative which was bifurcated from the convertible note, as host contract, requires significant judgment. We used the Cox-Rubinstein binomial tree model when determining the fair value of the conversion right, the embedded derivative which was bifurcated from the convertible note, as host contract. The primary inputs used in the model include stock price volatility, credit spreads, risk-free interest rate and foreign exchange forward rates. Stock price volatility is based on our implied volatility, credit risk is model implied and adjusted for movement in credit spreads for B-rated corporates at each valuation date, the risk-free interest rate is based on currency specific time congruent IBOR and swap rates whereas the foreign exchange forward rates are based on observable market data.

For further disclosures relating to financial instruments, see Note 12.

Income Taxes

We are subject to income taxes in more than one tax jurisdictions. Due to the increasing complexity of tax laws and the corresponding uncertainty regarding the legal interpretation by the fiscal authorities, tax calculations are generally subject to an elevated amount of uncertainty. To the extent necessary, possible tax risks are taken into account in form of provisions.

We do not recognize or impair deferred tax assets when it is unlikely that a corresponding amount of future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized. When determining whether sufficient future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized, significant management judgment is required. This includes management's assessment on the character and amounts of taxable future profits, the periods in which those profits are expected to occur, and the availability of tax planning opportunities. As a matter of policy, convincing evidence supporting the recognition of deferred tax assets is required if an entity has suffered a loss in either the current or the preceding periods.

As of December 31, 2021, our management continued to determine that deferred tax assets on tax losses carried forward that relate to subsidiaries which have a loss making history cannot be recognized. This includes the assessment that those subsidiaries neither have any taxable temporary difference nor any tax planning opportunities available that could support the recognition of deferred tax assets.

For further disclosures relating to deferred taxes, see Note 8.

4 Group Information

Information about Subsidiaries

The consolidated financial statements include the following subsidiaries:

			% equity interest	
Name	**Country of incorporation**	**Registered office**	**December 31, 2021**	**December 31, 2020**
BioNTech Cell & Gene Therapies GmbH	Germany	Mainz	100 %	100 %
BioNTech Delivery Technologies GmbH	Germany	Halle	100 %	100 %
BioNTech Diagnostics GmbH	Germany	Mainz	100 %	100 %
BioNTech Europe GmbH	Germany	Mainz	100 %	100 %
BioNTech Innovation GmbH (in establishment)	Germany	Mainz	100 %	n/a
BioNTech Innovative Manufacturing Services GmbH	Germany	Idar-Oberstein	100 %	100 %
BioNTech Manufacturing GmbH	Germany	Mainz	100 %	100 %
BioNTech Manufacturing Marburg GmbH	Germany	Marburg	100 %	100 %
BioNTech RNA Pharmaceuticals GmbH	Germany	Mainz	n/a[1]	100 %
BioNTech Innovation and Services Marburg GmbH (previously BioNTech Services Marburg GmbH)	Germany	Marburg	100 %	n/a
JPT Peptide Technologies GmbH	Germany	Berlin	100 %	100 %
reSano GmbH	Germany	Mainz	100 %	100 %
BioNTech Real Estate Holding GmbH	Germany	Holzkirchen	100 %	100 %
BioNTech Real Estate Verwaltungs GmbH	Germany	Holzkirchen	100 %	100 %
BioNTech Real Estate GmbH & Co. KG	Germany	Holzkirchen	100 %	100 %
BioNTech Real Estate An der Goldgrube GmbH & Co. KG	Germany	Holzkirchen	100 %	100 %
BioNTech Real Estate Haus Vier GmbH & Co. KG	Germany	Holzkirchen	100 %	100 %
BioNTech Real Estate Adam Opel Straße GmbH & Co. KG	Germany	Holzkirchen	100 %	100 %
BioNTech Real Estate an der Goldgrube 12 GmbH & Co. KG	Germany	Holzkirchen	100 %	n/a
BioNTech Austria Beteiligungen GmbH	Austria	Vienna	n/a[2]	100 %
BioNTech R&D (Austria) GmbH (previously PhagoMed Biopharma GmbH)	Austria	Vienna	100 %	n/a
BioNTech (Shanghai) Pharmaceuticals Co. Ltd.	China	Shanghai	100 %	n/a
BioNTech Pharmaceuticals Asia Pacific Pte. Ltd.	Singapore	Singapore	100 %	100 %
BioNTech Turkey Tıbbi Ürünler Ve Klinik Araştirma Ticaret Anonim Şirketi	Turkey	Istanbul	100 %	n/a
BioNTech UK Limited	United Kingdom	Reading	100 %	100 %
BioNTech Research and Development, Inc.	United States	Cambridge	100 %	100 %
BioNTech USA Holding, LLC	United States	Cambridge	100 %	100 %
BioNTech US Inc.	United States	Cambridge	100 %	100 %
JPT Peptide Technologies Inc.	United States	Cambridge	100 %	100 %

(1) BioNTech RNA Pharmaceuticals GmbH was merged onto BioNTech SE.

(2) BioNTech Austria Beteiligungen GmbH was liquidated in June 2021.

Parent Company

ATHOS KG, Holzkirchen, Germany is the sole shareholder of AT Impf GmbH, Munich, Germany and beneficial owner of the following percentage of ordinary shares in BioNTech at the dates as indicated. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which enabled it to exercise the majority of voting rights to pass resolutions at our Annual General Meeting, or AGM.

Name	Country of incorporation	Registered office	Ownership of ordinary shares in BioNTech (in %) December 31, 2021	December 31, 2020
AT Impf GmbH	Germany	Munich	43.75 %	47.37 %

Entity with significant Influence over the Group

Medine GmbH, Mainz owned the following percentage of ordinary shares in BioNTech at the following dates as indicated:

Name	Country of incorporation	Registered office	Ownership of ordinary shares in BioNTech (in %) December 31, 2021	December 31, 2020
Medine GmbH	Germany	Mainz	17.11 %	17.25 %

5 Business Combinations

Business Combinations during the year ended December 31, 2021

BioNTech R&D (Austria) GmbH, or BioNTech Austria (previously PhagoMed Biopharma GmbH)

On October 1, 2021, BioNTech Austria, an Austrian biotechnology company, specialized in the development of a new class of antibacterials, was fully acquired to expanded our infectious disease portfolio capabilities.

The total consideration comprised an upfront consideration of €50.0 million (less acquired debt) of which €23.2 million are considered remuneration and will be recognized as personnel expense over a three-year period in which services are to be provided. An additional consideration of maximum €100.0 million is dependent the achievement of certain clinical development milestones. At the acquisition date, the contingent consideration was recognized with its fair value of €5.5 million and is presented as non-current financial liabilities in the consolidated statements of financial position (see Note 12).

The acquisition of PhagoMed was accounted for as a business combination using the acquisition method of accounting.

The final fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech Austria as at the date of acquisition were as follows:

(in millions)	**Fair value recognized on acquisition** BioNTech R&D (Austria) GmbH
Assets	
Intangible assets	€43.3
Other assets non-current and current	1.5
Total assets	**€44.8**
Liabilities	
Other liabilities non-current and current	15.4
Total liabilities	**€15.4**
Total identifiable net assets at fair value	**€29.4**
Bargain purchase	(2.2)
Consideration transferred	**€27.2**
Consideration	
Cash paid	21.7
Contingent consideration liability	5.5
Total consideration	**€27.2**

(in millions)	BioNTech R&D (Austria) GmbH
Transaction costs of the acquisition (included in cash flows from operating activities)	€(0.5)
Net cash acquired (included in cash flows used in investing)	0.9
Cash paid (included in cash flow used in investing activities)	(21.7)
Net cash flow on acquisition	**€(21.3)**

The intangible assets comprise a pre-clinical candidate, PM-477 as well as a platform.

A bargain purchase of €2.2 million was recognized in other operating income.

The consolidated statements of profit or loss include the results of BioNTech Austria since the acquisition date. From the date of acquisition through December 31, 2021, BioNTech Austria did not have any significant impact onto the operating income or the revenues of the Group. The same applies if the transaction had occurred at the beginning of the reporting period.

Business Combinations during the year ended December 31, 2020

During the year ended December 31, 2020, the following material business combinations occurred.

BioNTech US Inc. (previously Neon Therapeutics, Inc., or Neon)

On May 6, 2020, we acquired Neon, a biotechnology company developing novel neoantigen-based T-cell therapies, to leverage Neon's expertise in the development of neoantigen therapies, with both vaccine and T cell capabilities.

Based on the acquisition date share price, the aggregate value of the merger consideration was €89.9 million ($97.1 million) financed by issuing 1,935,488 American Depositary Shares representing our ordinary shares as a stock transaction and including a de minimis cash consideration which was paid to settle Neon's outstanding stock options.

The fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech US Inc. as at the date of acquisition were as follows:

(in millions)	**Fair value recognized on acquisition** BioNTech US Inc.
Assets	
Intangible assets	€29.9
Property, plant and equipment	5.6
Right-of-use assets	6.9
Other assets non-current and current	2.7
Cash and cash equivalents	7.7
Total assets	**€52.8**
Liabilities	
Trade payables	1.7
Other liabilities non-current and current	17.8
Total liabilities	**€19.5**
Total identifiable net assets at fair value	**€33.3**
Goodwill from the acquisition	56.6
Consideration transferred	**€89.9**
Consideration	
Shares issued, at fair value	€89.5
Cash paid	€0.4
Total consideration	**€89.9**

The intangible assets comprise two neoantigen targeted therapies, BNT221 (NEO-PTC-01) and BNT222 (NEO-STC-01), which were identified and recorded as in-process R&D.

Deferred tax liabilities relating to temporary differences of the assets acquired in the business combination were recognized at an amount of €8.0 million. To the extent of those deferred tax liabilities assumed, deferred tax assets relating to temporary differences and tax loss carryforwards which existed as of the acquisition date were recognized. Since the conditions to offset were fulfilled, the deferred tax assets and liabilities were offset.

The consolidated statements of profit or loss included the results of BioNTech US since the acquisition date. From the date of acquisition through December 31, 2020, BioNTech US contributed €28.5 million operating loss to our respective result. If the transaction had occurred at the beginning of the reporting period, €59.8 million would have contributed to the operating loss. This amount includes expenses resulting from the merger and should not necessarily be considered representative of the future consolidated results of profit or loss or financial condition on a consolidated basis. From the date of acquisition, BioNTech US did not generate any revenue and no revenue would have been generated if the transaction had occurred at the beginning of the reporting period.

Goodwill recognized is primarily attributable to the expected synergies and other benefits from combining two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer

immunotherapy as described above. The goodwill resulting from the BioNTech US acquisition during the year ended December 31, 2020, was allocated to the CGU immunotherapies.

Transaction costs of €1.1 million relating to the acquisition were expensed and included in the general and administrative expenses in the consolidated statements of profit or loss. In the consolidated statements of cash flows they were included in cash flows used in operating activities. The attributable costs of the issuance of the shares of €1.3 million were recorded in equity as a deduction from the capital reserve and are included in cash flows from financing activities in the consolidated statements of cash flows.

BioNTech Manufacturing Marburg GmbH (previously Novartis Manufacturing GmbH)

On October 31, 2020, Novartis Manufacturing GmbH was acquired, a manufacturing facility in Marburg. Through the acquisition, we planned to produce our COVID-19 vaccine for global supply.

The fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech Manufacturing Marburg GmbH, or BioNTech Marburg, as at the date of acquisition were as follows:

(in millions)	**Fair value recognized on acquisition** BioNTech Manufacturing Marburg GmbH
Assets	
Property, plant and equipment	€79.8
Right-of-use assets	28.5
Inventories	2.4
Other assets non-current and current	4.3
Cash and cash equivalents	16.5
Total assets	**€131.5**
Liabilities	
Provisions non-current and current	5.1
Trade payables	8.1
Other liabilities non-current and current	33.4
Total liabilities	**€46.6**
Total identifiable net assets at fair value	**€84.9**
Bargain purchase	(7.0)
Consideration transferred	**€77.9**
Consideration	
Cash paid	€77.9
Total consideration	**€77.9**

The consolidated statements of profit or loss included the results of BioNTech Marburg since the acquisition date. From the date of acquisition, the transition into a GMP certified manufacturing facility for our COVID-19 vaccine was initiated rapidly. During this time, no revenues had been recognized and set-up, retooling and prepping expenses led to a €6.7 million operating loss, which contributed to our respective result. Projecting the revenues and result of the acquired company as if the acquisition had occurred at the beginning of the reporting period is impracticable, since BioNTech intends to use the facility for manufacturing its COVID-19 vaccine. Information about revenues and net income generated

by BioNTech Marburg before the acquisition were considered not to be useful as they are not representative of the future consolidated results of profit or loss or financial condition on a consolidated basis.

The contracting parties shared the understanding that the manufacturing facility is well-equipped to make an important contribution in our effort to develop and manufacture a COVID-19 vaccine. The possibility of acquiring a GMP certified manufacturing facility with well-established biotechnology drug substance and drug product manufacturing equipment as well as an experienced team was a very good opportunity for us to accelerate its efforts to scale-up the commercial manufacturing capacity for our COVID-19 vaccine production. The fact that the offer to sell and the need to acquire the facility overlapped at a convenient time, the underlying opportunities ultimately resulted in a bargain purchase of €7.0 million which was recognized in other operating income.

Transaction costs of €1.4 million relating to the acquisition were expensed and included in the general and administrative expenses in the consolidated statements of profit or loss and were included in cash flows used in operating activities in the consolidated statements of cash flows.

6 Revenues from Contracts with Customers

6.1 Disaggregated Revenue Information

Set out below is the disaggregation of the Group's revenues from contracts with customers:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Research & development revenues from collaborations	**€102.7**	**€178.8**	**€84.4**
Genentech Inc.	*45.9*	*49.2*	*64.0*
Pfizer Inc.	*43.4*	*121.6*	*14.3*
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	*7.4*	*5.1*	—
Other	*6.0*	*2.9*	*6.1*
Commercial revenues	**€18,874.0**	**€303.5**	**€24.2**
COVID-19 vaccine revenues	18,806.8	270.5	—
Sales to collaboration partners[1]	*970.9*	*61.4*	—
Direct product sales to customers	*3,007.2*	*20.6*	—
Share of collaboration partners' gross profit and sales milestones	*14,828.7*	*188.5*	—
Other sales	67.2	33.0	24.2
Total	**€18,976.7**	**€482.3**	**€108.6**

1) Represents sales to our collaboration partner of products manufactured by us.

Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Consequently, we have progressed from earning revenues primarily from research and development to earning revenues from commercial sales during the year ended December 31, 2021.

During the year ended December 31, 2021, revenues recognized from Pfizer Inc., or Pfizer (€15,500.0 million) and the German Federal Ministry of Health (€1,945.6 million), each account for more than 10% of total revenues. During the year ended December 31, 2020, revenues recognized from Pfizer (€371.5 million) and Genentech Inc., or Genentech (€49.2 million), each account for more than 10% of total revenues. During the year ended December 31, 2019, revenues recognized from Genentech (€64.0 million) and Pfizer (€14.3 million), accounted for more than 10% of total revenues. During the year ended December 31, 2021, based on the geographic region in which our customers and collaboration partners are located we mainly recognized revenues in the United States (€14,636.5 million) and Germany (€2,241.9 million). During the year ended December 31, 2020, the main geographic regions were United States (€381.9 million), Belgium (€56.2 million) and Germany (€31.7 million). During the year ended December 31, 2019, the main geographic regions were United States (€87.6 million) and Germany (€11.7 million).

Research and Development Revenues from Collaborations

During the year ended December 31, 2021, our collaborations with Genentech, Pfizer, Shanghai Fosun Pharmaceutical (Group) Co., Ltd, or Fosun Pharma, and other collaboration partners were progressed and respective research and development revenues were derived from deferred upfront payments as well as upon achieving development and regulatory milestones.

During the year ended December 31, 2021, our Influenza collaboration with Pfizer was progressed and research and development revenues of €43.4 million were derived from deferred upfront payments based on progress incurred and upon meeting certain development milestones. In comparison, during the year ended December 31, 2020, research and development revenues were mainly related to a non-refundable upfront cash payment of €66.3 million and a regulatory milestone payment of €51.7 million that became due based on our COVID-19 vaccine collaboration with Pfizer which was progressed to the commercial phase as well as €3.6 million incurred with respect to our Influenza collaboration with Pfizer.

As part of our BNT162 vaccine program against COVID-19, we are collaborating with Fosun Pharma to develop a COVID-19 vaccine in China. Upon receiving the authorization for emergency use and launching our COVID-19 vaccine in Hong Kong, development and regulatory milestones of €7.4 million have been achieved and recognized as research and development revenues during the year ended December 31, 2021. In comparison, during the year ended December 31, 2020, Fosun Pharma has paid a non-refundable upfront cash payment of €0.9 million and development milestones of €4.2 million that were recognized as revenues.

Other collaboration programs have been progressed during the year ended December 31, 2021, and revenues of €45.9 million under our collaboration with Genentech and €6.0 million under other collaborations have been derived from deferred upfront payments measured based on the costs incurred under the respective research programs. In comparison, during the year ended December 31, 2020, revenues of €49.2 million under our collaboration with Genentech and €2.9 million under other collaborations had been recognized.

The revenues recorded during the year ended December 31, 2019, mainly included revenues resulting from collaboration and license agreements processed in the research and development phase. The amounts were mainly derived from deferred upfront fees received under the Genentech, Pfizer (Influenza) and Sanofi collaboration. The amounts were recognized as revenues as we performed under the agreement and measured progress based on the costs or time incurred under the respective research programs.

Commercial Revenues

During the year ended December 31, 2021, commercial revenues increased due to the high demand for our COVID-19 vaccine. We are the marketing authorization holder in the United States, the European Union, the United Kingdom, Canada and other countries, and holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries, submissions to pursue regulatory approvals on those countries where emergency use authorizations or equivalent were initially granted are ongoing. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Turkey. Fosun Pharma has marketing and distribution rights in China, Hong Kong special administrative region, or SAR, Macau SAR and the region of Taiwan. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal.

Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and the COVID-19 vaccine is transferred, the vaccine is sold from one partner to the other. During the years ended December 31, 2021 and 2020, we recognized €970.9 million and €61.4 million of revenues, respectively, from selling drug product batches manufactured by us to our partners.

By supplying our territories during the years ended December 31, 2021 and 2020, we recognized €3,007.2 million and €20.6 million of revenues, respectively, from direct COVID-19 vaccine sales in Germany and Turkey. The share of gross profit that we owe our collaboration partner Pfizer based on our sales is recognized as cost of sales.

Based on COVID-19 vaccine sales in the collaboration partners' territories, we are eligible to receive a share of their gross profit which represents a net figure and is recognized as collaboration revenues during the commercial phase together with sales milestones that are recorded once the underlying thresholds are met. During the year ended December 31, 2021, €14,352.1 million gross profit share and €476.6 million of sales milestones have been recognized as revenues. During the year ended December 31, 2020, €188.5 million gross profit share has been recognized as revenues. In order to determine our share of our collaboration partners' gross profits, we used certain information from our collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available. The true-up recognized prospectively during the year ended December 31, 2021, with respect to the prior year was not material.

The revenues from contracts with customers disclosed above were recognized as follows:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Timing of revenue recognition			
Goods and services transferred at a point in time	€4,034.3	€108.8	€17.0
Goods and services transferred over time	14,942.4	373.5	91.6
Total	**€18,976.7**	**€482.3**	**€108.6**

6.2 Contract Balances

(in millions)	**December 31, 2021**	**December 31, 2020**
Trade and other receivables	€12,381.7	€165.5
Contract liabilities	195.1	371.5
Refund liabilities	90.0	—

Trade and other receivables significantly increased mainly due to the trade receivables from our COVID-19 collaboration with Pfizer as well as our own sales. The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's fiscal quarter for subsidiaries outside the United States differs from ours, it creates an additional time lag between the recognition of revenues and the payment receipt. Consequently, as of December 31, 2021, our trade receivables included in addition to the profit share for the fourth quarter of 2021, trade receivables which related to the gross profit share for the third quarter of 2021. The payment settling our gross profit share for the third quarter of 2021 (as defined by the contract) was received from our collaboration partner subsequent to the end of the reporting period in January 2022. From our trade receivables outstanding as of December 31, 2021, we had already collected €4,693.6 million in cash by January 16, 2022.

Contract liabilities mainly include upfront fees received from our major collaboration and license agreements as well as advance payments received for future COVID-19 vaccine sales and other sales. The contract liabilities from collaboration and commercial supply agreements as of December 31, 2021, comprise €61.9 million remaining upfront fees from collaboration agreements, €131.9 million of advance payments for future COVID-19 vaccine sales, which had been received during the year ended December 31, 2021, or for which an unconditional right of consideration exists (as of December 31, 2020: €131.7 million of remaining upfront fees from collaborations as well as €235.9 million of advance payments for future COVID-19 vaccine sales).

During the year ended December 31, 2021, the contract liabilities decreased as revenues were recognized from contract liabilities outstanding at the beginning of the year by fulfilling commercial performance obligations and progressing our research and development collaboration agreements (during the year ended December 31, 2020: increase in contract liabilities since payments received exceeded revenues recognized from contract liabilities recorded at the beginning of the year).

The refund liabilities relate to our collaboration with Fosun and represent consideration which has been received but which will need to be refunded to the collaboration partner.

Set out below is the amount of revenue recognized for the periods indicated:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Amounts included in contract liabilities at the beginning of the year	€73.7	€58.9	€84.1

6.3 Performance Obligations

The contract liabilities allocated to the remaining performance obligations from collaboration or commercial supply agreements (unsatisfied or partially unsatisfied) as at year-end are as follows:

(in millions)	December 31, 2021	December 31, 2020
Within one year	€186.1	€299.6
More than one year	9.0	71.9
Total	**€195.1**	**€371.5**

7 Income and Expenses

7.1 Costs of Sales

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Cost of sales related to COVID-19 vaccine revenues	€2,855.6	€35.6	€—
Cost related to other sales	55.9	23.7	17.4
Total	**€2,911.5**	**€59.3**	**€17.4**

During the year ended December 31, 2021, cost of sales increased compared to the year ended December 31, 2020, mainly due to recognizing cost of sales from our COVID-19 vaccine sales, which included the share of gross profit that we owe our collaboration partner Pfizer based on our sales.

7.2 Research and Development Expenses

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Purchased services	€572.6	€359.9	€65.6
Wages, benefits and social security expense	233.1	126.3	83.2
Laboratory supplies	53.8	107.8	37.2
Depreciation and amortization	32.9	30.2	27.5
Other	56.8	20.8	13.0
Total	**€949.2**	**€645.0**	**€226.5**

During the year ended December 31, 2021, research and development expenses increased compared to the year ended December 31, 2020, mainly due to increased research and development expenses from the BNT162 clinical trials launched and conducted in the year ended December 31, 2021, recorded as purchased services with respect to those expenses, which are initially incurred by Pfizer and subsequently charged to us under the collaboration agreement. The increase was further driven by an increase in wages, benefits and social security expenses resulting from an increase in headcount, recording expenses incurred under our share-based-payment arrangements as well as from recognizing inventor remuneration expenses.

During the year ended December 31, 2020, research and development expenses increased compared to the year ended December 31, 2019, mainly due to an increase in research and development expenses from our BNT162 program.

7.3 Sales and Marketing Expenses

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Purchased services	€26.5	€10.9	€0.2
Wages, benefits and social security expense	4.3	1.6	1.9
Other	19.6	2.0	0.6
Total	**€50.4**	**€14.5**	**€2.7**

During the year ended December 31, 2021, sales and marketing expenses increased compared to the year ended December 31, 2020, mainly due to an increase in purchased service which we incurred in connection with progressing our commercial activities with respect to our COVID-19 vaccine.

7.4 General and Administrative Expenses

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Wages, benefits and social security expense	€90.5	€33.0	€19.1
Purchased services	70.2	26.0	6.4
Insurance premiums	30.4	4.8	1.1
IT and office equipment	25.1	7.4	4.6
Depreciation and amortization	7.3	5.1	4.9
Other	62.3	17.7	9.4
Total	**€285.8**	**€94.0**	**€45.5**

During the year ended December 31, 2021, general and administrative expenses increased compared to the year ended December 31, 2020, mainly due to an increase in wages, benefits and social security expenses resulting from an increase in headcount and expenses incurred under the share-based-payment arrangements, increased expenses for purchased management consulting and legal services as well as higher insurance premiums caused by the increased business volume. Our M&A as well as our business development transactions also contributed to the increase in general and administrative expenses.

During the year ended December 31, 2020, general and administrative expenses increased compared to the year ended December 31, 2019, mainly influenced by higher expenses for purchased management consulting and legal services as well as an increase in headcount leading to higher wages, benefits and social security expenses and higher insurance premiums.

7.5 Other Operating Expenses

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Loss on derivative instruments at fair value through profit or loss	€86.3	€—	€—
Other	8.1	2.4	0.7
Total	**€94.4**	**€2.4**	**€0.7**

During the year ended December 31, 2021, the other expenses increased compared to the year ended December 31, 2020, mainly from recording the change in fair value of foreign exchange forward contracts that were entered into during the year ended December 31, 2021, to manage some of our foreign exchange exposures but were not designated as hedging instruments under IFRS.

7.6 Other Operating Income

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Foreign exchange differences, net	€446.3	€—	€—
Government grants	137.2	239.0	1.5
Income from derivative instruments at fair value through profit and loss	5.7	—	—
Bargain purchase	2.2	7.0	—
Other	7.0	4.5	1.2
Total	**€598.4**	**€250.5**	**€2.7**

During the year ended December 31, 2021, the other income increased compared to the year ended December 31, 2020, which was mainly due from recognizing foreign exchange differences and government grant funding. The foreign exchange differences included in operating income primarily arose from valuing our U.S. dollar denominated trade receivables which were mainly incurred under our COVID-19 collaboration with Pfizer, U.S. dollar denominated trade payables as well as U.S. dollar denominated other financial liabilities which mainly relate to obligations incurred from our license agreements.

The other operating income derived from government grants mainly relates to the government grant for which we became eligible during the year ended December 31, 2020, as part of an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the *BMBF*) to support our COVID-19 vaccine program, BNT162. The BMBF funding was granted to accelerate our vaccine development, to upscale manufacturing capabilities in Germany and compensate costs that incurred while continuing to test the COVID-19 vaccine in clinical trials. During the year ended December 31, 2021, the final drawdowns were made. Overall, during the years ended December 31, 2021 and 2020, €48.1 million and €326.9 million, respectively, were received in cash. The proportion of the grant that related to expenses incurred during the years ended December 31, 2021 and 2020, was recognized as other operating income with an amount of €136.1 million and €238.9 million, respectively.

The following table illustrates the changes regarding the government grants, including the government grant initiated by the BMBF:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
As of January 1	**€92.0**	**€—**	€—
Received during the year	48.2	331.0	1.5
Released to the consolidated statements of profit or loss	(137.2)	(239.0)	(1.5)
As of December 31	**€3.0**	**€92.0**	**€—**
Total current	3.0	92.0	—
Total non-current	—	—	—

The income from derivative instruments at fair value through profit and loss resulted from foreign exchange forward contracts that were entered into during the year ended December 31, 2021, to manage parts of our transactions' foreign exchange exposures but were not designated as hedging instruments under IFRS.

7.7 Finance Income

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Foreign exchange differences, net	€66.2	€—	€2.3
Interest income	1.5	1.6	1.8
Total	**€67.7**	**€1.6**	**€4.1**

During the year ended December 31, 2021, our finance income included €66.2 million foreign exchange gains. Foreign exchange differences on a cumulative basis, are either shown as finance income or expenses.

7.8 Finance Expenses

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Fair value adjustments of financial instruments measured at fair value	€277.8	€17.3	€—
Amortization of financial instruments	21.9	3.1	0.3
Interest expenses related to lease liabilities	2.9	2.0	1.7
Interest expenses related to financial assets	2.5	—	—
Foreign exchange differences, net	—	42.6	—
Total	**€305.1**	**€65.0**	**€2.0**

During the year ended December 31, 2021, the finance expenses increased compared to the year ended December 31, 2020, mainly due to increased expenses arising from fair value measurement adjustments of the derivative embedded within the convertible note from €17.3 million in 2020 to €277.8 million in 2021. The change in fair value was mainly driven by the increase in our share price and was recognized as finance expenses in our consolidated statements of profit or loss.

During the year ended December 31, 2021, finance expenses included €21.9 million amortization of financial instruments compared to €3.1 million in the prior year mainly due to the effective interest rate effect during the year ended December 31, 2021, derived from adjusting estimated future cash flows of our convertible note which will be redeemed early as of March 1, 2022. For further disclosures, see Note 12.

7.9 Employee Benefits Expense

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Wages and salaries	€345.9	€160.7	€98.7
Social security costs	31.7	17.9	12.3
Pension costs	1.2	0.8	0.5
Total	**€378.8**	**€179.4**	**€111.5**

Wages and salaries include, among other things, expenses for share-based payments.

8 Income Tax

Income tax for the years ended December 31, 2021, December 31, 2020, and December 31, 2019, comprised current income taxes, other taxes and deferred taxes. We are subject to corporate taxes, the solidarity surcharge and trade taxes. Our corporate tax rate in the reporting year remained unchanged (15.0%) as did the solidarity surcharge (5.5%) whereas the average trade tax rate changed resulting in a combined income tax rate of 30.72% in the year ended December 31, 2021 (during the years ended December 31, 2020 and 2019: 30.79% and 30.78%, respectively). Deferred taxes are calculated at a rate of 27.2% taking decreasing average trade tax rates in Mainz, Marburg and Idar-Oberstein from 2022 onwards into

consideration. Deferred taxes for Austria are calculated at a corporate tax rate of 25%. Austria's decrease of its corporate tax rate down to 23% in 2024 will be recognized from 2023 onwards. BioNTech USA Holding, LLC is subject to Federal Corporate Income Tax (21.0%) as well as State Income Tax in various state jurisdictions (average rate of 7.4%).

The following table illustrates the current and deferred taxes for the periods indicated:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Current income taxes	€4,535.0	€—	€(0.2)
Deferred taxes	218.9	(161.0)	—
Income taxes	**€4,753.9**	**€(161.0)**	**€(0.2)**

The following table reconciles the expected income taxes to the actual current income taxes and deferred taxes as presented in the table above. The expected income taxes were calculated using the combined income tax rates of BioNTech SE applicable to the Group and mentioned above which was applied to profit before taxes to calculate the expected income taxes.

	Years ended December 31,		
(in millions)	**2021**	**2020**[1]	**2019**[1]
Profit / (Loss) before tax	**€15,046.4**	**€(145.8)**	**€(179.4)**
Expected tax credit / (benefit)	€4,622.5	€(44.9)	€(55.2)
Effects			
Deviation due to local tax basis	9.1	0.6	0.1
Deviation due to deviating income tax rate (Germany and foreign countries)	9.4	1.3	0.1
Change in valuation allowance	3.0	(26.2)	(0.2)
Effects from tax losses	19.5	(90.4)	51.2
Change in deferred taxes due to tax rate change	(7.5)	—	—
Non-deductible expenses	90.5	0.8	0.1
Tax-free income	(0.3)	—	—
Non tax-effective share-based payment expenses	15.5	9.8	9.3
Tax-effective equity transaction costs	(1.2)	(10.2)	(5.1)
Adjustment prior year taxes	(2.9)	0.3	(0.3)
Non-tax effective bargain purchase	(0.7)	(2.2)	—
Other effects	(3.0)	0.1	(0.2)
Income taxes	**€4,753.9**	**€(161.0)**	**€(0.2)**
Effective tax rate	**31.6 %**	**n.m.**[2]	**n.m.**[2]

(1) Certain amounts have been combined in the prior period to conform with the current period presentation.

(2) The information is not meaningful due to the loss before tax in the respective periods.

Deferred Taxes

Deferred taxes for the periods indicated relate to the following:

Year ended December 31, 2021

(in millions)	**January 1, 2021**	**Recognized in P&L**	**Recognized in OCI**	**Acquisition of subsidiaries and businesses**	**December 31, 2021**
Fixed assets	€5.6	€(1.3)	€—	€(10.8)	€(6.5)
Right-of-use assets[1]	(30.0)	(17.5)	—	—	(47.5)
Inventories	1.0	0.8	—	—	1.8
Trade and other receivables	(3.0)	(92.6)	—	—	(95.6)
Lease liabilities[1]	25.4	23.3	—	—	48.7
Contract liabilities	23.4	(12.8)	—	—	10.6
Loans and borrowings	0.5	22.6	—	—	23.1
Net employee defined benefit liabilities	0.8	0.1	—	—	0.9
Other provisions	1.5	4.8	—	—	6.3
Other (incl. deferred expenses)	10.6	(9.0)	—	—	1.6
Tax losses / tax credits	175.7	(106.8)	—	2.0	70.9
Deferred tax assets / (liabilities), net (before valuation adjustment)	**€211.5**	**€(188.4)**	**€—**	**€(8.8)**	**€14.3**
Valuation adjustment	(50.5)	(30.5)	—	—	(81.0)
Deferred tax assets / (liabilities), net (after valuation adjustment)	**€161.0**	**€(218.9)**	**€—**	**€(8.8)**	**€(66.7)**

Year ended December 31, 2020

(in millions)	**January 1, 2020**	**Recognized in P&L[2]**	**Recognized in OCI**	**Acquisition of subsidiaries and businesses**	**December 31, 2020**
Fixed assets	€(0.7)	€(2.4)	€—	€8.7	€5.6
Right-of-use assets[1]	(16.9)	(3.4)	—	(9.7)	(30.0)
Inventories	0.6	—	—	0.4	1.0
Trade and other receivables	—	(3.0)	—	—	(3.0)
Lease liabilities[1]	17.4	(1.7)	—	9.7	25.4
Loans and borrowings	—	0.3	—	0.2	0.5
Contract liabilities	23.5	(0.1)	—	—	23.4
Net employee defined benefit liabilities	—	0.2	(0.1)	0.7	0.8
Other provisions	0.2	0.9	—	0.4	1.5
Other (incl. deferred expenses)	2.1	8.3	—	0.2	10.6
Tax losses / tax credits	109.8	41.6	—	24.3	175.7
Deferred tax assets net (before valuation adjustment)	**€136.0**	**€40.7**	**€(0.1)**	**€34.9**	**€211.5**
Valuation adjustment	(136.0)	120.3	—	(34.8)	(50.5)
Deferred tax assets net (after valuation adjustment)	**€—**	**€161.0**	**€(0.1)**	**€0.1**	**€161.0**

(1) Presentation has been adjusted to present right-of-use assets and lease liabilities as well as trade and other receivables separately.

(2) Includes all changes in deferred taxes related to U.S. tax group other than those acquired in business combination.

As of December 31, 2021, our accumulated tax losses comprised tax losses of German entities not within the tax group (as of December 31, 2021: BioNTech Innovation and Services Marburg GmbH, BioNTech Innovation GmbH i.G., BioNTech Real Estate Verwaltungs GmbH and the Real Estate partnerships; as of December 31, 2020: reSano GmbH, BioNTech Manufacturing Marburg GmbH, BioNTech Real Estate Verwaltungs GmbH and the Real Estate partnerships) and U.S. tax group. Up until the year ended December 31, 2020, our accumulated tax losses comprised also those of the German tax group. Our accumulated tax losses for the periods indicated amounted to the following:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Corporate tax	€272.0	€596.4	€356.0
Trade tax	170.6	513.6	352.3

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Federal tax credits	€4.0	€0.8	€—
State tax credits	1.6	0.3	—

Up until the year ended December 31, 2020, deferred tax assets on tax losses had not been recognized as there was not sufficient probability in terms of IAS 12 that there would have been future taxable profits available against which the unused tax losses could have been utilized.

Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, which resulted in recognition of revenues from the commercial sale of pharmaceutical products for the first time. Therefore as of December 31, 2020, it was considered highly probable that taxable profits for the German tax group would be available against which the tax losses could be utilized. On this basis, we had recognized deferred tax assets and liabilities with a net amount of €161.0 million for the cumulative tax losses and temporary differences determined for the German tax group as of December 31, 2020. During the year ended December 31, 2021, deferred tax assets on tax losses which had been recognized for the losses incurred by the German tax group were fully utilized (as per the end of each quarter during the year ended December 31, 2021, a proportionate amount of the deferred tax assets related to the tax loss carryforward was utilized). The change in deferred taxes was also supplemented by deferred taxes on temporary differences.

As of December 31, 2021, we have not recognized deferred tax asset for unused tax losses and temporary differences at amount of €81.0 million (December 31, 2020: €50.5 million, December 31, 2019: €136.0 million) as there is not sufficient probability in terms of IAS 12 that there will be future taxable income available against which the unused tax losses and temporary differences can be utilized.

These amounts included tax losses at an amount of €238.1 million US federal tax losses and €147.4 million US state tax losses (December 31, 2020: €136.8 million US federal tax losses and €60.9 million US state tax losses, December 31, 2019: nil) related to the US tax group, thereof €20.9 million US federal losses that begin to expire at various dates beginning in 2033. All other unused tax losses and temporary differences can be carried forward indefinitely.

9 Earnings per Share

Basic earnings per share (EPS) is calculated by dividing the profit / (loss) for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit / (loss) attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

On September 18, 2019, we effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from our own funds; thus, no outside proceeds were received. This capital increase came into effect upon registration with

the commercial register (*Handelsregister*). The accompanying financial statements and notes to the financial statements including the EPS information below which relate to the period before September 18, 2019, give retroactive effect to the share split.

The following table reflects the income and share data used in the basic and diluted EPS calculations:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Profit / (loss) attributable to ordinary equity holders of the parent for basic earnings	**€10,292.5**	**€15.2**	**€(179.1)**
Weighted average number of ordinary shares for basic EPS	**244.0**	**235.4**	**211.5**
Effects of dilution from share options	15.7	13.1	—
Weighted average number of ordinary shares adjusted for the effect of dilution	**259.7**	**248.5**	**211.5**
Earnings per share[1]			
Basic profit / (loss) for the period per share	€42.18	€0.06	€(0.85)
Diluted profit / (loss) for the period per share	€39.63	€0.06	€(0.85)

(1) Capital increase due to 1:18 share split occurred on September 18, 2019. Retroactive effect is reflected in number of shares which relate to the period before the share split.

In January 2022, we announced a new research, development and commercialization collaboration with Pfizer to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV). Under the terms of the agreement, we issued 497,727 ordinary shares with the nominal amount of €0.5 million to Pfizer which were registered with the commercial register (*Handelsregister*) on March 24, 2022.

Share options were not included in the calculation of diluted EPS for periods in which they were antidilutive; i.e., for the periods in which a loss was incurred.

10 Property, Plant and Equipment

(in millions)	**Land and buildings**	**Equipment, tools and installations**	**Construction in progress and advance payments**	**Total**
Acquisition and production costs				
As of January 1, 2020	**€29.4**	**€83.2**	**€29.7**	**€142.3**
Additions	14.9	10.1	41.0	66.0
Disposals	—	(6.9)	(1.0)	(7.9)
Reclassifications	8.6	1.8	(10.4)	—
Currency differences	—	(0.7)	—	(0.7)
Acquisition of subsidiaries and businesses	8.4	54.9	22.3	85.6
As of December 31, 2020	**€61.3**	**€142.4**	**€81.6**	**€285.3**
As of January 1, 2021	**€61.3**	**€142.4**	**€81.6**	**€285.3**
Additions	20.0	44.3	63.2	127.5
Disposals	(0.8)	(15.1)	(1.7)	(17.6)
Reclassifications	23.1	25.8	(48.9)	—
Currency differences	0.5	0.7	0.1	1.3
Acquisition of subsidiaries and businesses	—	0.2	—	0.2
As of December 31, 2021	**€104.1**	**€198.3**	**€94.3**	**€396.7**

(in millions) **Cumulative depreciation and impairment charges**	**Land and buildings**	**Equipment, tools and installations**	**Construction in progress and advance payments**	**Total**
As of January 1, 2020	**€8.3**	**€41.0**	**€—**	**€49.3**
Depreciation	2.1	13.8	—	15.9
Disposals	—	(6.7)	—	(6.7)
Currency differences	—	(0.2)	—	(0.2)
As of December 31, 2020	**€10.4**	**€47.9**	**€—**	**€58.3**
As of January 1, 2021	10.4	47.9	—	58.3
Depreciation	4.4	25.0	—	29.4
Disposals	(0.6)	(13.1)	—	(13.7)
Currency differences	—	0.2	—	0.2
As of December 31, 2021	**€14.2**	**€60.0**	**€—**	**€74.2**

(in millions) **Carrying amount**	**Land and buildings**	**Equipment, tools and installations**	**Construction in progress and advance payments**	**Total**
As of December 31, 2020	**50.9**	**94.5**	**81.6**	**227.0**
As of December 31, 2021	**€89.9**	**€138.3**	**€94.3**	**€322.5**

11 Intangible Assets

(in millions) **Acquisition costs**	**Goodwill**	**Concessions, licenses, in-process R&D and similar rights**	**Advance payments**	**Total**
As of January 1, 2020	**€3.0**	**€116.3**	**€2.4**	**€121.7**
Additions	—	4.2	4.4	8.6
Disposals	—	(5.4)	(0.6)	(6.0)
Reclassifications	—	0.2	(0.2)	—
Currency differences	(6.8)	(3.9)	—	(10.7)
Acquisition of subsidiaries and businesses	57.5	35.8	—	93.3
As of December 31, 2020	**€53.7**	**€147.2**	**€6.0**	**€206.9**
As of January 1, 2021	53.7	147.2	6.0	206.9
Additions	—	5.9	4.2	10.1
Disposals	—	(8.5)	(1.2)	(9.7)
Reclassifications	—	1.2	(1.2)	—
Currency differences	4.1	2.5	—	6.6
Acquisition of subsidiaries and businesses	—	43.3	—	43.3
As of December 31, 2021	**€57.8**	**€191.6**	**€7.8**	**€257.2**

(in millions) **Cumulative amortization and impairment charges**	**Goodwill**	**Concessions, licenses, in-process R&D and similar rights**	**Advance payments**	**Total**
As of January 1, 2020	**€—**	**€32.3**	**€—**	**€32.3**
Amortization	—	16.6	—	16.6
Disposals	—	(5.4)	—	(5.4)
Currency differences	—	(0.1)	—	(0.1)
As of December 31, 2020	**€—**	**€43.4**	**€—**	**€43.4**
As of January 1, 2021	**—**	43.4	—	43.4
Amortization	—	16.8	—	16.8
Disposals	—	(5.5)	—	(5.5)
Currency differences	—	0.1	—	0.1
As of December 31, 2021	**€—**	**€54.8**	**€—**	**€54.8**

(in millions) **Carrying amount**	**Goodwill**	**Concessions, licenses, in-process R&D and similar rights**	**Advance payments**	**Total**
As of December 31, 2020	**53.7**	**103.8**	**6.0**	**163.5**
As of December 31, 2021	**€57.8**	**€136.8**	**€7.8**	**€202.4**

Goodwill and Intangible Assets with Indefinite Useful Lives

	CGU Immunotherapies		**External Product Sales of JPT**		**Total**	
(in millions)	As of December 31, 2021	As of December 31, 2020	As of December 31, 2021	As of December 31, 2020	**As of December 31, 2021**	**As of December 31, 2020**
Goodwill	€57.3	€53.2	€0.5	€0.5	**€57.8**	**€53.7**

For the year ended December 31, 2021, we have total Goodwill of €57.3 million, which relates almost completely to the CGU immunotherapies. The CGU immunotherapies focus on the development of therapies to address a range of rare and infectious diseases and include our broad pipeline that includes mRNA-based immune activators, antigen-targeting T cells and antibodies, and defined immunomodulators of various immune cell mechanisms.

The recoverable amount of the CGU immunotherapies has been determined based on a fair value less cost of disposal (FVLCD) derived from our market capitalization as observable input parameter. As a result of the analysis, management did not identify an impairment for this CGU.

We concluded that no reasonable possible change of the recoverable amount would cause the carrying amount of the CGU Immunotherapies to exceed its recoverable amount.

Non-Current Assets by Region

As of December 31, 2021, non-current assets comprised €139.7 million intangible assets, property, plant and equipment, right-of-use assets and other assets of our subsidiaries incorporated in the United States (as of December 31, 2020: €89.2 million). The remaining non-current assets relate to subsidiaries incorporated in Germany.

12 Financial Assets and Financial Liabilities

12.1 Capital Risk Management

Our capital management objectives are designed primarily to finance our growth strategy.

Our controlling committee reviews the total amount of cash on a regular basis. As part of this review, the committee considers the total cash and cash equivalents, the cash outflow, currency translation differences and refinancing activities. We monitor cash using a burn rate. The cash burn rate is defined as the average monthly net cash flow from operating and investing activities during a financial year.

(in millions)	**December 31, 2021**	**December 31, 2020**
Cash and cash equivalents at banks and on hand	€1,692.7	€1,210.2
Total	**€1,692.7**	**€1,210.2**

When analyzing our liquidity, we anticipate certain significant balance sheet items that are expected to improve our cash and cash equivalents balance subsequent to the end of the reporting period. Please refer to Note 12.2 for details on cash deposits which were returned to cash and cash equivalents and Note 6.2 explains the settlement payments received under our COVID-19 collaboration with Pfizer.

In general, the aim is to maximize the financial resources available for further research and development projects.

As of December 1, 2021, an investment and asset management policy became effective which confirmed our previous objectives, policies and processes for managing cash which requires that our investment portfolio shall be maintained in a manner that minimizes risk of the invested capital. These risks include mainly credit risk and concentration risk. The portfolio must provide liquidity in a timely manner to accommodate operational and capital needs. The portfolio is managed efficiently by the Treasury department.

We are not subject to externally imposed capital requirements. Our capital management objectives were achieved in the reporting year.

12.2 Categories of Financial Instruments

Financial Assets: Financial Assets at Amortized Cost and at Fair Value through Profit or Loss

Set out below, is an overview of financial assets at amortized cost and at fair value through profit or loss, other than cash and cash equivalents, held by the Group as of the dates indicated:

Financial assets

(in millions)	**December 31, 2021**	**December 31, 2020**
Derivatives not designated as hedging instrument		
Foreign exchange forward contracts	€5.7	€—
Equity instruments designated at fair value through OCI		
InstaDeep Ltd.	19.5	—
Financial assets at amortized cost		
Trade and other receivables	12,381.7	165.5
Cash deposit with an original term of six months	375.2	—
Other financial assets	2.5	137.2
Total	**€12,784.6**	**€302.7**
Total current	12,763.3	302.7
Total non-current	21.3	—

Equity Instruments Designated at Fair Value through OCI

In December 2021, we acquired 5.3% of the shares (fully diluted as of closing) of InstaDeep Ltd., a provider of artificial intelligence-powered decision-making systems headquartered in London, United Kingdom. The equity investment complements the already established commercial cooperation based on the field of artificial intelligence and machine learning in the context of computational design of new precision immunotherapies. In accordance with IFRS 9 we elected to present gains and losses on this equity investment in OCI to avoid fluctuation to be disclosed in our consolidated financial statements of profit or loss. Since the acquisition date, no material gains and losses on this equity investment have occurred.

Financial Assets at Amortized Cost

Trade and other receivables significantly increased and remained outstanding as of December 31, 2021, mainly due to the contractual settlement of the gross profit share under our COVID-19 collaboration with Pfizer as described in Note 6.2. as well as from our direct product sales to customers in our territory.

Cash deposits with an original term of six months are presented as other financial assets. Within our interim condensed consolidated financial statements as of, and for the three and nine months ended, September 30, 2021, cash deposits in an amount of €367.0 million with a term of six months at inception had been classified as cash and cash equivalents. The presentation as other financial assets in our consolidated statements of financial position and cash flow used in investing activities in our consolidated statements of cash flows was corrected as of and for the year ended December 31, 2021. As of December 31, 2021, the remaining term until maturity for the investments made was on average less than one month and the cash deposits in the amount of €375.2 million, were returned to cash and cash equivalents during January and February 2022.

Financial Liabilities: Financial Liabilities at Amortized /Cost (including Loans and Borrowings and Other Financial Liabilities)

Set out below, is an overview of financial liabilities, other financial liabilities and trade payables held by the Group as of the dates indicated:

Loans and borrowings

(in millions)	**Maturity**	**December 31, 2021**	**December 31, 2020**
Lease liabilities		€181.6	€84.2
Convertible note – host contract	8/28/2024	99.7	87.5
3.5% €50,000,000 bank loan	[1]	—	47.2
2.2% €10,000,000 secured bank loan	12/30/2027[2]	7.7	9.0
2.1% €9,450,000 secured bank loan	9/30/2028[2]	7.8	8.7
1.9% €3,528,892 secured bank loan	6/30/2027	3.4	3.5
0.8% €1,305,167 loan	5/30/2039	1.3	—
Total		**€301.5**	**€240.1**
Total current		129.9	9.1
Total non-current		171.6	231.0

[1] The loan was fully repaid during December 2021.

[2] The loans were fully repaid in February 2022.

Other financial liabilities

(in millions)	**December 31, 2021**	**December 31, 2020**
Derivatives not designated as hedging instrument		
Convertible note – embedded derivative	€308.7	€30.9
Foreign exchange forward contracts	63.0	—
Financial liabilities at fair value through profit or loss		
Contingent consideration	6.1	0.6
Total financial liabilities at fair value	**€377.8**	**€31.5**
Trade payables and other financial liabilities at amortized cost, other than loans and borrowings		
Trade payables	160.0	102.3
Other financial liabilities	818.7	74.1
Total trade payables and other financial liabilities at amortized cost, other than loans and borrowings	**€978.7**	**€176.4**
Total other financial liabilities	**€1,356.5**	**€207.9**
Total current	1,350.4	176.4
Total non-current	6.1	31.5

Total financial liabilities

(in millions)	December 31, 2021	December 31, 2020
Loans and borrowings	€301.5	€240.1
Other financial liabilities	1,356.5	207.9
Total	**€1,658.0**	**€448.0**
Total current	1,480.3	185.5
Total non-current	177.7	262.5

Loans and Borrowings

2.2% and 2.1% Secured Bank Loan

We maintain two secured loans with Deutsche Bank AG, or Deutsche Bank, a €9.5 million secured credit facility at a rate of 2.1% and maturing on September 30, 2028 to finance the buildouts of our JPT Peptide Technologies GmbH facility and a €10.0 million secured credit facility at a rate of 2.2% and maturing on December 30, 2027, of Innovative Manufacturing Services GmbH facility, respectively. As of December 31, 2021, the full amounts under these facilities were drawn down and were started to be repaid. Each of these facilities is secured by liens over our property. Subsequent to the end of the reporting period, we agreed to repay both Deutsche Bank loans as of February 25, 2022.

EIB Manufacturing Financing – 3.5% Secured Bank Loan

A financing arrangement which was entered with the European Investment Bank, or the EIB, in June 2020 to partially support the development of BNT162 and fund expansion of our manufacturing capacity to provide worldwide supply of BNT162 in response to the COVID-19 pandemic comprised a €100.0 million credit facility. Under this arrangement, €50.0 million (Credit A) at a cash interest fixed rate of 1.0% per annum payable quarterly in arrears, plus deferred interest at fixed rate of 2.5% per annum had been drawn down but was effectively repaid during the year ended December 31, 2021. The additional €50.0 million (Credit B) was cancelled effectively during the year ended December 31, 2021. The guarantee agreements securing the financing arrangement were effectively released by fulfilling all payment obligations derived from and fully repaying the amounts drawn under the arrangements.

June 2020 Private Placement – Convertible Note

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor participated in a private investment which we refer to as the June 2020 Private Placement. The private placement includes an investment in a four years mandatory convertible note and an investment in ordinary shares and closed as of August 28, 2020, following the satisfaction of customary closing conditions. The private placement includes an investment in ordinary shares (see Note 16) and a €100.0 million investment in a four years mandatory convertible note with a coupon of 4.5% per annum and a conversion premium of 20% above its reference price. As of closing, the convertible note has been classified as a financial liability according to IAS 32 because the conversion features of the note lead to a conversion into a variable number of shares and is measured at amortized costs since the fair value option was not applied. On initial recognition, the financial liability was measured at the present value of the contractually determined future cash flows discounted at the effective interest rate of 9.0%. The financial liability is subsequently measured at amortized cost by using the effective interest rate method, reflecting actual and revised estimated contractual cash flows until extinguished upon conversion. In February 2022, we gave notice to Temasek that we will exercise our early redemption option and fully redeem the convertible note on March 1, 2022, the redemption date. The early redemption will be fulfilled by issuing the number of our ordinary shares calculated pursuant to the early redemption provisions of the convertible note, plus paying any fractional share and accrued but unpaid interest up to (but excluding) the redemption date. The early redemption was already expected and reflected in the presentation of the financial liability and our estimates for future cash flows and conversion effects under the convertible note as of December 31, 2021. The conversion features provided for in the contract were identified as a combined embedded derivative since they share the same risk exposure and are interdependent. The embedded derivative was bifurcated from the convertible note, as host contract, and is recognized as a separate financial instrument. Based on the classification as derivative, the instrument is measured at fair value through profit and loss until it is extinguished upon conversion. The fair value of the embedded derivative is determined by modeling the stock price movement using the Cox-Rubinstein binomial tree model to derive the value of the conversion right. The primary inputs used in the model include stock price volatility, credit spreads, risk-free interest rate and foreign exchange forward rates. Stock price volatility is

based on our implied volatility, credit risk is model implied and adjusted for movement in credit spreads for B-rated corporates at each valuation date, the risk-free interest rate is based on currency specific time congruent IBOR and swap rates whereas the foreign exchange forward rates are based on observable market data.

Derivatives Not Designated as Hedging Instrument

Derivatives not designated as hedging instruments relate to foreign exchange forward contracts that were entered into during the year ended December 31, 2021, to manage some of our foreign currency exposures. The foreign exchange forward contracts are intended to reduce the exposure to foreign currency risk resulting from trade receivables denominated in U.S. dollar.

Other Financial Liabilities at Amortized Cost

Other financial liabilities at amortized cost mainly include obligations derived from license agreements which are being incurred with respect to our COVID-19 vaccine sales in our and the collaboration partners' territories where we and our partners are using third party intellectual property. In addition, other financial liabilities at amortized cost comprise obligations from services received but not yet invoiced.

12.3 Fair Values

Fair values of cash and cash equivalents, trade receivables, trade payables and other current financial assets and liabilities approximate their carrying amounts as of December 31, 2021, largely due to the short-term maturities of these instruments.

After repaying the EIB loan, the financial liabilities measured at amortized cost include four fixed-interest rate loans as well as the convertible note. As of December 31, 2021, the carrying value approximates their fair values as there have been no significant changes in relevant interest rates since the inception of the respective loans and note.

The fair values of financial instruments measured at fair value are reassessed on a quarterly basis. The valuation technique used for measuring the fair value of the embedded derivative is based on significant observable inputs (Level 2). During the year ended December 31, 2021, the fair value adjustment derived from remeasuring the embedded derivative was recognized as finance expenses in our consolidated statements of profit or loss and amounted to €277.8 million. The foreign exchange forward contracts are valued using valuation techniques, which employ the use of foreign exchange spot and forward rates (Level 2). The fair value adjustment derived from remeasuring the foreign exchange forward contracts amounted to other operating expenses of €86.3 million and other operating income of €5.7 million in our consolidated statements of profit or loss. The initial fair value of the contingent consideration determined at acquisition was based on cash flow projections (unobservable Level 3 input factors) and remains valid since no changes of the underlying available information has occurred.

12.4 Financial Instruments Risk Management Objectives and Policies

Our financial liabilities comprise bank loans, lease liabilities, trade and other payables as well as the convertible note and hedging liabilities. The main purpose of these financial liabilities is to enable our operations. Our principal financial assets include mainly cash and trade receivables that derive directly from our operations.

We are exposed to market risk, credit risk and liquidity risk. Our Management Board oversees the management of these risks.

The controlling committee provides assurance to our Management Board that our financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with our policies and risk objectives. The Management Board reviews and agrees policies for managing each of these risks, which are summarized below.

12.5 Market Risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risk comprises of three types of risk: interest risk, foreign currency risk and other price risk. Financial instruments affected by market risk include financial assets like trade and other receivables, cash and cash equivalents as

well as financial liabilities like trade payables and other financial liabilities. Interest risk as well as other price risk are not considered as risks.

The sensitivity analysis in the following sections relate to the position as of December 31, 2021 and December 31, 2020.

There were no material changes in the our market risk exposures or changes in the way risk was managed and valued during the periods.

Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. We are subject to currency risk, as our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are exposed to exchange rate fluctuations between these currencies. Cash inflows denominated in U.S. dollar mainly result from generating proceeds under our collaboration agreements which significantly increased in the past year. Our commercial revenues are primarily collaboration revenues from earnings based on our partners' gross profit, which is shared under the respective collaboration agreements and represents payments we receive in U.S. dollar. Cash outflows dominated in U.S. dollar mainly result from amounts spent on research and development activities as well as expanding our global footprint further. Especially when funds are required in Euros, we are exposed to foreign currency exchange risks. With the aim of preserving capital, surplus liquidity is invested carefully for example into foreign currency investments. Exchange rate fluctuations can reduce the value of our financial positions. We limit the effects of the identified risks by means of a coordinated and consistently implemented risk strategy. Besides applying natural hedging relationships where possible, a matter of principle, foreign exchange forward contracts are concluded as instruments to mitigate foreign currency exchange risk associated with foreign currency-denominated payments. However, the foreign exchange forward contracts which we entered were not designated as hedging instrument under IFRS.

The carrying amount of the monetary assets and liabilities denominated in U.S. dollar at the dates indicated are as follows:

(in millions)	**December 31, 2021**	**December 31, 2020**
U.S. dollar Bank accounts	€436.2	€673.5
Other financial assets in U.S. dollar	11,895.5	85.6
Financial liabilities in U.S. dollar	656.7	72.8
Total	**€11,675.0**	**€686.3**

The following tables demonstrate the sensitivity to a reasonably possible change in U.S. dollar exchange rates or U.S. dollar forward rates, with all other variables held constant. The impact on our profit / (loss) before tax is due to changes in the fair value of monetary assets and liabilities. The exposure to foreign currency changes for all other currencies is not material.

		1 € =	**Closing rate**		**Average rate**	
Currency	**Country**		**2021**	**2020**	**2021**	**2020**
U.S. dollar	United States		1.1326	1.2271	1.1827	1.1422

(in millions)	**Change in U.S. dollar rate**	**Effect on profit / (loss) before tax**	**Effect on pre-tax equity**
2021	+5 %	€(329.5)	€(328.5)
	-5 %	364.3	363.0
2020	+5 %	(32.5)	(32.7)
	-5 %	35.9	36.1

12.6 Credit Risk Management

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk from its operating activities, including deposits with banks and financial institutions, foreign exchange transactions and trade and other receivables.

Trade and Other Receivables

Our exposure to credit risk of trade receivables and contract assets is primarily on transactions with corporate customers in the biopharma / biotech industry that operate in the United States or Germany as well as governments which are customers established in connection with fulfilling our commercial obligations in our territories as defined under our current COVID-19 collaboration agreements. An analysis of the aging of receivables and the creditworthiness of customers is used to evaluate this risk at each reporting date. The Group follows risk control procedures to assess the credit quality of the customers taking into account their financial position, past experience and other factors. The compliance with credit limits by corporate customers is regularly monitored by us.

As of December 31, 2021, the outstanding trade receivables were mainly due from our collaboration partner Pfizer as well as the Turkish government. Please see Note 12.1 for information on trade receivables received or expected to be received subsequent to the end of the reporting period. Besides well-established pharmaceutical companies and governmental institutions, to a smaller extent, our other customers are medical universities, other public institutions and peers in the biopharma industry, which all have a very high credit rating. Due to this customer portfolio, the credit risk on trade receivables and contract assets is generally very low. We have not incurred bad debt expense and do not expect that this will change with respect to the trade receivables recognized as of December 31, 2021.

Generally, if overdue by more than 90 days and not subject to enforcement activity trade receivables are considered for write-offs. The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in Note 12.2. The expected credit risk on trade receivables and other financial assets derived from applying the simplified approach in calculating expected credit losses was estimated to be not material as of December 31, 2021, as well as December 31, 2020. The Group does not hold collateral as security.

Cash and Cash Equivalents as well as Cash Deposits with an Original Term of Six Months

Credit risk from balances with banks and financial institutions is managed by our Treasury department in accordance with our policy.

Credit risk stemming from cash and cash equivalents as well as cash deposits with an original term of six months is very low due to its demand feature and the high credit rating of the respective banks.

The maximum exposure to credit risk for the components of the consolidated statements of financial position as of December 31, 2021, and December 31, 2020, are the carrying amounts as illustrated in Note 12.1 and Note 12.2.

12.7 Liquidity Risk

Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 100 countries and regions worldwide, resulting in commercial revenues respectively. We plan to invest heavily in R&D as we make a strong drive to build out our global development organization and diversify our therapeutic area footprint. Additionally, we plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing. Lack of external financial support could pose a risk of going concern. Our liquidity management ensures the availability of cash and cash equivalents, short term financial instruments for operational activities and further investments through appropriate budget planning. In addition, a sufficient level of cash and cash equivalents, which is managed centrally, is always maintained to finance the operational activities.

We monitor liquidity risks using a liquidity planning tool.

Ultimately, the responsibility for liquidity risk management lies with our Management Board, which has established an appropriate approach to managing short-, medium- and long-term financing and liquidity requirements. We manage

liquidity risks by holding appropriate reserves, as well as by monitoring forecasted and actual cash flows and reconciling the maturity profiles of financial assets and liabilities.

Risk Concentration

Concentrations arise when the number of counterparties is small or larger number of counterparties are engaged in similar business activities, or activities in the same geographical region, or have economic features that would cause their ability to meet contractual obligations to be affected similarly by changes in economic, political or other conditions. Concentrations indicate the relative sensitivity of our performance to developments affecting a particular industry.

In order to reduce the concentrations of risk derived from having only few customers, including the significant relationship maintained with our collaboration partner Pfizer, our policies and procedures include specific guidelines to constantly monitor the customers' credit risks.

The maturity profile of our financial liabilities based on contractual undiscounted payments is summarized as follows:

Year ended December 31, 2021

(in millions)	**Less than 1 year**	**1 to 5 years**	**More than 5 years**	**Total**
Loans and borrowings	€2.6	€11.5	€6.1	**€20.2**
Trade and other payables	160.0	—	—	**160.0**
Lease liabilities	31.3	89.1	88.9	**209.3**
Contingent consideration	—	—	6.1	**6.1**
Foreign exchange forward contracts	63.0	—	—	**63.0**
Other financial liabilities	818.7	—	—	**818.7**
Total	**€1,075.6**	**€100.6**	**€101.1**	**€1,277.3**

Year ended December 31, 2020

(in millions)	**Less than 1 year**	**1 to 5 years**	**More than 5 years**	**Total**
Loans and borrowings	€3.2	€12.6	€66.7	**€82.5**
Trade and other payables	102.3	—	—	**102.3**
Lease liabilities	8.5	27.3	71.8	**107.6**
Contingent consideration	—	—	0.6	**0.6**
Other financial liabilities	74.1	—	—	**74.1**
Total	**€188.1**	**€39.9**	**€139.1**	**€367.1**

The mandatory convertible note, which was issued during the year ended December 31, 2020, and which is expected to be settled in equity is excluded from the table above.

12.8 Changes in Liabilities Arising from Financing Activities

Year ended December 31, 2021

(in millions)	**January 1, 2021**	**Cash flows**	**Acquisition of subsidiaries and businesses**	**Changes in fair value**	**New leases and disposals**	**Reclassification**	**Other**	**December 31, 2021**
Current obligations under lease contracts	€6.1	€(14.1)	€—	€—	€22.1	€13.4	€0.4	**€27.9**
Non-current obligations under lease contracts	78.1	—	—	—	87.7	(13.4)	1.3	**153.7**
Loans and borrowings	155.9	(52.6)	1.3	—	—	—	15.3	**119.9**
Convertible note – embedded derivative	30.9	—	—	277.8	—	—	—	**308.7**
Total	**€271.0**	**€(66.7)**	**€1.3**	**€277.8**	**€109.8**	**€—**	**€17.0**	**€610.2**

Year ended December 31, 2020

(in millions)	**January 1, 2020**	**Cash flows**	**Acquisition of subsidiaries and businesses**	**Changes in fair value**	**New leases and disposals**	**Reclassification**	**Other**	**December 31, 2020**
Current obligations under lease contracts	€3.5	€(12.7)	€2.7	€—	€8.6	€4.0	€—	**€6.1**
Non-current obligations under lease contracts	54.1	—	32.3	—	(4.3)	(4.0)	—	**78.1**
Loans and borrowings	16.6	140.8	—	—	—	—	(1.5)	**155.9**
Convertible note – embedded derivative	—	13.6	—	17.3	—	—	—	**30.9**
Total	**€74.2**	**€141.7**	**€35.0**	**€17.3**	**€4.3**	**€—**	**€(1.5)**	**€271.0**

13 Inventories

(in millions)	**December 31, 2021**	**December 31, 2020**
Raw materials and supplies	€248.3	€44.3
Unfinished goods	84.5	19.4
Finished goods	169.7	0.4
Total	**€502.5**	**€64.1**

During the year ended December 31, 2021, inventory write-offs and reserves related to our COVID-19 vaccine amounting to €194.6 million were recognized in cost of sales as a result of the respective inventories not fulfilling the predefined quality-specifications (GMP) and / or regulatory requirements (approval of the respective authorities, i.e. FDA) and / or shelf-life expiration, compared to nil in the previous period. We have not pledged any inventories as securities for liabilities. During the years ended December 31, 2021 and 2020, €1,255.1 million and €32.1 million, respectively costs of inventories were recognized as cost of sales.

14 Other Assets

(in millions)	December 31, 2021	December 31, 2020
Sales tax receivable	€26.7	€4.2
Prepayments related to CRO and CMO contracts	22.8	14.2
Prepayments on inventories	6.1	29.8
Prepayments related to service contracts	6.5	3.8
Other	3.6	10.0
Total	**€65.7**	**€62.0**
Total current	64.9	61.0
Total non-current	0.8	1.0

15 Deferred Expenses

(in millions)	December 31, 2021	December 31, 2020
Deferred remuneration	€21.2	€—
Deferred transportation cost	12.7	—
Deferred expenses from CRO and CMO contracts	7.1	5.7
Deferred expenses from insurance contracts	5.0	13.8
Other	16.1	8.5
Total	**€62.1**	**€28.0**
Total current	48.5	28.0
Total non-current	13.6	—

16 Issued Capital and Reserves

On September 18, 2019, we effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from our own funds; thus, no outside proceeds were received. The capital increase came into effect upon registration with the commercial register (*Handelsregister*). The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the share split for all periods presented.

Proposed Cash Dividend Distributions

(in millions)	December 31, 2021
Proposed cash dividends on ordinary shares	
Cash dividend for 2021: €2.00 per share	**€486.0**

We will propose a special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which corresponds to an aggregate of approximately €486.0 million, based on the shares outstanding as of March 30, 2022. Since the cash dividend is subject to approval at our Annual General Meeting to be held in June 2022, no liability is recognized as of December 31, 2021. The Annual General Meeting expects to serve as the record date for the dividend.

Capital Transactions During the Year Ended December 31, 2021

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC and SVB Leerink LLC, as sales agents, to establish an at-the-market offering program, pursuant to which we may sell, from time to time, ADSs representing ordinary shares for aggregate gross proceeds of up to $500.0 million. During the year ended December 31, 2021, we sold 995,890 ADSs, each representing one of our ordinary shares that had previously been held in treasury, under the Sales Agreement for aggregate gross proceeds of $200.0 million (€163.6 million). As of December 31, 2021, the remaining capacity under the Sales Agreement is $207.1 million. Under the at-the-market offering program ADSs are sold via the stock exchange and therefore no shareholders' subscription rights are affected. As a result of the

transaction, treasury shares in the amount of €1.0 million were issued and the capital reserve increased by €162.6 million. Costs of €2.7 million related to the equity transaction were recorded in equity as deduction from the capital reserve.

Capital Transactions During the Year Ended December 31, 2020

During the year ended December 31, 2020, our issued share capital increased by €14.0 million. Each share has a nominal value of €1.00. As a result of the financing transactions, treasury shares decreased by €0.7 million and capital reserve increased by €861.0 million. Costs of €33.2 million related to these equity transactions were recorded in equity as deduction from the capital reserve. The financing transactions that occurred during the year ended December 31, 2020, were as follows:

Shanghai Fosun Pharmaceuticals (Group) Co., Ltd

As part of the BNT162 program, we entered into a strategic alliance with Fosun Pharma to develop COVID-19 vaccine candidates in China. Fosun Pharma agreed to make an equity investment of €45.6 million ($50.0 million) for 1,580,777 ordinary shares via Fosun Industrial Co., Limited, Hong Kong. The increase in share capital with a nominal amount of €1.6 million was subject to execution of share subscription documentation and approval from regulatory authorities in China and became effective with the registration with the commercial register (*Handelsregister*) on April 23, 2020. As a result of the transaction, the capital reserve increased by €44.0 million.

Pfizer Inc., New York, New York, United States

As part of the collaboration between us and Pfizer for the co-development of BNT162, Pfizer agreed to make an equity investment of €103.9 million ($113.0 million). The issuance of 2,377,446 ordinary shares with the nominal amount of €2.4 million was registered with the commercial register (*Handelsregister*) on May 5, 2020. As a result of the transaction the capital reserve increased by €101.5 million.

Neon Therapeutics, Inc., Cambridge, Massachusetts, United States

We acquired Neon by issuing 1,935,488 ADSs representing our ordinary shares with the nominal amount of €1.9 million to former stockholders of Neon in the Merger. The capital increase was registered with the commercial register (*Handelsregister*) on May 8, 2020. As a result of the transaction the capital reserve increased by €87.6 million.

Global Offering

On July 27, 2020, our share capital increased by €5.5 million ($6.4 million) in conjunction with the underwritten offering of 5,500,000 ADSs each representing one ordinary shares at a public offering price of $93.00 per ADS ("Underwritten Offering"). On August 27, 2020, following the Underwritten Offering, our share capital was increased by additional €16 thousand ($19 thousand) in conjunction with the rights offering of 16,124 ADSs each representing one of our ordinary shares at a public offering price of $93.00 per ADS ("Rights Offering"). The Underwritten Offering and the Rights Offering are part of a single, global offering which we refer to as the Global Offering. The gross proceeds of the Global Offering were €436.3 million ($513.0 million) including €5.5 million increase in share capital and €430.8 million increase in capital reserve.

June 2020 Private Placement – Equity Investment

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor, contributed a private investment. The private placement includes an investment in a 4-year mandatory convertible note (see Note 12) and an investment of €123.9 million in ordinary shares. The issuance of 2,595,996 ordinary shares with the nominal amount of €2.6 million was registered with the commercial register (*Handelsregister*) on September 8, 2020. As result of the transaction the capital reserve increased by €121.3 million.

At-The-Market Offering Program

During the year ended December 31, 2020, we sold 735,490 ADSs, each representing one of our ordinary shares and previously held in treasury, under the Sales Agreement with Jefferies LLC and SVB Leerink LLC in November 2020 for aggregate gross proceeds of $92.9 million (€76.5 million). As a result of the transaction the capital reserve increased by €75.8 million.

17 Share-Based Payments

During the years ended December 31, 2021 and 2020, our share-based payment arrangements led to the following expenses:

		Years ended December 31,		
(in millions)	**Note**	**2021**	**2020**	**2019**
Expense arising from equity-settled share-based payment arrangements		€61.0	€32.1	€30.2
Employee Stock Ownership Plan	17.5	*20.2*	*17.1*	*27.0*
Chief Executive Officer Grant	17.4	*5.9*	*11.3*	*3.2*
Management Board Grant[(1)]	17.3	*2.4*	*2.7*	—
BioNTech 2020 Employee Equity Plan for employees based outside North America	17.1	*32.5*	*1.0*	—
Expense arising from cash-settled share-based payment arrangements		32.7	0.7	—
Employee Stock Ownership Plan	17.5	*6.3*	—	—
Management Board Grant[(1)]	17.2, 17.3	*3.6*	*0.7*	—
BioNTech Restricted Stock Unit Plan for North America Employees	17.1	*22.8*	—	—
Total		**€93.7**	**€32.8**	**€30.2**
Cost of sales		7.0	1.1	0.9
Research and development expenses		60.5	24.9	23.2
Sales and marketing expenses		0.5	0.1	0.1
General and administrative expenses		25.7	6.7	6.0
Total		**€93.7**	**€32.8**	**€30.2**

(1) In May 2021, phantom options were granted under the Management Board Grant for the 2021 year which led to a modification from equity-settled to cash-settled share-based payment arrangement and a reclassification of €1.1 million between equity and non-current other liabilities, respectively. Expenses incurred before and after the modification date have been disclosed as equity-settled or cash-settled share-based payment arrangement, respectively. The amount includes expenses incurred with respect to a one-time signing bonus granted to Jens Holstein as of his appointment to the Management Board (see Note 21.2).

17.1 BioNTech Employee Equity Plan

BioNTech 2020 Employee Equity Plan for Employees Based Outside North America (Equity-Settled)

Description of Share-Based Payments

In December 2020, we approved the BioNTech 2020 Employee Equity Plan for employees based outside North America, the European Plan. Under the European Plan, Restricted Cash Units, or RSUs, are offered to our employees. As of the grant date in February 2021, the European Plan was implemented for the calendar year 2020 by entering into award agreements with our employees under the LTI 2020 program. In addition, further award agreements were entered into under the LTI-plus program with employees who did not participate in the Employee Stock Ownership Plan, or ESOP. In December 2021 and January 2022, award agreements were announced to and respectively entered into with our employees and the European Plan was granted for the calendar year 2021, the LTI 2021 program. Since employees obtained a valid expectation of the award already as of the announcement date and started rendering services as of such date, we concluded that the service commencement date for the LTI 2021 program was in December 2021 and started recognizing expenses related to the services received, respectively. RSUs issued under the LTI 2020 and LTI 2021 program vest annually in equal installments after four years and RSUs issued under the LTI-plus program vests annually in equal installments after two years, with the LTI 2020 and the LTI-plus programs commencing in December 2020 and the LTI 2021 program commencing in December 2021, respectively. Under the LTI-plus program, 50% of the RSUs awarded to the participant were awarded on commencement of the program in December 2020 and the remaining 50% were awarded to the participant

shortly after the U.S. Food and Drug Administration, or the FDA, fully approved BNT162b2, our COVID-19 vaccine in August 2021 (non-vesting condition). As we have the ability to determine the method of settlement, all programs were classified as equity-settled. The cost of the awards will be recognized over the relevant service period, applying the graded vesting method.

Measurement of Fair Values

For the LTI 2020 and the LTI-plus program, the fair value of the awards was based upon the price of our ADSs representing ordinary shares at grant date. For the LTI 2021 program, the fair value of the awards for services received in advance of grant date was based upon the share price as of December 31, 2021, the reporting date. The estimate is revised at subsequent reporting periods until the date of grant has been established. A retention assumption is applied when estimating the number of equity instruments for which service conditions are expected to be satisfied and will be revised in case material differences arise. Ultimately, a true-up to the number satisfied until settlement date will be recorded.

Reconciliation of Outstanding Share-Options

	Restricted stock units	Weighted average fair value (€)
Granted under LTI 2020 and LTI-plus program	627,486	€89.41
Forfeited	(13,059)	88.84
Allocated under LTI 2021 program	110,036	227.62
As of December 31, 2021	**724,463**	**€110.4**

BioNTech 2020 Restricted Stock Unit Plan for North America Employees (Cash-Settled)

Description of Share-Based Payments

In December 2020, we approved the BioNTech 2020 Restricted Stock Unit Plan for North America Employees, or the North American Plan. Under the North American Plan, RSUs are offered to our employees. These RSUs generally vest over four years, with 25% vesting one year after the service commencement date and the remainder vesting in equal quarterly installments thereafter. The first awards under the North American Plan were granted in February 2021. The service date for these awards is the date as of which the employee became employed by BioNTech US. During the year ended December 31, 2021, further awards were granted under the North American Plan, which included awards granted to new hire employees and ongoing recurring awards to existing employees on the approximate anniversary of each employee's start date of employment with BioNTech US. As these RSUs are intended to be cash-settled upon vesting, the awards were defined as a cash-settled share-based payment arrangement. The liability related to these awards is measured, initially and at the end of each reporting period until settled, at the fair value of the award considering the price of the ADSs representing our ordinary shares. The cost of the awards will be recognized over the relevant service period, applying the graded vesting method.

17.2 Management Board Grant – Short-Term Incentive (Cash-Settled)

The following sets forth the effective and termination dates of the current service agreements of our Management Board:

- Prof. Ugur Sahin, M.D.: September 1, 2019 – December 31, 2022
- Sean Marett: September 1, 2019 – September 30, 2022
- Dr. Sierk Poetting: September 1, 2019 – November 30, 2026 (renewed as of December 1, 2021)
- Prof. Özlem Türeci, M.D.: September 1, 2019 – May 31, 2022 (renewed as of March 1, 2022 until May 31, 2025)
- Ryan Richardson: January 1, 2020 – December 31, 2022
- Jens Holstein: July 1, 2021 – June 30, 2025

The service agreements with our Management Board provide for a short-term incentive compensation which is an annual performance-related bonus for the years of their respective service periods. Effective January 1, 2020, the maximum short-term incentive compensation for our Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Prof. Özlem Türeci was 50% of their annual fixed compensation. The same applied to Ryan Richardson's maximum short-term incentive compensation effective since January 1, 2020. Effective July 1, 2021, the maximum short-term incentive compensation for Jens Holstein was defined as €300,000. Effective January 1, 2022, the maximum short-term incentive compensation for Dr. Sierk Poetting has been increased to €300,000.The payout amount of the short-term incentive compensation depends on the achievement of certain financial performance criteria and non-financial performance criteria (performance targets) of the Group in a particular financial year, which goals are set uniformly for all members of the Management Board. 50% percent of the compensation are paid following the determination on the actual achievement of the performance targets (first installment), with the remaining amount payable one year after such determination, subject to adjustment relative to the performance of the price of the American Depositary Shares representing our ordinary shares during that year (second installment).

For each of the yearly awards, the second installment of the short-term incentive compensation that is dependent on the price of the American Depositary Shares representing our ordinary shares, represents a cash-settled share-based payment arrangement. The fair values of the liabilities are recognized over the award's vesting period beginning as of service agreements' effective dates, being the service commencement date until each separate determination date and are remeasured until settlement date.

17.3 Management Board Grant Long-Term Incentive (partly Equity-Settled, partly Cash-Settled)

Description of Share-Based Payments

The service agreements with our Management Board provide for a long-term incentive compensation in terms of an annual grant of options to purchase BioNTech shares for the years of their respective service periods. The options granted each year will be subject to the terms, conditions, definitions and provisions of our Employee Stock Ownership Plan (ESOP) and the applicable option agreement thereunder. Effective January 1, 2020, the number of options to be granted each year to Prof. Ugur Sahin, Sean Marett, Prof. Özlem Türeci and Ryan Richardson are to be calculated based on a value of €750,000, €300,000, €300,000 and €260,000, respectively. The value used to calculate the number of options for Ryan Richardson increases to €280,000 for the year 2022. Effective December 1, 2021, with entering into a new service contract, the value on which the number of options to be granted each year to Dr. Sierk Poetting is based was increased from €300,000 to €550,000 for new awards. Effective as of his appointment to the Management Board on July 1, 2021, the number of options to be granted each year to Jens Holstein was to be calculated based on a value of €550,000. In each case the values must be divided by the amount by which a certain target share price exceeds the exercise price.

The right to receive options generally represents an equity-settled share-based payment arrangement. The allocation of the number of issued options in 2020 occurred in February 2020 (2020 allocation date). In May 2021 (2021 allocation date), phantom options equivalent to the number of options the Management Board members would have been entitled to receive for the year 2021 were granted under the Management Board Grant which led to a modification from equity-settled to cash-settled share-based payment arrangement and a reclassification of €1.1 million between equity and non-current other liabilities. As of December 31, 2021, the assessment about options expected to be allocated in future years was based on estimated allocation dates in the middle of the respective years.

The share options allocated and expected to be allocated to our Management Board as of the dates indicated are presented in the tables below.

	Share options (expected to be allocated)	Weighted-average exercise price (€)
Granted share options as of allocation date February 2020	248,096	€28.32
Granted phantom options as of allocation dates May 2021[2]	51,742	163.72
Estimated allocation date 2022[1]	38,674	229.00
Estimated allocation date 2023[1]	16,848	233.16
Estimated allocation date 2024[1]	16,680	235.52
Estimated allocation date 2025[1]	12,265	240.21
Estimated allocation date 2026[1]	7,314	246.18
As of December 31, 2021	**391,619**	**€83.81**

[1] Valuation parameter derived from the Monte-Carlo simulation model.

[2] Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled.

For the awards with estimated allocation dates the numbers of options expected to be allocated have been derived from a Monte-Carlo simulation model. Those will be adjusted until the actual allocation has occurred and the number of options granted has ultimately been determined. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be exercisable four years after the allocation date.

The options will be subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder. The vested options can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, $8.5 billion divided by the total number of the ordinary shares outstanding immediately following the initial public offering (other than ordinary shares owned by BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. The options expire ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

Measurement of Fair Values

A Monte-Carlo simulation model has been used to measure the fair values at the (estimated) allocation dates of the Management Board Grant. This model incorporates the impact of the performance criteria regarding share price and index

development described above. The parameters used for measuring the fair values as of the respective (estimated) allocation dates were as follows:

	Allocation date February 2020	Allocation date May 12, 2021[2]	Allocation date May 17, 2021[2]	Estimated allocation date 2022
Weighted average fair value[1]	€10.83	€115.64	€91.66	€111.80
Weighted average share price[1]	€28.20	€164.34	€175.08	€227.62
Exercise price[1]	€28.32	€163.54	€164.96	€229.00
Expected volatility (%)	36.6 %	47.2 %	47.2 %	43.7 %
Expected life (years)[1]	4.8	4.6	4.6	5.8
Risk-free interest rate (%)	1.6 %	1.5 %	1.5 %	1.5 %

[1] Valuation parameter for estimated allocation dates derived from the Monte-Carlo simulation model.

[2] Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled.

	Estimated allocation date 2023	Estimated allocation date 2024	Estimated allocation date 2025	Estimated allocation date 2026
Weighted average fair value[1]	€98.77	€90.31	€90.20	€82.31
Weighted average share price[1]	€227.62	€227.62	€227.62	€227.62
Exercise price[1]	€233.16	€235.52	€240.21	€246.18
Expected volatility (%)	45.3 %	41.0 %	42.9 %	43.6 %
Expected life (years)[1]	5.8	5.8	5.8	5.8
Risk-free interest rate (%)	1.5 %	1.6 %	1.6 %	1.6 %

[1] Valuation parameter for estimated allocation dates derived from the Monte-Carlo simulation model

The exercise of the option rights in accordance with the terms of the ESOP gives the Management Board members the right to obtain shares against payment of the exercise price. The per share exercise price of the options is the Euro equivalent of the arithmetic mean of the closing prices of the ten last trading days prior to the allocation date. For the awards allocated as of February 2020, the exercise price has been determined to be $30.78 (€28.32), calculated as of grant date using the foreign exchange rate as published by the German Central Bank (*Deutsche Bundesbank*). As of December 31, 2021, the awards allocated as of February 2020 are subject to the effective exercise price cap. This means that the exercise price shall effectively be adjusted to ensure that the current price of an ADS as of the exercise date does not exceed 800% of the exercise price. For the awards allocated as of May 12, 2021, and May 17, 2021, the exercise price has been determined to be$185.23 (€163.54) and $186.83 (€164.96), respectively (both amounts calculated as of December 31, 2021, using the foreign exchange rate as published by the German Central Bank (*Deutsche Bundesbank*)). For the awards with estimated allocation dates the exercise prices of options expected to be allocated have been derived from the Monte-Carlo simulation model. Those will be adjusted until the actual allocation has occurred and the exercise price has ultimately been determined. With respect to the phantom share options issued in May 2021, as of December 31, 2021, all agreements include the effective exercise price cap and an additional maximum compensation clause limiting the total cash payment that the Management Board members are entitled to receive to €20.0 million for Ugur Sahin as Chief Executive Officer (CEO) or €10.0 million for all other Management Board members, less other compensation components received by each such board member in the respective grant year. Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected option term. The expected term was based on general option holder behavior for employee options.

Reconciliation of Outstanding Share-Options

The share options allocated and expected to be allocated under the Management Board Grant were as follows:

Allocation date February 13, 2020	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	97,420	€28.32
Sean Marett	38,968	28.32
Dr. Sierk Poetting	38,968	28.32
Prof. Özlem Türeci, M.D.	38,968	28.32
Ryan Richardson	33,772	28.32

Allocation dates May 12 and May 17, 2021[1]	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	17,780	€163.54
Sean Marett	7,112	163.54
Dr. Sierk Poetting	7,112	163.54
Prof. Özlem Türeci, M.D.	7,112	163.54
Ryan Richardson	6,163	163.54
Jens Holstein	6,463	164.96

(1) Classified as cash-settled share-based payment arrangement; all other share-based payment arrangements are classified as equity-settled. Allocation date May 17, 2021 concerns Jens Holstein.

Estimated allocation date 2022[1]	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	11,696	€229.00
Sean Marett	3,509	229.00
Dr. Sierk Poetting	8,577	229.00
Prof. Özlem Türeci, M.D.	1,949	229.00
Ryan Richardson	4,366	229.00
Jens Holstein	8,577	229.00

(1) Valuation parameters for estimated allocation dates derived from the Monte-Carlo simulation model.

Estimated allocation date 2023[1]	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Dr. Sierk Poetting	8,424	€233.16
Jens Holstein	8,424	233.16

(1) Valuation parameters for estimated allocation dates derived from the Monte-Carlo simulation model.

Estimated allocation date 2024[1]	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Dr. Sierk Poetting	8,340	€235.52
Jens Holstein	8,340	235.52

(1) Valuation parameters for estimated allocation dates derived from the Monte-Carlo simulation model.

Estimated allocation date 2025[1]	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Dr. Sierk Poetting	8,177	€240.21
Jens Holstein	4,088	240.21

(1) Valuation parameters for estimated allocation dates derived from the Monte-Carlo simulation model.

Estimated allocation date 2026[1]	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Dr. Sierk Poetting	7,314	€246.18

(1) Valuation parameters for estimated allocation dates derived from the Monte-Carlo simulation model.

As of December 31, 2021, the share options allocated and expected to be allocated had a remaining weighted-average expected life of 3.7 years (as of December 31, 2020: 4.6 years).

17.4 Chief Executive Officer Grant (Equity-Settled)

Description of Share-Based Payments

In September 2019, we granted Prof. Ugur Sahin, M.D. an option to purchase 4,374,963 ordinary shares, subject to Prof. Sahin's continuous employment with us. The options' exercise price per share is the Euro translation of the public offering price from our initial public offering, €13.60 ($15.00) which, as of December 31, 2021, is subject to the effective exercise price cap. The option vests annually in equal installments after four years commencing on the first anniversary of the initial public offering and will be exercisable four years after the initial public offering. The option is subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder. The vested option rights can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the Target Price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, $8.5 billion divided by the total number of the shares outstanding immediately following the initial public offering (other than shares owned by us), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. The option rights can be exercised up to ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

Measurement of Fair Values

A Monte-Carlo simulation model has been used to measure the fair value at grant date of the Chief Executive Officer Grant. This model incorporates the impact of the performance criteria regarding share price and index development

described above in the calculation of the award's fair value at grant date. The inputs used in the measurement of the fair value at grant date of the Chief Executive Officer Grant were as follows:

	Grant date October 10, 2019
Weighted average fair value	€5.63
Weighted average share price	€13.60
Exercise price	€13.60
Expected volatility (%)	41.4 %
Expected life (years)	5.4
Risk-free interest rate (%)	1.5 %

Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected term. The expected term was based on general option holder behavior for employee options.

Reconciliation of Outstanding Share-Options

During the years ended December 31, 2021 and 2020, no further options were granted or forfeited.

As of December 31, 2021, the share options outstanding had a remaining weighted-average expected life of 3.1 years (as of December 31, 2020: 4.1 years).

17.5 Employee Stock Ownership Plan (Equity-Settled)

Description of Share-Based Payments

On November 15, 2018, we established a share option program that grants selected employees options to receive shares in the Company. The program is designed as an ESOP. We had offered the participants a certain number of rights (Option Rights) by explicit acceptance of the participants. Grants under the ESOP took place from November 2018 until December 2019. The exercise of the Option Rights in accordance with the terms of the ESOP, gives the participants the right to obtain shares against payment of the exercise price. The Option Rights vest over four years and can only be exercised if we have executed a public offering in the United States (IPO) and when the Threshold Amount is met. Threshold Amount means the exercise price provided that such price increases by eight percentage points on the first and then each subsequent anniversary of the Allocation Date (September 26, 2018). The Option Rights can be exercised at the latest eight years after the Allocation Date. If they have not been exercised by that date, they will be forfeited without compensation.

As of December 31, 2021, with respect to the Management Board members, other than Ryan Richardson who was not a Management Board member at the time the options were granted, the options are subject to the effective exercise price cap.

Measurement of Fair Values

The fair value of the ESOP has been measured using a binomial model. Service conditions attached to the arrangement were not taken into account in measuring the fair value.

The share options can only be exercised by the grantee if the price of the share is equal or greater to the Threshold Amount as defined in the arrangement. Moreover, the option rights can only be exercised if the IPO has occurred. Both conditions have been incorporated into the fair value at grant date.

The inputs used in the measurement of the fair values at grant date of the ESOP were as follows:

	Grant date November 15, 2018	Grant dates between February 21 - April 3, 2019	Grant dates between April 29 - May 31, 2019	Grant date December 1, 2019
Weighted average fair value	€7.41	€6.93	€7.04	€9.49
Weighted average share price	€14.40	€15.72	€16.03	€19.84
Exercise price	€10.14	€15.03	€15.39	€15.82
Expected volatility (%)	46.0 %	46.0 %	46.0 %	46.0 %
Expected life (years)	5.8	6.0	6.0	5.5
Risk-free interest rate (%)	0.1 %	0.1 %	0.1 %	0.1 %

Expected volatility has been based on an evaluation of the historical and the implied volatilities of comparable companies over the historical period commensurate with the expected term. The expected term has been based on general option holder behavior for employee options.

Reconciliation of Outstanding Share-Options

Set out below is an overview of changes to share options outstanding and number of ordinary shares underlying these options that occurred during the periods indicated:

	Share options outstanding	Number of ordinary shares underlying options	Weighted-average exercise price (€)
As of January 1, 2020	655,383	11,796,894	€10.38
Forfeited	(9,491)	(170,838)	10.78
As of December 31, 2020	**645,892**	**11,626,056**	**10.23**
As of January 1, 2021	645,892	11,626,056	10.23
Forfeited	(3,885)	(69,932)	10.14
As of December 31, 2021	**642,007**	**11,556,124**	**€10.23**

As of December 31, 2021, the share options outstanding had a remaining weighted-average expected life of 2.7 years (as of December 31, 2020: 3.7 years).

The share options outstanding as of December 31, 2021, issued to the Management Board Grant were as follows:

	Share options outstanding	Number of ordinary shares underlying options	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	101,686	1,830,348	€10.14
Sean Marett	33,895	610,110	10.14
Dr. Sierk Poetting	33,895	610,110	10.14
Prof. Özlem Türeci, M.D.[1]	108,463	1,952,334	10.14
Ryan Richardson[2]	8,306	149,508	10.14

(1) Options fully vested on March 16, 2019; however these options will not become exercisable until September 16, 2022.

(2) Ryan Richardson was appointed to the Management Board as Chief Strategy Officer (CSO) and Managing Director on January 12, 2020. The share options granted on November 15, 2018, under the Employee Stock Ownership Plan were granted before his appointment to the Management Board. Options fully vested on October 10, 2019; however these options will not become exercisable until September 16, 2022.

18 Provisions and Contingencies

Provisions

As of December 31, 2021, certain claims were pending or threatened against us or our subsidiaries, mainly related to purported obligations arising out of use or alleged use of third party intellectual property. Our best estimate of potential outflow of economic resources from such proceedings amounts to €177.9 million, which is expected not to be settled within the next twelve months and is therefore included in non-current provisions in our consolidated statements of financial position as of December 31, 2021,and was recognized in cost of sales in our consolidated statements of profit or loss (nil as of December 31, 2020). This assessment is based on assumptions deemed reasonable by management including those about future events and uncertainties. The outcome of these matters is ultimately uncertain, such that unanticipated events and circumstances might occur that might cause us to change those assumptions and give rise to a material adverse effect on our financial position in the future.

As of December 31, 2021, our current provisions include €35.4 million (nil as of December 31, 2020) estimated deferred expenses in the form of inventor remuneration, which represents compensation used to honor service inventions made by employees related to our COVID-19 vaccine development and was recognized as research and development expenses in our consolidated statements of profit or loss. The inventor's compensation is determined on the basis of the so-called license analogy and is therefore related to our revenues.

As of December 31, 2021, our current provisions include €58.5 million (nil as of December 31, 2020) international trade obligations including customs value calculation, customs tariff number classification and other related securities requirements whereof €42.1 million related to our commercial sales were recognized as cost of sales and €16.4 million related to clinical trials were recognized as research and development expenses in our consolidated statements of profit or loss. The expenses are partially subject to reimbursement under our collaboration agreement with Pfizer.

Contingencies

In addition to the above, from time to time, in the normal course and conduct of our business, we may be involved in discussions with third parties about considering, for example, the use and/or remuneration for use of such third party's IP. As of December 31, 2021, none of such IP-related considerations that we have been notified of and for which potential claims could be brought against us or our subsidiaries in the future, fulfill the criteria for recording a provision. We will continue to evaluate whether, if circumstances were to change in the future, the recording of a provision may be needed and whether potential indemnification entitlements exist against any such claim. It is currently not practical to estimate the potential liability, if any.

19 Other Liabilities

(in millions)	**December 31, 2021**	**December 31, 2020**
Liabilities to employees	€54.6	€24.3
Other	1.3	4.4
Total	**€55.9**	**€28.7**
Total current	43.1	28.0
Total non-current	12.8	0.7

20 Leases

20.1 Amounts Recognized in the Consolidated Statements of Financial Position

Right-of-Use Assets

The following amounts are presented as right-of-use assets within the consolidated statements of financial position as of the dates indicated:

(in millions)	December 31, 2021	December 31, 2020
Buildings	€175.0	€80.9
Equipment, tools and installations	0.8	—
Automobiles	0.1	0.1
Production facilities	19.4	7.2
Advance payments	2.6	10.8
Total	**€197.9**	**€99.0**

Additions to the right-of-use assets during the year ended December 31, 2021, were €126.5 million (during the year ended December 31, 2020: €22.1 million) including advanced payments of €2.6 million (during the year ended December 31, 2020: €10.8 million) related to embedded leases under contract manufacturing agreements that not yet commenced. Since the advanced lease payments have already been settled, the amounts are not included in the lease liability presented below.

Lease Liability

The following amounts are included in loans and borrowings as of the dates indicated:

(in millions)	December 31, 2021	December 31, 2020
Current	€27.9	€6.1
Non-current	153.7	78.1
Total	**€181.6**	**€84.2**

20.2 Amounts Recognized in the Consolidated Statements of Profit or Loss

Depreciation Charge of Right-of-Use Assets

	Years ended December 31,		
(in millions)	2021	2020	2019
Buildings	€14.7	€4.7	€4.7
Equipment, tools and installations	0.2	—	—
Automobiles	0.1	—	—
Production facilities	14.0	1.6	—
Total depreciation charge	**€29.0**	**€6.3**	**€4.7**
Interest on lease liabilities	2.9	2.0	1.7
Expense related to short-term leases (included in other expenses)	9.1	0.9	0.4
Expense relating to leases of low-value assets that are not short-term leases (included in other expenses)	0.4	0.3	0.1
Total amounts recognized in profit or loss	**€41.4**	**€9.5**	**€6.9**

20.3 Amounts Recognized in the Consolidated Statements of Cash Flows

During the year ended December 31, 2021, the total cash outflow for leases amounted to €17.0 million (during the year ended December 31, 2020: €14.7 million; during the year ended December 31, 2019: €4.8 million).

20.4 Extension Options

The Group has several lease contracts that include extension options. These options are negotiated by management to provide flexibility in managing the leased-asset portfolio and align with the Group's business needs. Management exercises judgement in determining whether these extension options are reasonably certain to be exercised. The undiscounted potential future lease payments, which relate to periods after the exercise date of renewal options and are not included in lease liabilities, amount to up to €82.8 million until 2049 (during the year ended December 31, 2020: €38.3 million until 2049).

21 Related Party Disclosures

21.1 Parent and Ultimate Controlling Party

ATHOS KG, Holzkirchen, Germany is the sole shareholder of AT Impf GmbH, Munich, Germany and beneficial owner of our ordinary shares. Entities controlled by ATHOS KG mainly provide rental and property management activities and sell property, plant and equipment to us. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which enabled it to exercise the majority of voting rights to pass resolutions at BioNTech's Annual General Meeting, or AGM.

21.2 Transactions with Key Management Personnel

Key Management Personnel Compensation

Our key management personnel has been defined as the members of the Management Board and the Supervisory Board. Key management personnel compensation is comprised of the following:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Management Board	**€20.4**	**€23.7**	**€19.8**
Fixed compensation	2.2	1.9	1.3
Short-term incentive – first installment	0.6	0.5	—
Short-term incentive – second installment[1]	1.2	0.6	—
Other performance-related variable compensation[2]	—	—	0.4
Share-based payments (incl. long-term incentive)[3]	16.4	20.7	18.1
Supervisory Board	**€0.4**	**€0.4**	**€0.5**
Total compensation paid to key management personnel	**€20.8**	**€24.1**	**€20.3**

(1) The fair value of the second installment of the short-term incentive compensation which has been classified as cash-settled share-based payment arrangement was determined pursuant to the regulations of IFRS 2 "Share-based Payments." This table shows the pro-rata share of personnel expenses for the respective financial year that are recognized over the award's vesting period beginning as of the service commencement date (date when the respective service agreement becomes effective) until each separate determination date and are remeasured until settlement date.

(2) Includes a one time bonus payment for the year ended December 31, 2019.

(3) The fair value of the share-based payments was determined pursuant to the regulations of IFRS 2 "Share-based Payments." This table shows the pro-rata share of personnel expenses resulting from stock-based compensation for the respective financial year. During the year ended December 31, 2021, the amount included a one-time signing bonus of €800,000 granted to Jens Holstein as of his appointment to the Management Board by awarding 4,246 phantom shares. The phantom shares vest in four equal installments on July 1 of 2022, 2023, 2024 and 2025 but will only be settled in cash on July 1, 2025. As of December 31, 2021, the cash payment is subject to an effective settlement closing price cap. This means that the settlement closing price shall effectively be adjusted to ensure that the current price of an ADS as of the settlement date does not exceed 800% of the closing price applied when the award was initially granted. In addition, the total cash payment under the award shall not exceed €6.4 million. During the year ended December 31, 2020, the amount included expenses from a bonus arrangement agreed with Ryan Richardson in advance of his appointment to the Management Board. During the year ended December 31, 2020, the arrangement was modified from an all-equity share-based payment arrangement into a partly cash and partly equity settled share-based payment arrangement including 4,534

ordinary shares which were issued during the year ended December 31, 2021. In September 2019, we agreed to grant Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, an option to purchase 4,374,963 ordinary shares (see Note 17). Management Board members participate in our ESOP program (see Note 17).

Key Management Personnel Transaction

A number of key management personnel, or their related parties, hold positions in other companies that result in them having control or significant influence over these companies. A number of these companies have entered into transactions with us during the year.

We purchased various goods and services from Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz gemeinnützige GmbH, or TRON.

The aggregate value of transactions related to key management personnel were as follows for the periods indicated:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Consulting services / patent assignment	€—	€—	€0.1
Purchases of various goods and services from TRON[1]	—	10.1	9.9
Total	**€—**	**€10.1**	**€10.0**

(1) We purchase various goods and services from TRON, an institute where Prof. Ugur Sahin, M.D served as Managing Director. TRON is no longer considered to be a related party for the year ended December 31, 2021, as the criteria for such classification are no longer fulfilled.

The outstanding balances of transactions related to key management personnel were as follows as at the periods indicated:

(in millions)	**December 31, 2021**	**December 31, 2020**
TRON[1]	€—	€1.2
Total	**€—**	**€1.2**

(1) We purchase various goods and services from TRON, an institute where Prof. Ugur Sahin, M.D served as Managing Director. TRON is no longer considered to be a related party for the year ended December 31, 2021, as the criteria for such classification are no longer fulfilled.

21.3 Related Party Transactions

The total amount of transactions with ATHOS KG or entities controlled by it was as follows for the periods indicated:

	Years ended December 31,		
(in millions)	**2021**	**2020**	**2019**
Purchases of various goods and services from entities controlled by ATHOS KG	€0.9	€2.3	€2.1
Purchases of property and other assets from entities controlled by ATHOS KG	—	2.3	—
Total	**€0.9**	**€4.6**	**€2.1**

The outstanding balances of transactions with ATHOS KG or entities controlled by them were as follows as at the periods indicated:

(in millions)	**December 31, 2021**	**December 31, 2020**
ATHOS KG	€0.3	€0.5
Total	**€0.3**	**€0.5**

In addition to the transactions above, we have lease arrangements with ATHOS KG or entities controlled by them in place.

None of the balances are secured and no bad debt expense has been recognized in respect of amounts owed by related parties.

22 Events After the Reporting Period

In January 2022, we announced a new research, development and commercialization collaboration with Pfizer to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV). The collaboration builds on the companies' success in developing the first approved and most widely used mRNA vaccine to help prevent COVID-19. Under the terms of the agreement, we will leverage a proprietary antigen technology identified by Pfizer's scientists and our proprietary mRNA platform technology used in the our COVID-19 vaccine. The parties will share development costs. Clinical trials are planned to start in the second half of 2022. Pfizer will have rights to commercialize the potential vaccine on a global basis, with the exception of Germany, Turkey and certain developing countries where we will have commercialization rights. Under the terms of the agreement, Pfizer will pay $225.0 million in upfront payments, including a cash payment and an equity investment as we will pay Pfizer $25.0 million for the company's proprietary antigen technology. In addition, we are eligible to receive future regulatory and sales milestone payments of up to $200.0 million as well as a share of gross profits arising from future product sales. The issuance of 497,727 ordinary shares with the nominal amount of €0.5 million was registered with the commercial register (*Handelsregister*) on March 24, 2022.

In February 2022, we gave notice to Temasek that we will exercise our early redemption option and fully redeem the convertible note on March 1, 2022, the redemption date. The early redemption will be fulfilled by issuing the number of our ordinary shares calculated pursuant to the early redemption provisions of the convertible note, plus paying any fractional share and accrued but unpaid interest up to (but excluding) the redemption date. The early redemption was already expected and reflected in the presentation of the financial liability and our estimates for future cash flows and conversion effects under the convertible note as of December 31, 2021.

In February 2022, we announced that we have entered into a multi-target research collaboration with Medigene AG, or Medigene, to develop T-cell receptor (TCR) based immunotherapies against cancer. The initial term of the collaboration is three years. Under the terms of the agreement, we will acquire Medigene's next generation preclinical TCR program, will obtain the exclusive option to acquire additional existing TCRs in Medigene's discovery pipeline and will receive licenses to Medigene's PD1-41BB switch receptor and precision pairing library. We are responsible for global development and hold exclusive worldwide commercialization rights on all TCR therapies resulting from this research collaboration. Medigene will receive a €26.0 million upfront, as well as research funding for the period of the collaboration and will be eligible to receive development, regulatory and commercial milestone payments up to a triple digit million EUR amount per program in addition to tiered deferred option payments on global net sales for products based on TCRs arising from the collaboration and royalties on products utilizing at least one of the licensed technologies.

The escalation of the conflict between Russia and Ukraine which has led to armed conflicts in Ukraine has created uncertainties regarding the development of the world economy. As of the date of this filing, we do not anticipate any material impact of the conflict on our business. Russia and Ukraine are part of our collaboration partner Pfizer's distribution territory and are currently not expected to have a material effect on our revenues. We also do not expect an impact on our clinical trial execution as we do not have active clinical sites in Russia or Ukraine. We do not have any local subsidiaries in the affected countries, do not have direct relationships with Russian banks and do not purchase raw materials or services from Russian suppliers. Together with our third party vendors, we are monitoring the situation closely to ensure that risk

mitigations are implemented. We will continue to assess any impact, including the medium- to long-term implications on our business and on the world economy, as well as to continue to evaluate any risks as they arise.

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

LEASE AGREEMENT

THIS LEASE AGREEMENT ("**this Lease**") is made as of this 1 day of December, 2017, between **TECH PARK 270 III, LLC**, a Maryland limited liability company ("**Landlord**"), and **KITE PHARMA, INC.**, a Delaware corporation ("**Tenant**").

BASIC LEASE PROVISIONS

Address: Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301.

Premises: That portion of the Project, containing approximately 26,103 rentable square feet, as shown as the hatched area on **Exhibit A**. Gaudreau, Inc., Landlord's architect, has measured the area of the Premises pursuant to the 1996 Standard Method of Measuring Floor Area in Office Buildings as adopted by the Building Owners and Managers Association (ANSI/BOMA Z65.1-1996) ("**BOMA Standards**"). Tenant acknowledges receipt of such measurement and confirms that (a) Tenant has had an opportunity to confirm such measurement with an architect of its selection before the Commencement Date, and (b) such measurement shall be conclusive as to the area of the Premises.

Project: The real property on which the building ("**Building**") in which the Premises are located, together with all improvements thereon and appurtenances thereto as described on **Exhibit B**.

Base Rent: [***] per month **Rentable** **Rentable Area of Premises**: [***] sq. ft.

Area of Project: [***] sq. ft. **Security** **Tenant's Share of Operating Expenses**: [***]%

Deposit: None **Target Commencement Date**: December 1, 2017

Rent Adjustment Percentage: [***]%

Base Term: Beginning on the Commencement Date and ending 144 months from the first day of the first full month following the Rent Commencement Date. For clarity, if the Rent Commencement Date occurs on the first day of a month, the Base Term will be measured from that date. If the Rent Commencement Date occurs on a day other than the first day of a month, the Base Term will be measured from the first day of the following month.

Permitted Use: Biopharmaceutical research and manufacturing, research and development laboratory, related office and other related uses consistent with the character of the Project and otherwise in compliance with the provisions of Section 7 hereof.

Address for Rent Payment: For check payments remit to:

[***]
[***]
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Landlord's Notice Address:
[***]
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[***]

For overnight courier remit to:

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Tenant's Notice Address:
[***]
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[***]

With a copy to:

[***]
[***]
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The following Exhibits and Addenda are attached hereto and incorporated herein by this reference:

[X] **EXHIBIT A** - PREMISES DESCRIPTION
[X] **EXHIBIT B** - DESCRIPTION OF PROJECT
[X] **EXHIBIT C-1** – LANDLORD'S WORK
[X] **EXHIBIT C-2** – WORK LETTER
[X] **EXHIBIT D** - COMMENCEMENT DATE
[X] **EXHIBIT E** - RULES AND REGULATIONS
[X] **EXHIBIT F** - TENANT'S PERSONAL PROPERTY

1. **Lease of Premises**. Upon and subject to all of the terms and conditions hereof, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. The portions of the Project that are for the non-exclusive use of tenants of the Project are collectively referred to herein as the "**Common Areas**." Landlord reserves the right to modify Common Areas, provided that such modifications do not materially adversely affect Tenant's use of the Premises for the Permitted Use or Tenant's rights hereunder. Subject to a Taking (as defined in Section 19) and Force Majeure (as defined in Section 34), Tenant shall have access to the Premises (and the right to use the Common Areas and parking facilities subject to a Taking, Force Majeure, and the provisions of Section 13) 24 hours per day, 7 days per week, 365/366 days per year during the Term. Tenant shall have the exclusive right to use the loading dock serving the Premises.

2. **Delivery; Acceptance of Premises; Commencement Date**. Landlord shall use reasonable efforts to deliver the Premises to Tenant on or before the Target Commencement Date so as to make the Premises available to Tenant for Tenant's Work under the Work Letter (as long as Tenant delivers evidence of the insurance required hereby and by the Work Letter) and to allow Landlord to perform Landlord's Work ("**Delivery**" or "**Deliver**"). If Landlord fails to timely Deliver the Premises, Landlord shall not be liable to Tenant for any loss or damage resulting therefrom, and this Lease shall not be void or voidable except as provided herein. If Landlord does not Deliver the Premises within 60 days of the Target Commencement Date for any reason other than Force Majeure Delays and Tenant Delays, this Lease may be terminated by Tenant by written notice to Landlord, and if so terminated by either: (a) the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), shall be returned to Tenant, and (b) neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease, except with respect to provisions that expressly survive termination of this Lease. As used herein, (a) "**Landlord's Work**"

means the work of constructing the improvements to the Premises described on **Exhibit C-1**, (b) "**Force Majeure Delays**" means delays arising by reason of any Force Majeure, and (c) "**Substantially Completed**" or variations thereof shall have the meaning set forth in the Work Letter attached hereto as **Exhibit C-2**. If Tenant does not elect to void this Lease within 5 business days of the lapse of such 60 day period, such right to void this Lease shall be waived and this Lease shall remain in full force and effect.

The "**Commencement Date**" shall mean the date of this Lease. The "**Rent Commencement Date**" shall be the date that is 10 months after the date on which Landlord Delivers the Premises to Tenant, subject to extension to the extent that Tenant is actually delayed in the design or construction of the Tenant Improvements (as defined in **Exhibit C-2**) by Landlord or by Force Majeure Delays. Upon request of Landlord, Tenant shall execute and deliver a written acknowledgment of the Commencement Date, the Rent Commencement Date, and the expiration date of the Term when such are established in the form of the "Acknowledgement of Commencement Date" attached to this Lease as **Exhibit D**; provided, however, Tenant's failure to execute and deliver such acknowledgment shall not affect Landlord's rights hereunder. The "**Term**" of this Lease shall be the Base Term, as defined above in the Basic Lease Provisions and the Extension Term that Tenant may elect pursuant to Section 40 hereof.

Except as set forth in the Work Letter, if applicable, and in this Section 2: (i) Tenant shall accept the Premises in their condition as of the Commencement Date, subject to all applicable Legal Requirements (as defined in Section 7 hereof); (ii) Landlord shall have no obligation for any defects in the Premises; and (iii) Tenant's taking possession of the Premises shall be conclusive evidence that Tenant accepts the Premises and that the Premises were in good condition at the time possession was taken. Any occupancy of the Premises by Tenant before the Commencement Date shall be subject to all of the terms and conditions of this Lease (other than the obligation to pay Rent).

Tenant agrees and acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of all or any portion of the Premises or the Project, and/or the suitability of the Premises or the Project for the conduct of Tenant's business, and Tenant waives any implied warranty that the Premises or the Project are suitable for the Permitted Use. This Lease constitutes the complete agreement of Landlord and Tenant with respect to the subject matter hereof and supersedes any and all prior representations, inducements, promises, agreements, understandings and negotiations that are not contained herein. Landlord in executing this Lease does so in reliance upon Tenant's representations, warranties, acknowledgments and agreements contained herein.

Notwithstanding the foregoing provisions of this Section 2, Tenant shall have a period of 60 days after the Substantial Completion of Landlord's Work to reasonably identify in writing any latent defects in the mechanical, electrical, and plumbing systems and the structural components serving the Premises. For purposes of this paragraph, "**latent defects**" means those material defects in such systems or components that could not have been identified or discovered through a reasonable inspection of such systems or components conducted by a qualified technician. Landlord will promptly repair such identified latent defects at Landlord's cost (and not as part of "Operating Expenses (as defined below)), subject to Landlord's confirmation that such defects are, in fact, latent defects.

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3. **Rent**.

(a) **Base Rent**. The first month's Base Rent shall be due and payable on delivery of an executed copy of this Lease to Landlord. Beginning on the Rent Commencement Date, Tenant shall pay to Landlord in advance, without demand, abatement, deduction or set-off, monthly installments of Base Rent on or before the first day of each calendar month during the Term hereof, in lawful money of the United States of America, at the office of Landlord for payment of Rent set forth above, or to such other person or at such other place as Landlord may from time to time designate in writing. Payments of Base Rent for any fractional calendar month shall be prorated. The obligation of Tenant to pay Base Rent and other sums to Landlord and the obligations of Landlord under this Lease are independent obligations. Tenant shall have no right at any time to abate, reduce, or set-off any Rent (as defined in Section 5) due hereunder except for any abatement as may be expressly provided in this Lease.

(b) **Additional Rent**. In addition to Base Rent, Tenant agrees to pay to Landlord as additional rent ("**Additional Rent**"): (i) Tenant's Share of "Operating Expenses" (as defined in Section 5), and (ii) any and all other amounts Tenant assumes or agrees to pay under the provisions of this Lease, including, without limitation, any and all other sums that may become due by reason of any default of Tenant or failure to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after any applicable notice and cure period.

4. **Base Rent Adjustments**. Base Rent shall be increased on each anniversary of the Rent Commencement Date (each an "**Adjustment Date**") by multiplying the Base Rent payable immediately before such Adjustment Date by the Rent Adjustment Percentage and adding the resulting amount to the Base Rent payable immediately before such Adjustment Date. Base Rent, as so adjusted, shall thereafter be due as provided herein. Base Rent adjustments for any fractional calendar month shall be prorated.

5. **Operating Expense Payments**. Landlord shall deliver to Tenant a written estimate of Operating Expenses for each calendar year during the Term ("**Annual Estimate**"), which may be revised by Landlord from time to time during such calendar year. Beginning on the Rent Commencement Date, Tenant shall pay Landlord on or before the first day of each calendar month during the Term hereof an amount equal to 1/12th of Tenant's Share of the Annual Estimate. Payments for any fractional calendar month shall be prorated. With the exception of utilities consumed within the Premises, Tenant shall not be obligated to pay Tenant's Share of Operating Expenses before the Rent Commencement Date.

The term "**Operating Expenses**" means all costs and expenses of any kind or description whatsoever incurred or accrued each calendar year by Landlord with respect to the Project (including, without duplication, Taxes (as defined in Section 9), capital repairs and improvements amortized on a straight-line basis over the useful life of such capital items, and the costs of Landlord's third party property manager in the amount of [***]% of Base Rent or, if there is no third party property manager, administration rent in the amount of [***]% of Base Rent), excluding only:

(a) the original construction costs of the Project and renovation prior to the date of this Lease and costs of correcting defects in such original construction or renovation or latent defects;

(b) capital expenditures for expansion of the Project or any other capital improvements, equipment, replacements, or repairs incurred in connection with the Project except for any capital improvements, equipment, replacements, or repairs (i) that are reasonably intended to reduce Operating Expenses, but only to the extent of reasonably intended cost savings, or (ii) that are required under any Legal Requirement enacted after the date of Delivery, and in each case amortized as set forth in the second paragraph of this Section 5;

(c) interest, principal payments of Mortgage (as defined in Section 27) debts of Landlord, financing costs and amortization of funds borrowed by Landlord, whether secured or unsecured and all payments of base rent (but not taxes or operating expenses) under any ground lease or other underlying lease of all or any portion of the Project;

(d) depreciation of the Project (except for capital improvements, the cost of which are includable in Operating Expenses);

(e) advertising, legal and space planning expenses and leasing commissions and other costs and expenses incurred in procuring and leasing space to tenants for the Project, including any leasing office maintained in the Project, free rent and construction allowances for tenants;

(f) legal and other expenses incurred in the negotiation or enforcement of leases;

(g) completing, fixturing, improving, renovating, painting, redecorating or other work, which Landlord pays for or performs for other tenants within their premises, and costs of correcting defects in such work;

(h) costs of utilities outside normal business hours sold to tenants of the Project;

(i) costs to be reimbursed by other tenants of the Project or Taxes to be paid directly by Tenant or other tenants of the Project, whether or not actually paid;

(j) the wages and benefits of any employees who do not devote substantially all of their employed time to the Project unless such wages and benefits are prorated to reflect time spent on operating and managing the Project vis-à-vis time spent on matters unrelated to operating and managing the Project; provided, however, that in no event shall Operating Expenses include wages and/or benefits attributable to personnel above the level of property manager;

(k) general organizational, administrative and overhead costs relating to maintaining Landlord's existence, either as a corporation, partnership, or other entity, including general corporate, legal and accounting expenses;

(l) costs (including attorneys' fees and costs of settlement, judgments and payments in lieu thereof) incurred in connection with disputes with tenants, other occupants, or prospective tenants, and costs and expenses, including legal fees, incurred in connection with negotiations or disputes with employees, consultants, management agents, leasing agents, purchasers or mortgagees of the Building;

(m) costs incurred by Landlord due to the violation by Landlord, its employees, agents or contractors or any tenant of the terms and conditions of any lease of space in the Project or any Legal Requirement (as defined in Section 7);

(n) penalties, fines or interest incurred as a result of Landlord's inability or failure to make payment of Taxes and/or to file any tax or informational returns when due, or from Landlord's failure to make any payment of Taxes required to be made by Landlord hereunder before delinquency;

(o) overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and/or services in or to the Project to the extent the same exceeds the costs of such goods and/or services rendered by unaffiliated third parties on a competitive basis;

(p) costs of Landlord's charitable or political contributions, or of fine art maintained at the Project;

(q) costs in connection with services (including electricity), items or other benefits of a type that are not standard for the Project and that are not available to Tenant without specific charges therefor, but which are provided to another tenant or occupant of the Project, whether or not such other tenant or occupant is specifically charged therefor by Landlord;

(r) costs incurred in the sale or refinancing of the Project;

(s) net income taxes of Landlord or the owner of any interest in the Project (except to the extent such net income taxes are in substitution for any Taxes payable hereunder), franchise, capital stock, gift, estate or inheritance taxes or any federal, state or local documentary taxes imposed against the Project or any portion thereof or interest therein;

(t) reserves for future repairs and replacements;

(u) any expenses otherwise includable within Operating Expenses to the extent actually reimbursed by persons other than tenants of the Project under leases for space in the Project; and

(v) any liabilities, costs, or expenses associated with or incurred in connection with the remediation of environmental conditions or otherwise arising from the presence of any Hazardous Materials (as defined below) in, on, or about the Project (i) that existed before the Commencement Date, (ii) caused solely by Landlord, or (iii) caused by another tenant of the Project or a third party unrelated to Tenant and any Tenant Party (collectively, "**Excluded Hazardous Materials Events**") and the cost of defending against claims in regard to any Excluded Hazardous Materials Events.

In no event shall Landlord collect Operating Expenses from Tenant and all other tenants of the Building in an amount in excess of what Landlord actually incurred for the items included Operating Expenses (without mark-up).

In addition, notwithstanding anything to the contrary contained in this Lease, Operating Expenses incurred or accrued by Landlord with respect to any capital improvements that are reasonably expected by Landlord to reduce overall Operating Expenses (for example, without limitation, by reducing energy usage at the Project) ("**Energy Savings Costs**") shall be amortized over a period of years equal to the least of (A) 7 years, (B) the useful life of such capital items, and (C) the quotient of (i) the Energy Savings Costs, divided by (ii) the annual amount of Operating Expenses reasonably expected by Landlord to be saved as a result of such capital improvements.

Notwithstanding any contrary provision contained in this Lease, the Controllable Operating Expenses (as defined below) shall be capped so that no increase in the Controllable Operating Expenses exceeds [***]% per calendar year based on the actual Controllable Operating Expenses incurred during calendar year 2017. As a result, the actual annual increase in Controllable Operating Expenses in any given calendar year from and after calendar year 2017 may be less than or equal to [***]% (but shall not

exceed [***]%). The calculations made under this paragraph shall be made on a current basis with reference to the calendar year in question, and no retroactive adjustments shall be made at the end of the Term for the preceding calendar years. For purposes of this Lease, (1) "**Controllable Operating Expenses**" means all Operating Expenses except Non-Controllable Operating Expenses, and (2) "**Non-Controllable Operating Expenses**" means insurance premiums, real estate taxes, costs of snow and ice removal, utilities costs, and costs of repairs and replacements to Building Systems (as defined below) as long as such repairs and replacements are consistent in quality and kind with the Building Systems being repaired or replaced.

Within 90 days after the end of each calendar year (or such longer period as may be reasonably required), Landlord shall furnish to Tenant a statement (an "**Annual Statement**") showing in reasonable detail: (a) the total and Tenant's Share of actual Operating Expenses for the previous calendar year, and (b) the total of Tenant's payments in respect of Operating Expenses for such year. If Tenant's Share of actual Operating Expenses for such year exceeds Tenant's payments of Operating Expenses for such year, the excess shall be due and payable by Tenant as Rent within 30 days after delivery of such Annual Statement to Tenant. If Tenant's payments of Operating Expenses for such year exceed Tenant's Share of actual Operating Expenses for such year Landlord shall pay the excess to Tenant within 30 days after delivery of such Annual Statement, except that after the expiration, or earlier termination of the Term or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord.

Operating Expenses for the calendar years in which Tenant's obligation to share therein begins and ends shall be prorated. Notwithstanding anything set forth herein to the contrary, if the Project is not at least 95% occupied on average during any year of the Term, Tenant's Share of Operating Expenses for such year shall be computed as though the Project had been 95% occupied on average during such year. Notwithstanding the foregoing, Tenant shall not be responsible for Tenant's Share of Operating Expenses that are first billed to Tenant more than one year after the end of the year to which such Operating Expenses relate.

Within one year after receipt of an Annual Statement by Tenant ("**Review Period**"), if Tenant disputes the amount set forth in the Annual Statement, Tenant's employees or an independent certified public accountant designated by Tenant, may, after reasonable notice to Landlord and at reasonable times, inspect Landlord's records at Landlord's offices. If Tenant does not so dispute the Annual Statement by the expiration of the Review Period, the Annual Statement shall be final and binding on Tenant. If after such inspection Tenant notifies Landlord in writing that Tenant still disputes such amounts, a certification as to the proper amount shall be made by an independent certified public accountant selected by Landlord and reasonably approved by Tenant and who is a member of a nationally or regionally recognized accounting firm, which certification shall be binding upon Landlord and Tenant. Landlord shall cooperate in good faith with Tenant and the accountant to show Tenant and the accountant the information upon which the certification is to be based. However, if such certification by the accountant proves that the Operating Expenses set forth in the Annual Statement were overstated by more than 3%, then the reasonable cost of Tenant's initial review, the accountant, and the cost of such certification shall be paid for by Landlord. Promptly following the parties' receipt of such certification, the parties shall make such appropriate payments or reimbursements, as the case may be, to each other, as are determined to be owing pursuant to such certification.

"**Tenant's Share**" shall be the percentage set forth in the Basic Lease Provisions as Tenant's Share as reasonably adjusted by Landlord for changes in the physical size of the Premises or the Project occurring thereafter. Landlord may equitably adjust Tenant's Share for any item of expense or cost reimbursable by Tenant that relates to a repair, replacement, or service that benefits only the Premises or only a portion of the Project that includes the Premises or that varies with occupancy or use. Base Rent, Tenant's Share of Operating Expenses and all other amounts payable by Tenant to Landlord hereunder are collectively referred to herein as "**Rent**."

6. **Reserved**.

7. **Use**. The Premises shall be used solely for the Permitted Use set forth in the Basic Lease Provisions, and in compliance with all laws, orders, judgments, ordinances, regulations, codes, directives, permits, licenses, covenants and restrictions now or hereafter applicable to the Premises, and to the use and occupancy thereof, including, without limitation, the Americans With Disabilities Act, 42 U.S.C. § 12101, et seq. (together with the regulations promulgated pursuant thereto, "**ADA**") (collectively, "**Legal Requirements**" and each, a "**Legal Requirement**"). Tenant shall, upon 5 days' written notice from Landlord, discontinue any use of the Premises that is declared by any Governmental Authority (as defined in Section 9) having jurisdiction to be a violation of a Legal Requirement. Tenant will not use or permit the Premises to be used for any purpose or in any manner that would void Tenant's or Landlord's insurance, increase the insurance risk, or cause the disallowance of any sprinkler or other credits. Tenant shall not permit any part of the Premises to be used as a "place of public accommodation", as defined in the ADA or any similar legal requirement. Tenant shall reimburse Landlord promptly upon demand for any additional premium charged for any such insurance policy by reason of Tenant's failure to comply with the provisions of this Section or otherwise caused by Tenant's use and/or occupancy of the Premises. Tenant will use the Premises in a careful, safe and proper manner and will not commit or permit waste, overload the floor or structure of the Premises, subject the Premises to use that would damage the Premises or obstruct or interfere with the rights of Landlord or other tenants or occupants of the Project, including conducting or giving notice of any auction, liquidation, or going out of business sale on the Premises, or using or allowing the Premises to be used for any unlawful purpose. Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations from the Premises from extending into Common Areas, or other space in the Project. Tenant shall not place any machinery or equipment weighing 500 pounds or more in or upon the Premises or transport or move such items through the Common Areas of the Project without the prior written consent of Landlord. Except as may be provided under the Work Letter, Tenant shall not, without the prior written consent of Landlord, use the Premises in any manner that will require ventilation, air exchange, heating, gas, steam, electricity or water beyond the existing capacity of the Project as proportionately allocated to the Premises based upon Tenant's Share as usually furnished for the Permitted Use.

(a) **Modifications to Common Areas**. Landlord shall be responsible for the compliance of the Common Areas of the Project with the ADA and other Legal Requirements as of the Commencement Date (and shall not include such costs in Operating Expenses). From and after the Commencement Date, Landlord shall, as an Operating Expense (to the extent such Legal Requirement is generally applicable to similar buildings in the area in which the Project is located) or at Tenant's expense (to the extent such Legal Requirement is applicable solely by reason of Tenant's, as compared to other tenants of the Project, particular use of the Premises) make any alterations or modifications to the Common Areas or the exterior of the Building that are required by Legal Requirements, including the ADA. Tenant, at its sole expense, shall make any alterations or modifications to the interior of the Premises that are required by Legal Requirements (including, without limitation, compliance of the Premises with the ADA). Notwithstanding any other provision herein to the contrary, Tenant shall be responsible for any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages or judgments, and all reasonable expenses incurred in investigating or resisting the same (including, without limitation, reasonable attorneys' fees, charges and disbursements and costs of suit) (collectively, "**Claims**") arising out of or in connection with the failure of the Premises to comply with any Legal Requirements, and Tenant shall indemnify, defend, hold and save Landlord harmless from and against any and all Claims arising out of or in connection with any failure of the Premises to comply with any Legal Requirement.

(b) **Alexandria FitLab**. As long as Tenant is not in Default, Tenant's on-site employees shall have a non-exclusive license to use on a complimentary basis the Alexandria FitLab located at 910 Clopper Road, Gaithersburg, Maryland that is owned by an affiliate of Landlord ("**910 Clopper Landlord**"). Although the Alexandria FitLab does not form a part of the Premises, the provisions of this Lease (i) governing Tenant's use, operation, and enjoyment of the Premises as applicable to Tenant's

use of the Alexandria FitLab, (ii) imposing obligations on Tenant for matters occurring in, on, within, or about the Premises or arising out of the use or occupancy of the Premises (including, but not limited to, those obligations relating to insurance and indemnification) as applicable to Tenant's use of the Alexandria FitLab, or (iii) limiting Landlord's liability, shall apply with equal force to Tenant's use of the Alexandria FitLab. Landlord shall have the right at any time and from time to time in the exercise of its sole and absolute subjective discretion to eliminate, reconfigure, relocate, or modify the Alexandria FitLab or modify its hours of availability for Tenant's use, it being understood and agreed that Landlord makes no guaranty, assurance, or representation to Tenant that the Alexandria FitLab will remain available for use by Tenant during all or any part of the Term. Landlord or its designee may specifically condition the use of the Alexandria FitLab by any employee of Tenant upon such employee's execution and delivery of the standard license, indemnification, and waiver agreement required by Landlord or, if applicable, any operator of the Alexandria FitLab. Tenant and its employees shall be required to comply with all of the rules, regulations, conditions, and scheduling procedures of the 910 Clopper Landlord in connection with the use of the Alexandria FitLab. As of the Commencement Date, Tenant shall cause the 910 Clopper Landlord to be named as an additional insured under the commercial general liability policy of insurance that Tenant is required to maintain under this Lease. If Tenant Defaults in its obligations under this Section 7(b), Landlord shall have the right, in addition to any other rights and remedies available to Landlord for a Default by Tenant, to terminate immediately Tenant's license to use the Alexandria FitLab. The expiration or earlier termination of this Lease shall automatically terminate the license hereby granted to Tenant to so use the Alexandria FitLab.

(c) **Food Vending Machines; Micro-Market Systems**. Tenant shall have the right to install within the Premises, without Landlord's consent but otherwise subject to the provisions of Section 12, one or more food vending machines and micro-market systems for the use by Tenant's employees (collectively, "**Food Service Equipment**"). Tenant shall install, use, operate, maintain, and replace the Food Service Equipment in accordance with applicable Legal Requirements (including, but not limited to, obtaining and maintaining at Tenant's sole cost and expense any permits or licenses to install, use, and operate the Food Service Equipment). In no event shall the Food Service Equipment dispense or offer any alcoholic beverages, tobacco products, or chewing gum. Landlord shall have no obligation, responsibility, or liability for the operation of the Food Service Equipment. All food sold or dispensed from the Food Service Equipment shall be free from spoilage and decay and shall not be suspect of contamination from organisms causing foodborne illness.

8. **Holding Over**. If Tenant remains in possession of the Premises after the expiration or earlier termination of the Term, (a) Tenant shall become a tenant at sufferance upon the terms of this Lease except that (i) the monthly rental for the first 60 days of the holdover shall be equal to [***]% of Base Rent (and [***]% of the Additional Rent) in effect during the last 30 days of the Term, and (ii) from and after the initial 60 days of the holdover, the monthly rental shall be equal to [***]% of Base Rent (and [***]% of the Additional Rent) in effect during the last 30 days of the Term, and (b) Tenant shall be responsible for all damages suffered by Landlord resulting from or occasioned by Tenant's holding over, including consequential damages. No holding over by Tenant, whether with or without consent of Landlord, shall operate to extend this Lease except as otherwise expressly provided, and this Section 8 shall not be construed as consent for Tenant to retain possession of the Premises. Acceptance by Landlord of Rent after the expiration of the Term or earlier termination of this Lease shall not result in a renewal or reinstatement of this Lease.

9. **Taxes**. Landlord shall pay, as part of Operating Expenses, all taxes, levies, fees, assessments and governmental charges of any kind, existing as of the Commencement Date or thereafter enacted (collectively referred to as "**Taxes**"), imposed by any federal, state, regional, municipal, local or other governmental authority or agency, including, without limitation, quasi-public agencies (collectively, "**Governmental Authority**") during the Term with respect to the land, buildings, and other improvements comprising the Project, including, without limitation, all Taxes: (i) imposed on or measured by or based, in whole or in part, on rent payable to (or gross receipts received by) Landlord under this

Lease and/or from the rental by Landlord of the Project or any portion thereof, or (ii) based on the square footage, assessed value or other measure or evaluation of any kind of the Premises or the Project, or (iii) assessed or imposed by or on the operation or maintenance of any portion of the Premises or the Project, including parking, or (iv) assessed or imposed by, or at the direction of, or resulting from Legal Requirements, or interpretations thereof, promulgated by any Governmental Authority, or (v) imposed as a license or other fee, charge, tax, or assessment on Landlord's business or occupation of leasing space in the Project. Landlord may contest by appropriate legal proceedings the amount, validity, or application of any Taxes or liens securing Taxes. Taxes shall not include any net income taxes imposed on Landlord except to the extent such net income taxes are in substitution for any Taxes payable hereunder. If any such Tax is levied or assessed directly against Tenant, then Tenant shall be responsible for and shall pay the same at such times and in such manner as the taxing authority shall require. Tenant shall pay, prior to delinquency, any and all Taxes levied or assessed against any personal property or trade fixtures placed by Tenant in the Premises, whether levied or assessed against Landlord or Tenant. If any Taxes on Tenant's personal property or trade fixtures are levied against Landlord or Landlord's property, or if the assessed valuation of the Project is increased by a value attributable to improvements in or alterations to the Premises, whether owned by Landlord or Tenant and whether or not affixed to the real property so as to become a part thereof, higher than the base valuation on which Landlord from time-to-time allocates Taxes to all tenants in the Project, Landlord shall have the right, but not the obligation, to pay such Taxes. Landlord's determination of any excess assessed valuation shall be binding and conclusive, absent manifest error. The amount of any such payment by Landlord shall constitute Additional Rent due from Tenant to Landlord immediately upon demand.

10. **Parking**. Subject to all Legal Requirements, Force Majeure, a Taking (as defined in Section 19 below) and the exercise by Landlord of its rights hereunder, Tenant shall have the right, in common with other tenants of the Project pro rata in accordance with the rentable area of the Premises and the rentable areas of the Project occupied by such other tenants, to park in those areas designated for non-reserved parking, subject in each case to Landlord's reasonable rules and regulations at no cost to Tenant. Landlord may allocate parking spaces among Tenant and other tenants in the Project pro rata as described above if Landlord determines that such parking facilities are becoming crowded. Landlord shall not be responsible for enforcing Tenant's parking rights against any third parties, including other tenants of the Project. As of the Commencement Date, the current parking ratio is 3.3 standard sized spaces per 1,000 leased rentable square feet.

11. **Utilities, Services.**

(a) **General**. Landlord shall provide, subject to the terms of this Section 11, janitorial services to the Common Areas, water, electricity, heat, light, power, telephone, sewer, and other utilities (including gas and fire sprinklers to the extent the Project is plumbed for such services), and refuse and trash collection (collectively, "**Utilities**"). Landlord shall pay, as Operating Expenses or subject to Tenant's reimbursement obligation, for all Utilities used on the Premises, all maintenance charges for Utilities, and any storm sewer charges or other similar charges for Utilities imposed by any Governmental Authority or Utility provider, and any taxes, penalties, surcharges or similar charges thereon. Landlord may cause, at Tenant's expense, any Utilities to be separately metered or charged directly to Tenant by the provider. Landlord shall, at its cost and as part of Landlord's Work, install separate electrical submeters in the Premises. Tenant shall pay directly to the Utility provider or reimburse Landlord (as Additional Rent), prior to delinquency, any separately metered Utilities and services that may be furnished to Tenant or the Premises during the Term. Tenant shall pay, as part of Operating Expenses, its share of all charges for jointly metered Utilities based upon consumption, as reasonably determined by Landlord based upon the actual utility rates without markup. Except as provided in paragraph (b) below, no interruption or failure of Utilities from any cause whatsoever shall result in eviction or constructive eviction of Tenant, termination of this Lease or the abatement of Rent. Tenant agrees to limit use of water and sewer with respect to Common Areas to normal restroom use. Landlord shall use commercially

reasonable efforts to promptly restore the utilities to the extent the cause of the interruption or the means to restore the same is within Landlord's reasonable control.

(b) **Abatement**. Notwithstanding the provisions of paragraph (a) above, if Tenant is prevented from using, and does not use, the Premises or any material portion thereof as a result of any failure of Landlord to provide or repair/restore Utilities in accordance with this Section 11, then Tenant shall give Landlord written notice of such failure. If such failure continues for 3 consecutive days after Landlord's receipt of any such notice ("**Eligibility Period**") and is solely due to Landlord's gross negligence or willful misconduct (to the extent within Landlord's reasonable control) ("**Abatement Event**"), then Base Rent and Operating Expenses shall be abated or reduced, as the case may be, after the expiration of the Eligibility Period, for such time that such Abatement Event continues ("**Abatement Period**"), in the proportion that the rentable area of the portion of the Premises that Tenant is actually prevented from using, and does not use, bears to the total rentable area of the Premises. Tenant's right to abate Base Rent under this Section 11 shall be Tenant's sole and exclusive remedy at law or in equity for an Abatement Event. This Section shall not apply to any event described in Section 18 or 19.

(c) **Energy Usage Data**. Tenant agrees to provide Landlord with access to Tenant's water and/or energy usage data on a monthly basis, either by providing Tenant's applicable utility login credentials to Landlord's designated online portal, or by another delivery method reasonably agreed to by Landlord and Tenant. The costs and expenses incurred by Landlord in connection with receiving and analyzing such water and/or energy usage data (including, without limitation, as may be required pursuant to applicable Legal Requirements) shall be included as part of Operating Expenses.

12. **Alterations and Tenant's Property**. Any alterations, additions, or improvements made to the Premises by or on behalf of Tenant, including additional locks or bolts of any kind or nature upon any doors or windows in the Premises, but excluding installation, removal or realignment of furniture systems (other than removal of furniture systems owned or paid for by Landlord) not involving any modifications to the structure or connections (other than by ordinary plugs or jacks) to Building Systems (as defined in Section 13) ("**Alterations**") shall be subject to Landlord's prior written consent, which may be given or withheld in Landlord's sole discretion if any such Alteration affects the structure or Building Systems, but which shall otherwise not be unreasonably withheld or delayed. Tenant may construct nonstructural Alterations in the Premises without Landlord's prior approval if the aggregate cost of all such work in any 12 month period does not exceed $[***] (a "**Notice-Only Alteration**"), provided Tenant notifies Landlord in writing of such intended Notice-Only Alteration, and such notice shall be accompanied by plans, specifications, work contracts and such other information concerning the nature and cost of the Notice-Only Alteration as may be reasonably requested by Landlord, which notice and accompanying materials shall be delivered to Landlord not less than 15 days in advance of any proposed construction. If Landlord approves any Alterations, Landlord may impose such conditions on Tenant in connection with the commencement, performance and completion of such Alterations as Landlord may deem appropriate in Landlord's reasonable discretion. Any request for approval shall be in writing, delivered not less than 15 business days in advance of any proposed construction, and accompanied by plans, specifications, bid proposals, work contracts and such other information concerning the nature and cost of the alterations as may be reasonably requested by Landlord, including the identities and mailing addresses of all persons performing work or supplying materials. Landlord's right to review plans and specifications and to monitor construction shall be solely for its own benefit, and Landlord shall have no duty to ensure that such plans and specifications or construction comply with applicable Legal Requirements. Tenant shall cause, at its sole cost and expense, all Alterations to comply with insurance requirements and with Legal Requirements and shall implement at its sole cost and expense any alteration or modification required by Legal Requirements as a result of any Alterations. Tenant shall pay to Landlord, as Additional Rent, within 30 days after receipt of a reasonably detailed invoice specifying any reasonable out of pocket costs incurred by Landlord in connection with any Alteration that is not a Notice-Only Alteration. Before Tenant begins any Alteration, Landlord may post on and about the Premises notices of non-responsibility pursuant to applicable law. Tenant shall reimburse Landlord for,

and indemnify and hold Landlord harmless from, any expense incurred by Landlord by reason of faulty work done by Tenant or its contractors, delays caused by such work, or inadequate cleanup.

(a) **Insurance**. Tenant shall provide (and cause each contractor or subcontractor to provide) certificates of insurance (in form and substance satisfactory to Landlord; form ACORD 28 [2006/07] is not satisfactory to Landlord) for workers' compensation and other coverage in amounts and from an insurance company satisfactory to Landlord protecting Landlord against liability for personal injury or property damage during construction. Upon completion of any Alterations, Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and subcontractors who did the work and final lien waivers from all such contractors and subcontractors; and (ii) "as built" plans for any such Alteration (if applicable).

(b) **Tenant's Property; Installations**. Other than (i) the items, if any, listed on **Exhibit F** attached hereto, (ii) any items agreed by Landlord in writing to be included on **Exhibit F** in the future, and (iii) any trade fixtures, machinery, equipment and other personal property not paid for out of the TI Allowance (as defined in the Work Letter) that may be removed without material damage to the Premises, which damage shall be repaired (including capping or terminating utility hook-ups behind walls) by Tenant during the Term (collectively, "**Tenant's Property**"), all property of any kind paid for with the TI Allowance, all Alterations, real property fixtures, built-in machinery and equipment, built-in casework and cabinets and other similar additions and improvements built into the Premises so as to become an integral part of the Premises, such as fume hoods that penetrate the roof or plenum area, built-in cold rooms, built-in warm rooms, walk-in cold rooms, walk-in warm rooms, deionized water systems, glass washing equipment, autoclaves, chillers, built-in plumbing, electrical and mechanical equipment and systems, and any power generator and transfer switch (collectively, "**Installations**") shall be and shall remain the property of Landlord during the Term and following the expiration or earlier termination of the Term, shall not be removed by Tenant at any time during the Term and shall remain upon and be surrendered with the Premises as a part thereof in accordance with Section 28 following the expiration or earlier termination of this Lease; provided, however, that (A) Landlord shall, at the time its approval of such Installation is requested or at the time it receives notice of a Notice-Only Alteration, notify Tenant if it has elected to cause Tenant to remove such Installation upon the expiration or earlier termination of this Lease, and (B) in no event shall Tenant have any obligation to remove from the Premises at the expiration or earlier termination of the Term those Installations approved by Landlord in the nature of HVAC, mechanical, electrical, and plumbing systems that form an integral part of the Premises. If Landlord so elects, Tenant shall remove such Installation upon the expiration or earlier termination of this Lease and restore any damage caused by or occasioned as a result of such removal, including, when removing any of Tenant's Property that was plumbed, wired or otherwise connected to any of the Building Systems, capping off all such connections behind the walls of the Premises and repairing any holes. During any such restoration period, Tenant shall pay Rent to Landlord as provided herein as if said space were otherwise occupied by Tenant.

(c) **Lien Waivers**. At Tenant's request, Landlord shall execute and deliver commercially reasonable lien waivers in favor of Tenant's equipment lender for Tenant's Property located on the Premises, which lien waivers shall (i) be limited to specific items of equipment (instead of so-called "blanket" lien waivers), and (ii) , in all cases, be in the form of the lien waivers, if any, used by Landlord and its affiliates with the lender in question.

13. **Landlord's Repairs**. Landlord, as an Operating Expense, shall maintain all of the structural portions of the Building (including the structural portions of the foundation, structural portions of the walls, structural portions of the floor/ceiling slabs, roof, exterior glass and mullions, columns, beams, shafts (including elevator shafts), elevators, and structural portions of the stairs), exterior, parking and other Common Areas of the Project, including electrical, life safety, plumbing, fire sprinklers, and all other building systems serving the Premises and other portions of the Project ("**Building Systems**"), in good repair, reasonable wear and tear and uninsured losses and damages caused by Tenant, or by any of

Tenant's agents, servants, employees, invitees and contractors (collectively, "**Tenant Parties**") excluded. Losses and damages caused by Tenant or any Tenant Party shall be repaired by Landlord, to the extent not covered by insurance, at Tenant's sole cost and expense, subject to the terms of Section 17 below regarding each party's waiver of subrogation. Landlord reserves the right to stop Building Systems services when necessary (i) by reason of accident or emergency, or (ii) for planned repairs, alterations or improvements, which are, in the judgment of Landlord, desirable or necessary to be made, until said repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply Building Systems services during any such period of interruption; provided, however, that Landlord shall, except in case of emergency, make a commercially reasonable effort to give Tenant 48 hours advance notice of any planned stoppage of Building Systems services for routine maintenance, repairs, alterations or improvements. Tenant shall promptly give Landlord written notice of any repair required by Landlord pursuant to this Section, after which Landlord shall have a reasonable opportunity to effect such repair. Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after Tenant's written notice of the need for such repairs or maintenance. Tenant waives its rights under any state or local law to terminate this Lease or to make such repairs at Landlord's expense and agrees that the parties' respective rights with respect to such matters shall be solely as set forth herein. Repairs required as the result of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction shall be controlled by Section 18.

14. **Tenant's Repairs**. Subject to Section 13 hereof, Tenant, at its expense, shall repair, replace and maintain in good condition all portions of the Premises, including, without limitation, entries, doors, ceilings, interior windows, interior walls, the interior side of demising walls, and HVAC systems serving the Premises. Such repair and replacement may include capital expenditures and repairs whose benefit may extend beyond the Term. Should Tenant fail to make any such repair or replacement or fail to maintain the Premises, Landlord shall give Tenant notice of such failure. If Tenant fails to commence cure of such failure within 10 days of Landlord's notice, and thereafter diligently prosecute such cure to completion, Landlord may perform such work and shall be reimbursed the actual, reasonable cost thereof by Tenant within 10 days after demand therefor; provided, however, that if such failure by Tenant creates or could create an emergency, Landlord may immediately commence cure of such failure and shall thereafter be entitled to recover the actual, reasonable costs of such cure from Tenant. Subject to Sections 17 and 18, Tenant shall bear the full uninsured cost of any repair or replacement to any part of the Project that results from damage caused by Tenant or any Tenant Party and any repair that benefits only the Premises.

(a) **HVAC Maintenance Contracts**. Tenant, at its expense, shall at all times during the Term maintain with qualified contractors maintenance and repair contracts ("**HVAC Maintenance Contracts**") for all HVAC units serving the Premises. The HVAC Maintenance Contracts shall be in form and content reasonably satisfactory to Landlord. Landlord shall be a third party beneficiary of the HVAC Maintenance Contracts and, within 30 days after Landlord's request, Tenant shall deliver a copy of the HVAC Maintenance Contracts to Landlord.

(b) **HVAC Condition; Replacement**. Within 15 days after the Commencement Date, Landlord shall obtain and provide to Tenant a copy of a report prepared by a reputable mechanical engineer evaluating the condition of the base building HVAC system serving the Premises. If the report indicates that such HVAC system is not in good operating condition, Landlord shall, at its sole cost and expense, promptly replace such HVAC system with a new HVAC systems of comparable tonnage. Tenant shall thereafter maintain, repair, and replace such HVAC system as provided in this Section 14.

15. **Mechanic's Liens**. Tenant shall discharge, by bond or otherwise, any mechanic's lien filed against the Premises or against the Project for work claimed to have been done for, or materials claimed to have been furnished to, Tenant within 10 days after the filing thereof, at Tenant's sole cost and shall otherwise keep the Premises and the Project free from any liens arising out of work performed,

materials furnished or obligations incurred by Tenant. Should Tenant fail to discharge any lien described herein, Landlord shall have the right, but not the obligation, to pay such claim or post a bond or otherwise provide security to eliminate the lien as a claim against title to the Project and the cost thereof shall be immediately due from Tenant as Additional Rent. If Tenant shall lease or finance the acquisition of office equipment, furnishings, or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code Financing Statement filed as a matter of public record by any lessor or creditor of Tenant will upon its face or by exhibit thereto indicate that such Financing Statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Project be furnished on the statement without qualifying language as to applicability of the lien only to removable personal property, located in an identified suite held by Tenant.

16. **Indemnification.**

(a) **By Tenant**. Tenant hereby indemnifies and agrees to defend, save and hold Landlord harmless from and against any and all third party Claims for injury or death to persons or damage to property occurring within or about the Premises, arising directly or indirectly out of use or occupancy of the Premises or a breach or default by Tenant in the performance of any of its obligations hereunder, except to the extent caused by the willful misconduct or negligence of Landlord or its employees. Landlord shall not be liable to Tenant for, and Tenant assumes all risk of damage to, personal property at the Premises (including, without limitation, loss of records kept within the Premises). Tenant further waives any and all Claims for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property (including, without limitation, any loss of records). Landlord shall not be liable for any damages arising from any act, omission or neglect of any tenant in the Project or of any other third party.

(b) **By Landlord**. Landlord hereby indemnifies and agrees to defend, save and hold Tenant harmless from and against (i) any and all Claims for injury or death to persons or damage to property occurring within or about the Project (excluding, however, the Premises) to the extent arising directly or indirectly out of a breach or default by Landlord in the performance of any of its obligations hereunder, except to the extent caused by the willful misconduct or negligence of Tenant or its employees, and (ii) any and all Claims relating to the presence of Hazardous Materials in, on, under, or about the Project before the Commencement Date ("**Pre-Existing Environmental Condition**"), including Claims relating to the removal or remediation of Hazardous Materials that are a Pre-Existing Environmental Condition.

17. **Insurance**. Landlord shall maintain all risk property and, if applicable, sprinkler damage insurance covering the full replacement cost of the Project or such lesser coverage amount as Landlord may elect provided such coverage amount is not less than [***]% of such full replacement cost. Landlord shall further procure and maintain commercial general liability insurance with a single loss limit of not less than $[***] for bodily injury and property damage with respect to the Project. Landlord may, but is not obligated to, maintain such other insurance and additional coverages as it may deem necessary, including, but not limited to, flood, environmental hazard and earthquake, loss or failure of building equipment, errors and omissions, rental loss during the period of repair or rebuilding, workers' compensation insurance and fidelity bonds for employees employed to perform services and insurance for any improvements installed by Tenant or that are in addition to the standard improvements customarily furnished by Landlord without regard to whether or not such are made a part of the Project. All such insurance shall be included as part of the Operating Expenses. The Project may be included in a blanket policy (in which case the cost of such insurance allocable to the Project will be determined by Landlord based upon the insurer's cost calculations). Tenant shall also reimburse Landlord for any increased premiums or additional insurance that Landlord reasonably deems necessary as a result of Tenant's use of the Premises.

Tenant, at its sole cost and expense, shall maintain during the Term: all risk property insurance with business interruption and extra expense coverage, covering the full replacement cost of all property and improvements installed or placed in the Premises by Tenant at Tenant's expense; workers' compensation insurance with no less than the minimum limits required by law; employer's liability insurance with such limits as required by law; and commercial general liability insurance, with a minimum limit of not less than $[***] per occurrence for bodily injury and property damage with respect to the Premises. The commercial general liability insurance policy shall name Landlord and Alexandria Real Estate Equities, Inc., and its and their respective members, officers, directors, employees, managers, and agents (collectively, "**Landlord Parties**"), as additional insureds; insure on an occurrence and not a claims-made basis; be issued by insurance companies that have a rating of not less than policyholder rating of A and financial category rating of at least Class VII in "Best's Insurance Guide"; shall not be cancelable for nonpayment of premium unless 10 days prior written notice shall have been given to Landlord from the insurer; contain a hostile fire endorsement and a contractual liability endorsement; and provide primary coverage to Landlord (any policy issued to Landlord providing duplicate or similar coverage shall be deemed excess over Tenant's policies). Copies of such policies (if requested by Landlord), or certificates of insurance (in form and substance satisfactory to Landlord; form ACORD 28 [2006/07] is not satisfactory to Landlord) showing the limits of coverage required hereunder and showing Landlord as an additional insured, along with reasonable evidence of the payment of premiums for the applicable period, shall be delivered to Landlord by Tenant upon Tenant's execution and delivery of this Lease and upon each renewal of said insurance. Tenant's policy may be a "blanket policy" with an aggregate per location endorsement that specifically provides that the amount of insurance shall not be prejudiced by other losses covered by the policy. Tenant shall, at least 5 days prior to the expiration of such policies, furnish Landlord with renewal certificates.

In each instance where insurance is to name Landlord as an additional insured, Tenant shall upon written request of Landlord also designate and furnish certificates so evidencing Landlord as additional insured to: (i) any lender of Landlord holding a security interest in the Project or any portion thereof, (ii) the landlord under any lease wherein Landlord is tenant of the real property on which the Project is located, if the interest of Landlord is or shall become that of a tenant under a ground or other underlying lease rather than that of a fee owner, and/or (iii) any management company retained by Landlord to manage the Project.

The property insurance obtained by Landlord and Tenant shall include a waiver of subrogation by the insurers and all rights based upon an assignment from its insured, against Landlord or Tenant, and their respective officers, directors, employees, managers, agents, invitees and contractors ("**Related Parties**"), in connection with any loss or damage thereby insured against. Neither party nor its respective Related Parties shall be liable to the other for loss or damage caused by any risk insured against under property insurance required to be maintained hereunder, and each party waives any claims against the other party, and its respective Related Parties, for such loss or damage. The failure of a party to insure its property shall not void this waiver. Landlord and its respective Related Parties shall not be liable for, and Tenant hereby waives all claims against such parties for, business interruption and losses occasioned thereby sustained by Tenant or any person claiming through Tenant resulting from any accident or occurrence in or upon the Premises or the Project from any cause whatsoever. If the foregoing waivers shall contravene any law with respect to exculpatory agreements, the liability of Landlord or Tenant shall be deemed not released but shall be secondary to the other's insurer.

Landlord may require insurance policy limits to be raised to conform with requirements of Landlord's lender and/or to bring coverage limits to levels then being generally required of new tenants within the Project, provided that such limits shall not exceed the limits being required by other owners of comparable projects in the vicinity of the Project.

18. **Restoration**. If, at any time during the Term, the Project or the Premises are damaged or destroyed by a fire or other insured casualty, Landlord shall notify Tenant within 60 days after

discovery of such damage as to the amount of time Landlord reasonably estimates it will take to restore the Project or the Premises, as applicable ("**Restoration Period**"). If the Restoration Period is estimated to exceed 12 months ("**Maximum Restoration Period**"), Landlord may, in such notice, elect to terminate this Lease as of the date that is 75 days after the date of discovery of such damage or destruction; provided, however, that notwithstanding Landlord's election to restore, Tenant may elect to terminate this Lease by written notice to Landlord delivered within 5 business days of receipt of a notice from Landlord estimating a Restoration Period for the Premises longer than the Maximum Restoration Period. Unless either Landlord or Tenant so elects to terminate this Lease, Landlord shall, subject to receipt of sufficient insurance proceeds (with any deductible to be treated as a current Operating Expense), promptly restore the Premises (excluding the improvements installed by Tenant or by Landlord and paid for by Tenant), subject to delays arising from the collection of insurance proceeds, from Force Majeure events or as needed to obtain any license, clearance or other authorization of any kind required to enter into and restore the Premises issued by any Governmental Authority having jurisdiction over the use, storage, handling, treatment, generation, release, disposal, removal or remediation of Hazardous Materials (as defined in Section 30) in, on or about the Premises (collectively referred to herein as "**Hazardous Materials Clearances**"); provided, however, that if repair or restoration of the Premises is not substantially complete as of the end of the Maximum Restoration Period or, if longer, the Restoration Period, Landlord may, in its sole and absolute discretion, elect not to proceed with such repair and restoration, or Tenant may by written notice to Landlord delivered within 5 business days of the expiration of the Maximum Restoration Period or, if longer, the Restoration Period, elect to terminate this Lease, in which event Landlord shall be relieved of its obligation to make such repairs or restoration and this Lease shall terminate as of the date that is 75 days after the later of: (i) discovery of such damage or destruction, or (ii) the date all required Hazardous Materials Clearances are obtained, but Landlord shall retain any Rent paid and the right to any Rent payable by Tenant prior to such election by Landlord or Tenant.

Tenant, at its expense, shall promptly perform, subject to delays arising from the collection of insurance proceeds, from Force Majeure (as defined in Section 34) events or to obtain Hazardous Material Clearances, all repairs or restoration not required to be done by Landlord and shall promptly re-enter the Premises and commence doing business in accordance with this Lease. Notwithstanding the foregoing, either Landlord or Tenant may terminate this Lease if the Premises are damaged during the last year of the Term and Landlord reasonably estimates that it will take more than 2 months to repair such damage, or if insurance proceeds are not available for such restoration. Rent shall be abated from the date all required Hazardous Material Clearances are obtained until the Premises are repaired and restored, in the proportion that the area of the Premises, if any, that is not usable by Tenant bears to the total area of the Premises, unless Landlord provides Tenant with other space during the period of repair that is suitable for the temporary conduct of Tenant's business (in Tenant's reasonable discretion). Such abatement shall be the sole remedy of Tenant, and except as provided in this Section 18, Tenant waives any right to terminate this Lease by reason of damage or casualty loss.

The provisions of this Lease, including this Section 18, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, or any other portion of the Project, and any statute or regulation that is now or may hereafter be in effect shall have no application to this Lease or any damage or destruction to all or any part of the Premises or any other portion of the Project, the parties hereto expressly agreeing that this Section 18 sets forth their entire understanding and agreement with respect to such matters.

19. **Condemnation**. If the whole or any material part of the Premises or the Project is taken for any public or quasi-public use under governmental law, ordinance, or regulation, or by right of eminent domain, or by private purchase in lieu thereof (a "**Taking**" or "**Taken**"), and the Taking would either prevent or materially interfere with Tenant's use of the Premises or materially interfere with or impair Landlord's ownership or operation of the Project, then upon written notice by Landlord or Tenant to the other party this Lease shall terminate and Rent shall be apportioned as of said date. If part of the

Premises shall be Taken, and this Lease is not terminated as provided above, Landlord shall promptly restore the Premises and the Project as nearly as is commercially reasonable under the circumstances to their condition prior to such partial Taking and the rentable square footage of the Building, the rentable square footage of the Premises, Tenant's Share of Operating Expenses and the Rent payable hereunder during the unexpired Term shall be reduced to such extent as may be fair and reasonable under the circumstances. Upon any such Taking, Landlord shall be entitled to receive the entire price or award from any such Taking without any payment to Tenant, and Tenant hereby assigns to Landlord Tenant's interest, if any, in such award. Tenant shall have the right, to the extent that same shall not diminish Landlord's award, to make a separate claim against the condemning authority (but not Landlord) for such compensation as may be separately awarded or recoverable by Tenant for moving expenses and damage to improvements paid for by Tenant and Tenant's trade fixtures, if a separate award for such items is made to Tenant. Tenant hereby waives any and all rights it might otherwise have pursuant to any provision of state law to terminate this Lease upon a partial Taking of the Premises or the Project.

20. **Events of Default**. Each of the following events shall be a default ("**Default**") by Tenant under this Lease:

(a) **Payment Defaults**. Tenant shall fail to pay any installment of Rent or any other payment hereunder within 5 days of written notice of default from Landlord.

(b) **Insurance**. Any insurance required to be maintained by Tenant pursuant to this Lease shall be canceled or terminated or shall expire or shall be reduced or materially changed, or Landlord shall receive a notice of nonrenewal of any such insurance and Tenant shall fail to obtain replacement insurance before the expiration of the current coverage.

(c) **Abandonment**. Tenant shall abandon the Premises without (i) the release of the Premises of all Hazardous Materials Clearances and free of any residual impact from the Tenant HazMat Operations, and (ii) complying with the provisions of Section 28.

(d) **Improper Transfer**. Tenant shall assign, sublease or otherwise transfer or attempt to transfer all or any portion of Tenant's interest in this Lease or the Premises except as expressly permitted herein, or Tenant's interest in this Lease shall be attached, executed upon, or otherwise judicially seized and such action is not released within 90 days of the action.

(e) **Liens**. Tenant shall fail to discharge or otherwise obtain the release of any lien placed upon the Premises in violation of this Lease within 10 days after any such lien is filed against the Premises.

(f) **Insolvency Events**. Tenant or any guarantor or surety of Tenant's obligations hereunder shall: (A) make a general assignment for the benefit of creditors; (B) commence any case, proceeding or other action seeking to have an order for relief entered on its behalf as a debtor or to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, liquidation, dissolution or composition of it or its debts or seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or of any substantial part of its property (collectively a "**Proceeding for Relief**"); (C) become the subject of any Proceeding for Relief that is not dismissed within 90 days of its filing or entry; or (D) die or suffer a legal disability (if Tenant, guarantor, or surety is an individual) or be dissolved or otherwise fail to maintain its legal existence (if Tenant, guarantor or surety is a corporation, partnership or other entity).

(g) **Estoppel Certificate or Subordination Agreement**. Tenant fails to execute any document required from Tenant under Sections 23 or 27 within 5 business days after a second notice requesting such document.

(h) **Other Defaults**. Tenant shall fail to comply with any provision of this Lease other than those specifically referred to in this Section 20, and, except as otherwise expressly provided herein, such failure shall continue for a period of 15 days after written notice thereof from Landlord to Tenant.

Any notice given under Section 20(h) hereof shall: (i) specify the alleged default, (ii) demand that Tenant cure such default, (iii) be in lieu of, and not in addition to, or shall be deemed to be, any notice required under any provision of applicable law, and (iv) not be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice; provided that if the nature of Tenant's default pursuant to Section 20(h) is such that it cannot be cured by the payment of money and reasonably requires more than 15 days to cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said 15 day period and thereafter diligently prosecutes the same to completion; provided, however, that such cure shall be completed no later than 90 days from the date of Landlord's notice.

21. **Landlord's Remedies**.

(a) **Interest**. Upon a Default by Tenant hereunder, Landlord may, without waiving or releasing any obligation of Tenant hereunder, make such payment or perform such act. All sums so paid or incurred by Landlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to [***]% per annum or the highest rate permitted by law ("**Default Rate**"), whichever is less, shall be payable to Landlord on demand as Additional Rent. Except as provided in Section 21(g) below, nothing herein shall be construed to create or impose a duty on Landlord to mitigate any damages resulting from Tenant's Default hereunder.

(b) **Late Payment Rent**. Late payment by Tenant to Landlord of Rent and other sums due will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges that may be imposed on Landlord under any Mortgage covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within 5 days after the date such payment is due, Tenant shall pay to Landlord an additional sum of 5% of the overdue Rent as a late charge (provided that Tenant shall not be required to pay such late charge upon the first occurrence of a late payment by Tenant of Rent). The parties agree that this late charge represents a fair and reasonable estimate of the costs Landlord will incur by reason of late payment by Tenant. In addition to the late charge, Rent not paid when due shall bear interest at the Default Rate from the 5th day after the date due until paid.

(c) **Re-Entry**. Landlord shall have the right, immediately or at any time thereafter, without further notice to Tenant (unless otherwise provided herein), to enter the Premises, without terminating this Lease or being guilty of trespass, and do any and all acts as Landlord may deem necessary, proper or convenient to cure such default, for the account and at the expense of Tenant, any notice to quit or notice of Landlord's intention to re-enter being hereby expressly waived, and Tenant agrees to pay to Landlord as Additional Rent all damage and/or expense incurred by Landlord in so doing, including interest at the Default Rate, from the due date until the date payment is received by Landlord.

(d) **Termination**. Landlord shall have the right to terminate this Lease and Tenant's right to possession of the Premises and, in accordance with applicable Legal Requirements, take possession of the Premises and remove Tenant, any occupant and any property therefrom, without being guilty of trespass and without relinquishing any rights of Landlord against Tenant, any notice to quit, or notice of Landlord's intention to re-enter being hereby expressly waived. Landlord shall be entitled to recover damages from Tenant for all amounts covenanted to be paid during the remainder of the Term (except for the period of any holdover by Tenant, in which case the monthly rental rate stated at Section 8 herein shall apply), which may be accelerated by Landlord at its option to the present value of the amounts owed (which discount to present value shall be made in accordance with accepted financial practice using a rate of [***]% per annum), together with (i) all expenses of any proceedings (including, but not limited to, the

expenses set forth in Section 43(p) below) that may be necessary in order for Landlord to recover possession of the Premises, (ii) the expenses of the re-renting of the Premises (including, but not limited to, any commissions paid to any real estate agent, advertising expense and the costs of such alterations, repairs, replacements or modifications that Landlord, in its sole judgment, considers advisable and necessary for the purpose of re-renting), in each case prorated based on the remaining length of the Term, and (iii) interest computed at the Default Rate from the due date until paid; provided, however, that there shall be credited against the amount of such damages all amounts received by Landlord from such re-renting of the Premises, with any overage being refunded to Tenant (or, if Landlord has elected to accelerate the amounts due, then Tenant shall have the right to deduct the present value of the amount for which Landlord, in its reasonable determination, should reasonably be able to relet the Premises). Landlord shall in no event be liable in any way whatsoever for failure to re-rent the Premises or, in the event that the Premises are re-rented, for failure to collect the rent thereof under such re-renting and, except as provided in Section 21(g) below, Tenant expressly waives any duty of the Landlord to mitigate damages. No act or thing done by Landlord shall be deemed to be an acceptance of a surrender of the Premises, unless Landlord shall execute a written agreement of surrender with Tenant. Tenant's liability hereunder shall not be terminated by the execution of a new lease of the Premises by Landlord, unless that new lease expressly so states. In the event Landlord does not exercise its option to accelerate the payment of amounts owed as provided hereinabove, then Tenant agrees to pay to Landlord, upon demand, the amount of damages herein provided after the amount of such damages for any month shall have been ascertained; provided, however, that any expenses incurred by Landlord shall be deemed to be a part of the damages for the month in which they were incurred. Separate actions may be maintained each month or at other times by Landlord against Tenant to recover the damages then due, without waiting until the end of the term of this Lease to determine the aggregate amount of such damages. Tenant hereby expressly waives any and all rights of redemption granted by or under any present or future laws in the event of Tenant being evicted or being dispossessed for any cause, or in the event of Landlord obtaining possession of the Premises by reason of the violation by Tenant of any of the covenants and conditions of this Lease.

(e) **Suspension of Funding/Performance**. Upon a Default by Tenant hereunder and during the continuance thereof, Landlord shall have the right to suspend funding of any TI Allowance or the performance of Landlord's Work (and such suspension shall constitute a Tenant Delay [as defined in **Exhibit C-1** attached hereto]).

(f) **Other Remedies**. In addition to the remedies set forth in this Section 21, Landlord, at its option, without further notice or demand to Tenant, shall have all other rights and remedies provided at law or in equity.

(g) **Mitigation**. Nothing herein shall be construed to create or impose a duty on Landlord to mitigate any damages resulting from Tenant's Default hereunder; provided, however, that to the extent required by applicable Legal Requirements, each party shall use commercially reasonable efforts to mitigate its damages in the event of a default or breach hereunder by the other party.

22. **Assignment and Subletting**.

(a) **General Prohibition**. Without Landlord's prior written consent subject to and on the conditions described in this Section 22, Tenant shall not, directly or indirectly, voluntarily or by operation of law, assign this Lease or sublease the Premises or any part thereof or mortgage, pledge, or hypothecate its leasehold interest or grant any concession or license within the Premises, and any attempt to do any of the foregoing shall be void and of no effect. If Tenant is a corporation, partnership or limited liability company, the shares or other ownership interests thereof that are not actively traded upon a stock exchange or in the over-the-counter market, a transfer or series of transfers whereby 49% or more of the issued and outstanding shares or other ownership interests of such corporation are, or voting control is, transferred (but excepting transfers upon deaths of individual owners) from a person or persons

or entity or entities that were owners thereof at time of execution of this Lease to persons or entities who were not owners of shares or other ownership interests of the corporation, partnership or limited liability company at time of execution of this Lease, shall be deemed an assignment of this Lease requiring the consent of Landlord as provided in this Section 22. Notwithstanding the foregoing, any public offering of shares or other ownership interest in Tenant shall not be deemed an assignment.

(b) **Permitted Transfers**. If Tenant desires to assign, sublease, hypothecate or otherwise transfer this Lease or sublet the Premises other than pursuant to a Permitted Assignment (as defined below), then at least 15 business days, but not more than 45 business days, before the date Tenant desires the assignment or sublease to be effective ("**Assignment Date**"), Tenant shall give Landlord a notice ("**Assignment Notice**") containing such information about the proposed assignee or sublessee, including the proposed use of the Premises and any Hazardous Materials proposed to be used, stored handled, treated, generated in or released or disposed of from the Premises, the Assignment Date, any relationship between Tenant and the proposed assignee or sublessee, and all material terms and conditions of the proposed assignment or sublease, including a copy of any proposed assignment or sublease in its final form, and such other information as Landlord may deem reasonably necessary or appropriate to its consideration whether to grant its consent. Landlord may, by giving written notice to Tenant within 10 business days after receipt of the Assignment Notice: (i) grant such consent, or (ii) refuse such consent, in its reasonable discretion (provided that Landlord shall further have the right to review and approve or disapprove the proposed form of sublease prior to the effective date of any such subletting). Tenant shall pay to Landlord a fee equal to $1,500 in connection with its consideration of any Assignment Notice and/or its preparation or review of any consent documents.

Tenant shall have the right to assign this Lease, upon 30 days prior written notice to Landlord but without obtaining Landlord's prior written consent, to a corporation or other entity that is a successor-in-interest to Tenant, by way of merger, consolidation or corporate reorganization, or by the purchase of all or substantially all of the assets or the ownership interests of Tenant provided that (i) such merger or consolidation, or such acquisition or assumption, as the case may be, is for a good business purpose and not principally for the purpose of transferring this Lease, and (ii) the net worth (as determined in accordance with generally accepted accounting principles ("**GAAP**")) of the assignee is not less than the net worth (as determined in accordance with GAAP) of Tenant as of the date of Tenant's most current quarterly or annual financial statements, and (iii) such assignee shall agree in writing to assume all of the terms, covenants and conditions of this Lease arising after the effective date of the assignment (a "**Permitted Assignment**").

(c) **Additional Conditions**. As a condition to any such assignment or subletting, whether or not Landlord's consent is required, Landlord may require:

(i) that any assignee or subtenant agree, in writing at the time of such assignment or subletting, that if Landlord gives such party notice that Tenant is in default under this Lease, such party shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments will be received by Landlord without any liability except to credit such payment against those due under this Lease, and any such third party shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, in no event shall Landlord or its successors or assigns be obligated to accept such attornment; and

(ii) A list of Hazardous Materials, certified by the proposed assignee or sublessee to be true and correct, which the proposed assignee or sublessee intends to use, store, handle, treat, generate in or release or dispose of from the Premises, together with copies of all documents relating to such use, storage, handling, treatment, generation, release or disposal of Hazardous Materials by the proposed assignee or subtenant in the Premises or on the Project, prior to the proposed assignment or subletting, including, without limitation: permits;

approvals; reports and correspondence; storage and management plans; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); and all closure plans or any other documents required by any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks. Neither Tenant nor any such proposed assignee or subtenant is required, however, to provide Landlord with any portion(s) of the such documents containing information of a proprietary nature that, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities.

(d) **No Release of Tenant, Sharing of Excess Rents**. Notwithstanding any assignment or subletting, Tenant and any guarantor or surety of Tenant's obligations under this Lease shall at all times remain fully and primarily responsible and liable for the payment of Rent and for compliance with all of Tenant's other obligations under this Lease; provided, however, that the initial Tenant hereunder (i.e., Kite Pharma, Inc., shall have no responsibility or liability for such payment and compliance obligations under this Lease first arising from and after the date of a Permitted Assignment of this Lease to the initial Tenant's parent, Gilead Sciences, Inc., a Delaware corporation. If the Rent due and payable by a sublessee or assignee (or a combination of the rental payable under such sublease or assignment plus any bonus or other consideration therefor or incident thereto in any form) exceeds the sum of the rental payable under this Lease (excluding, however, any Rent payable under this Section and actual and reasonable brokerage fees, legal costs, any design or construction fees directly related to and required pursuant to the terms of any such sublease, and the unamortized cost of any improvements [calculated on a straight-line basis over the useful life of the improvement in question] made to the subleased area paid for by Tenant outside of the TI Allowance) ("**Excess Rent**"), then Tenant shall be bound and obligated to pay Landlord as Additional Rent hereunder 50% of such Excess Rent within 10 days following receipt thereof by Tenant; provided, however, that Tenant's obligation to pay Excess Rent in connection with a sublease or assignment shall not apply to any sublease or assignment made pursuant to a Permitted Assignment. If Tenant shall sublet the Premises or any part thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any such subletting, and Landlord may collect such rent and apply it toward Tenant's obligations under this Lease; except that, until the occurrence of a Default, Tenant shall have the right to collect such rent. Notwithstanding the foregoing, Tenant may convey, in connection with an assignment or subletting, but pursuant to a separate legally binding agreement, Tenant's non-real property assets, goodwill, intellectual property, business and trade fixtures, inventory, equipment, or furniture as well as all other Tenant's Property to the extent paid for by Tenant ("**Tenant's FF&E**"), and Tenant shall be entitled to retain any and all consideration received in connection with such conveyance to the extent such consideration does not exceed the fair market value of Tenant's FF&E, and the value thereof shall not be included in the calculation of Excess Rent to the extent such consideration does not exceed the fair market value of Tenant's FF&E.

(e) **No Waiver**. The consent by Landlord to an assignment or subletting shall not relieve Tenant or any assignees of this Lease or any sublessees of the Premises from obtaining the consent of Landlord to any further assignment or subletting nor shall it release Tenant or any assignee or sublessee of Tenant from full and primary liability under this Lease. The acceptance of Rent hereunder, or the acceptance of performance of any other term, covenant, or condition thereof, from any other person or entity shall not be deemed to be a waiver of any of the provisions of this Lease or a consent to any subletting, assignment or other transfer of the Premises.

(f) **Prior Conduct of Proposed Transferee**. Notwithstanding any other provision of this Section 22, if (i) the proposed assignee or sublessee of Tenant has been required by any prior landlord, lender or Governmental Authority to take remedial action in connection with Hazardous Materials contaminating a property, where the contamination resulted from such party's action or use of the

property in question, (ii) the proposed assignee or sublessee is subject to an enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority), or (iii) because of the existence of a pre-existing environmental condition in the vicinity of or underlying the Project, the risk that Landlord would be targeted as a responsible party in connection with the remediation of such pre-existing environmental condition would be materially increased or exacerbated by the proposed use of Hazardous Materials by such proposed assignee or sublessee, Landlord shall have the absolute right to refuse to consent to any assignment or subletting to any such party.

(g) **Business Entity Occupancy**. Tenant shall have the right, upon 30 days prior written notice to Landlord but without obtaining Landlord's prior written consent, to permit a business entity that is a contractor of Tenant (or an entity for whom Tenant is a subcontractor), collaborator, affiliate, subsidiary, client, customer, co-developer, or otherwise has a business relationship with Tenant, and is providing Tenant services in the course of Tenant's business operations at the Premises or is occupying the Building in furtherance of such business relationship with Tenant (a "**Business Entity**" or "**Business Entities**") to use not more than 5,000 rentable square feet of the Premises for any Permitted Use; provided, however, that (i) Tenant receives no compensation for such use in excess of that portion of the Rent attributable to such portion of the Premises, (ii) the entity remains a Business Entity for the entire duration of such use and the entity is not indicated on the Building directory or any signage on the Premises ("**Business Entity Occupancy**"), (iii) no new demising walls are constructed to accomplish the Business Entity Occupancy, (iv) Tenant shall be responsible for any and all Claims arising out of or in connection with the Business Entity Occupancy or any act or omission of any Business Entity, and Tenant shall indemnify, defend, hold and save Landlord harmless from and against any and all Claims arising out of or in connection with any Business Entity Occupancy or any act or omission of any Business Entity, and (v) the provisions of this paragraph are personal to Kite Pharma, Inc. and the transferee under any Permitted Assignment. Such Business Entity Occupancy shall not be deemed a sublease or assignment hereunder, nor shall it vest in any such Business Entity any right, title, or interest in this Lease or the Premises nor shall it relieve, release, impair, or discharge any of Tenant's obligations hereunder. Tenant shall ensure that the Business Entity complies with the terms of this Lease. A failure or breach of any term, covenant, condition, or other provision of this Lease by any Business Entity shall constitute a breach of such term, covenant, condition, or other provision of this Lease by Tenant and, if such failure or breach is not cured within any applicable notice and cure period under this Lease, shall constitute a Default by Tenant.

23. **Estoppel Certificate**. Tenant shall, within 10 business days of written notice from Landlord, execute, acknowledge and deliver a statement in writing in any form reasonably requested by a proposed lender or purchaser, (i) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which the rental and other charges are paid in advance, if any, (ii) acknowledging that to the actual knowledge of Tenant there are not any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (iii) setting forth such further information with respect to the status of this Lease or the Premises as may be requested thereon. Any such statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the real property of which the Premises are a part. Tenant's failure to deliver such statement within such time shall, at the option of Landlord, be conclusive upon Tenant that this Lease is in full force and effect and without modification except as may be represented by Landlord in any certificate prepared by Landlord and delivered to Tenant for execution.

24. **Quiet Enjoyment**. So long as Tenant shall perform all of the covenants and agreements herein required to be performed by Tenant, Tenant shall, subject to the terms of this Lease, at all times during the Term, have peaceful and quiet enjoyment of the Premises against any person claiming by, through or under Landlord.

25. **Prorations**. All prorations required or permitted to be made hereunder shall be made on the basis of a 360 day year and 30 day months.

26. **Rules and Regulations**. Tenant shall, at all times during the Term and any extension thereof, comply with all reasonable rules and regulations at any time or from time to time established by Landlord covering use of the Premises and the Project. The current rules and regulations are attached hereto as **Exhibit E**. If there is any conflict between said rules and regulations and other provisions of this Lease, the terms and provisions of this Lease shall control. Landlord shall not have any liability or obligation for the breach of any rules or regulations by other tenants in the Project and shall not enforce such rules and regulations in a discriminatory manner.

27. **Subordination**. As of the Commencement Date, the Project and the Premises are not encumbered by a Mortgage. This Lease and Tenant's interest and rights hereunder are hereby made and shall be subject and subordinate at all times to the lien of any Mortgage hereafter created on or against the Project or the Premises, and all amendments, restatements, renewals, modifications, consolidations, refinancing, assignments and extensions thereof, without the necessity of any further instrument or act on the part of Tenant; provided, however that so long as there is no Default hereunder, Tenant's right to possession of the Premises shall not be disturbed by the Holder of any such Mortgage. Tenant agrees, at the election of the Holder of any such Mortgage, to attorn to any such Holder. Tenant agrees upon demand to execute, acknowledge and deliver such instruments, confirming such subordination, and such instruments of attornment as shall be requested by any such Holder, provided any such instruments contain appropriate non-disturbance provisions assuring Tenant's quiet enjoyment of the Premises as set forth in Section 24 hereof. Notwithstanding the foregoing, any such Holder may at any time subordinate its Mortgage to this Lease, without Tenant's consent, by notice in writing to Tenant, and thereupon this Lease shall be deemed prior to such Mortgage without regard to their respective dates of execution, delivery or recording and in that event such Holder shall have the same rights with respect to this Lease as though this Lease had been executed prior to the execution, delivery and recording of such Mortgage and had been assigned to such Holder. On Tenant's written request, Landlord shall obtain from any Holder of a first lien Mortgage at any time during the Term covering any or all of the Project or the Premises a non-disturbance agreement on Holder's standard form in favor of Tenant assuring Tenant's quiet enjoyment of the Premises as set forth in Section 24 hereof. The term "**Mortgage**" whenever used in this Lease shall be deemed to include deeds of trust, security assignments and any other encumbrances, and any reference to the "**Holder**" of a Mortgage shall be deemed to include the beneficiary under a deed of trust.

28. **Surrender**. Upon the expiration of the Term or earlier termination of Tenant's right of possession, Tenant shall surrender the Premises to Landlord in the same condition as received, subject to any Alterations or Installations permitted by Landlord to remain in the Premises, free of Hazardous Materials brought upon, kept, used, stored, handled, treated, generated in, or released or disposed of from, the Premises by any person other than a Landlord Party (collectively, "**Tenant HazMat Operations**") and released of all Hazardous Materials Clearances, broom clean, ordinary wear and tear and casualty loss and condemnation covered by Sections 18 and 19 excepted. At least 3 months prior to the surrender of the Premises, Tenant shall deliver to Landlord a narrative description of the actions proposed (or required by any Governmental Authority) to be taken by Tenant in order to surrender the Premises (including any Installations permitted by Landlord to remain in the Premises) at the expiration or earlier termination of the Term, in the condition required by this Lease ("**Surrender Plan**"). Such Surrender Plan shall be accompanied by a current listing of (i) all Hazardous Materials licenses and permits held by or on behalf of any Tenant Party with respect to the Premises, and (ii) all Hazardous Materials used, stored, handled, treated, generated, released or disposed of from the Premises, and shall be subject to the review and approval of Landlord's environmental consultant. In connection with the review and approval of the Surrender Plan, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning Tenant HazMat Operations as Landlord shall request. On or before such surrender, Tenant shall deliver to Landlord evidence that the

approved Surrender Plan shall have been satisfactorily completed and Landlord shall have the right, subject to reimbursement at Tenant's expense as set forth below, to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the effective date of such surrender or early termination of this Lease, free from any residual impact from Tenant HazMat Operations. Tenant shall reimburse Landlord, as Additional Rent, for the actual out-of-pocket expense incurred by Landlord for Landlord's environmental consultant to review and approve the Surrender Plan and to visit the Premises and verify satisfactory completion of the same, which cost shall not exceed $5,000. Landlord shall have the unrestricted right to deliver such Surrender Plan and any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties.

If Tenant shall fail to prepare or submit a Surrender Plan approved by Landlord, or if Tenant shall fail to complete the approved Surrender Plan, or if such Surrender Plan, whether or not approved by Landlord, shall fail to adequately address any residual effect of Tenant HazMat Operations in, on or about the Premises, Landlord shall have the right to take such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Project are surrendered free from any residual impact from Tenant HazMat Operations, the cost of which actions shall be reimbursed by Tenant as Additional Rent, without regard to the limitation set forth in the first paragraph of this Section 28.

Tenant shall immediately return to Landlord all keys and/or access cards to parking, the Project, restrooms or all or any portion of the Premises furnished to or otherwise procured by Tenant. If any such access card or key is lost, Tenant shall pay to Landlord, at Landlord's election, either the cost of replacing such lost access card or key or the cost of reprogramming the access security system in which such access card was used or changing the lock or locks opened by such lost key. Any Tenant's Property, Alterations and property not so removed by Tenant as permitted or required herein shall be deemed abandoned and may be stored, removed, and disposed of by Landlord at Tenant's expense, and Tenant waives all claims against Landlord for any damages resulting from Landlord's retention and/or disposition of such property. All obligations of Tenant hereunder not fully performed as of the termination of the Term, including the obligations of Tenant under Section 30 hereof, shall survive the expiration or earlier termination of the Term, including, without limitation, indemnity obligations, payment obligations with respect to Rent and obligations concerning the condition and repair of the Premises.

29. **Waiver of Jury Trial**. TENANT AND LANDLORD WAIVE ANY RIGHT TO TRIAL BY JURY OR TO HAVE A JURY PARTICIPATE IN RESOLVING ANY DISPUTE, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE, BETWEEN LANDLORD AND TENANT ARISING OUT OF THIS LEASE OR ANY OTHER INSTRUMENT, DOCUMENT, OR AGREEMENT EXECUTED OR DELIVERED IN CONNECTION HEREWITH OR THE TRANSACTIONS RELATED HERETO.

30. **Environmental Requirements**.

(a) **Prohibition/Compliance/Indemnity**. Tenant shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises or the Project in violation of applicable Environmental Requirements (as hereinafter defined) by Tenant or any Tenant Party. If Tenant breaches the obligation stated in the preceding sentence, or if the presence of Hazardous Materials in the Premises during the Term or any holding over results in contamination of the Premises, the Project or any adjacent property or if contamination of the Premises, the Project or any adjacent property by Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises by anyone other than Landlord and Landlord's employees, agents and contractors otherwise occurs during the Term or any holding over, Tenant hereby indemnifies and shall defend and hold Landlord, its officers, directors, employees, agents and contractors harmless from any and all actions (including, without limitation, remedial or enforcement actions of any kind, administrative or judicial proceedings, and orders or judgments arising out of or resulting therefrom), costs, claims,

damages (including, without limitation, punitive damages and damages based upon diminution in value of the Premises or the Project, or the loss of, or restriction on, use of the Premises or any portion of the Project), expenses (including, without limitation, attorneys', consultants' and experts' fees, court costs and amounts paid in settlement of any claims or actions), fines, forfeitures or other civil, administrative or criminal penalties, injunctive or other relief (whether or not based upon personal injury, property damage, or contamination of, or adverse effects upon, the environment, water tables or natural resources), liabilities or losses (collectively, "**Environmental Claims**") that arise during or after the Term as a result of such contamination; provided, however, that Tenant shall have no indemnification, remediation, or other obligation or responsibility under this Section 30 for any contamination or Environmental Claim if Tenant proves by a preponderance of the evidence that such contamination or Environmental Claim arises from any Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from the Premises by Landlord, its employees or contractors, or another tenant unrelated or unaffiliated with Tenant or that existed in the Premises as of the Commencement Date and were not brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from the Premises by Tenant or any Tenant Party. This indemnification of Landlord by Tenant includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, treatment, remedial, removal, or restoration work required by any federal, state or local Governmental Authority because of Hazardous Materials present in the air, soil or ground water above, on, or under the Premises. Without limiting the foregoing, if the presence of any Hazardous Materials on the Premises, the Project, or any adjacent property caused or permitted by Tenant or any Tenant Party results in any contamination of the Premises, the Project, or any adjacent property, Tenant shall promptly take all actions at its sole expense and in accordance with applicable Environmental Requirements as are necessary to return the Premises, the Project, or any adjacent property to the condition existing prior to the time of such contamination, provided that Landlord's approval of such action shall first be obtained, which approval shall not unreasonably be withheld so long as such actions would not potentially have any material adverse long-term or short-term effect on the Premises or the Project.

(i) **Remediation of Pre-Existing Environmental Condition**. Landlord shall, at no expense to Tenant, remediate any Pre-Existing Environmental Condition in the Premises as required by applicable Legal Requirements that Tenant proves by a preponderance of the evidence is a Pre-Existing Environmental Condition.

(b) **Business**. Landlord acknowledges that it is not the intent of this Section 30 to prohibit Tenant from using the Premises for the Permitted Use. Tenant may operate its business according to prudent industry practices so long as the use or presence of Hazardous Materials is strictly and properly monitored according to all then applicable Environmental Requirements. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord prior to the Commencement Date a list identifying each type of Hazardous Materials to be brought upon, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises ("**Hazardous Materials List**"). Tenant shall deliver to Landlord an updated Hazardous Materials List at least once a year upon request of Landlord and shall also deliver an updated list before any new Hazardous Material is brought onto, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises. Tenant shall deliver to Landlord true and correct copies of the following documents ("**Haz Mat Documents**") relating to the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials prior to the Commencement Date, or if unavailable at that time, concurrent with the receipt from or submission to a Governmental Authority: permits; approvals; reports and correspondence; storage and management plans, notice of violations of any Legal Requirements; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); all closure plans or any other documents required by any and all federal, state and local Governmental

Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks; and a Surrender Plan (to the extent surrender in accordance with Section 28 cannot be accomplished in 3 months). Tenant is not required, however, to provide Landlord with any portion(s) of the Haz Mat Documents containing information of a proprietary nature that, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities. It is not the intent of this Section to provide Landlord with information that could be detrimental to Tenant's business should such information become possessed by Tenant's competitors.

(c) **Tenant Representation and Warranty**. Tenant hereby represents and warrants to Landlord that (i) neither Tenant nor any of its legal predecessors has been required by any prior landlord, lender, or Governmental Authority at any time to take remedial action in connection with Hazardous Materials contaminating a property, which contamination was permitted by Tenant of such predecessor or resulted from Tenant's or such predecessor's action or use of the property in question, and (ii) Tenant is not subject to any enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority). If Landlord determines that this representation and warranty was not true as of the date of this lease, Landlord shall have the right to terminate this Lease in Landlord's sole and absolute discretion.

(d) **Testing**. Landlord shall have access to, and a right to perform inspections and tests of, the Premises and the Project to determine Tenant's compliance with Environmental Requirements (as defined below), its obligations under this Section 30, or the environmental condition of the Premises and the Project. In connection with such testing, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such non-proprietary information concerning the use of Hazardous Materials in or about the Premises by Tenant or any Tenant Party. Access shall be granted to Landlord upon Landlord's prior notice to Tenant and at such times so as to minimize, so far as may be reasonable under the circumstances, any disturbance to Tenant's operations. Such inspections and tests shall be conducted at Landlord's expense, unless such inspections or tests are conducted pursuant to Section 21 hereof or reveal that Tenant has not complied with any Environmental Requirement, in which case Tenant shall reimburse Landlord for the reasonable cost of such inspection and tests. Tenant shall, at its sole cost and expense, promptly and satisfactorily remediate any environmental conditions identified by such testing in accordance with all Environmental Requirements. Landlord's receipt of or satisfaction with any environmental assessment in no way waives any rights that Landlord may have against Tenant.

(e) **Underground Tanks**. Under no circumstances whatsoever will Tenant have the right to install any underground storage tank on or about the Premises or the Project. If underground or other storage tanks storing Hazardous Materials located on the Premises or the Project before the Commencement Date are used by Tenant, Tenant shall install, use, monitor, operate, maintain, upgrade and manage such storage tanks, maintain appropriate records, obtain and maintain appropriate insurance, implement reporting procedures, properly close any underground storage tanks if required by applicable Legal Requirements, and take or cause to be taken all other actions necessary or required under applicable state and federal Legal Requirements, as such now exists or may hereafter be adopted or amended in connection with the installation, use, maintenance, management, operation, upgrading and closure of such storage tanks.

(f) **Control Areas**. Tenant shall be allowed to utilize up to its pro rata share of the Hazardous Materials inventory within any control area or zone (located within the Premises), as designated from time to time by the applicable building code or other Legal Requirement, for Hazardous Materials use or storage. As used in the preceding sentence, Tenant's pro rata share of any control area or zone located within the Premises shall be determined based on the rentable square footage that Tenant leases within the applicable control area or zone. For purposes of example only, if a control area or zone contains 10,000 rentable square feet and 2,000 rentable square feet of a tenant's premises are

located within such control area or zone (while such premises as a whole contains 5,000 rentable square feet), the applicable tenant's pro rata share of such control area or zone would be 20%.

(g) **Tenant's Obligations**. Tenant's obligations under this Section 30 shall survive the expiration or earlier termination of this Lease for the applicable statute of limitations period under federal, state, or local Legal Requirement. During any period of time after the expiration or earlier termination of this Lease required by Tenant or Landlord to complete the removal from the Premises of any Hazardous Materials (including, without limitation, the release and termination of any licenses or permits restricting the use of the Premises and the completion of the approved Surrender Plan), Tenant shall continue to pay the full Rent in accordance with this Lease for any portion of the Premises not relet by Landlord in Landlord's sole discretion, which Rent shall be prorated daily.

(h) **Definitions**. As used herein, (i) the term "**Environmental Requirements**" means all applicable present and future statutes, regulations, ordinances, rules, codes, judgments, orders or other similar enactments of any Governmental Authority regulating or relating to health, safety, or environmental conditions on, under, or about the Premises or the Project, or the environment, including without limitation, the following: the Comprehensive Environmental Response, Compensation and Liability Act; the Resource Conservation and Recovery Act; and all state and local counterparts thereto, and any regulations or policies promulgated or issued thereunder, and (ii) the term "**Hazardous Materials**" means and includes any substance, material, waste, pollutant, or contaminant listed or defined as hazardous or toxic, or regulated by reason of its impact or potential impact on humans, animals and/or the environment under any Environmental Requirements, asbestos and petroleum, including crude oil or any fraction thereof, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). As defined in Environmental Requirements, Tenant is and shall be deemed to be the "**operator**" of Tenant's "**facility**" and the "**owner**" of all Hazardous Materials brought on the Premises by Tenant or any Tenant Party, and the wastes, by-products, or residues generated, resulting, or produced therefrom.

31. **Tenant's Remedies/Limitation of Liability**. Landlord shall not be in default hereunder unless Landlord fails to perform any of its obligations hereunder within 30 days after written notice from Tenant specifying such failure (unless such performance will, due to the nature of the obligation, require a period of time in excess of 30 days, then after such period of time as is reasonably necessary). Upon any default by Landlord, Tenant shall give notice by registered or certified mail to any Holder of a Mortgage covering the Premises and to any landlord of any lease of property in or on which the Premises are located and Tenant shall offer such Holder and/or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Project by power of sale or a judicial action if such should prove necessary to effect a cure; provided Landlord shall have furnished to Tenant in writing the names and addresses of all such persons who are to receive such notices. All obligations of Landlord hereunder shall be construed as covenants, not conditions; and, except as may be otherwise expressly provided in this Lease, Tenant may not terminate this Lease for breach of Landlord's obligations hereunder.

Notwithstanding the foregoing, if any claimed Landlord default hereunder will immediately, materially and adversely affect Tenant's ability to conduct its business in the Premises or creates the reasonable likelihood of damage to persons or material damage to property or material financial loss to Tenant (a "**Material Landlord Default**"), and if Tenant gives Landlord written notice of such claim, Landlord shall then have 2 business days to commence cure of such claimed Material Landlord Default and shall diligently prosecute such cure to completion. If such claimed Material Landlord Default is subsequently determined to not be a default by Landlord hereunder, Landlord shall be entitled to recover from Tenant, as Additional Rent, any costs reasonably incurred by Landlord to effect such cure. If Landlord fails to commence cure of any claimed Material Landlord Default as provided above, Tenant may commence and prosecute such cure to completion, and shall be entitled to recover the costs of such cure (but not any consequential or other damages) within 30 days after receipt of invoice to Landlord, together with interest at the Default Rate accruing upon any late payment thereof, from

Landlord, to the extent of Landlord's obligation to cure such claimed Material Landlord Default hereunder, subject to the limitations set forth in the immediately preceding sentence of this paragraph and the other provisions of this Lease.

The term "**Landlord**" in this Lease shall mean only the owner for the time being of the Premises. Upon the transfer by such owner of its interest in the Premises, such owner shall thereupon be released and discharged from all obligations of Landlord thereafter accruing, but such obligations shall be binding during the Term upon each new owner for the duration of such owner's ownership.

32. **Inspection and Access**. Landlord and its agents, representatives, and contractors may enter the Premises at any reasonable time to inspect the Premises and to make such repairs as may be required or permitted pursuant to this Lease and for any other business purpose. Landlord and Landlord's representatives may enter the Premises during business hours on not less than 48 hours advance written notice (except in the case of emergencies in which case no such notice shall be required and such entry may be at any time) for the purpose of effecting any such repairs, inspecting the Premises, showing the Premises to prospective purchasers and, during the last year of the Term, to prospective tenants or for any other business purpose; provided, however, that except for emergencies, Landlord shall use commercially reasonable efforts in connection with any entry not to materially interfere with Tenant's use of the Premises. Landlord may erect a suitable sign on the Premises stating the Premises are available to let or that the Project is available for sale. Landlord may grant easements, make public dedications, designate Common Areas and create restrictions on or about the Premises, provided that no such easement, dedication, designation or restriction materially, adversely affects Tenant's use or occupancy of the Premises for the Permitted Use. At Landlord's request, Tenant shall execute such instruments as may be reasonably necessary for such easements, dedications or restrictions. Tenant shall at all times, except in the case of emergencies, have the right to escort Landlord or its agents, representatives, contractors or guests while the same are in the Premises, provided such escort does not materially and adversely affect Landlord's access rights hereunder.

33. **Security**. Tenant acknowledges and agrees that security devices and services, if any, while intended to deter crime may not in given instances prevent theft or other criminal acts and that Landlord is not providing any security services with respect to the Premises. Tenant agrees that Landlord shall not be liable to Tenant for, and Tenant waives any claim against Landlord with respect to, any loss by theft or any other damage suffered or incurred by Tenant in connection with any unauthorized entry into the Premises or any other breach of security with respect to the Premises. Tenant shall be solely responsible for the personal safety of Tenant's officers, employees, agents, contractors, guests and invitees while any such person is in, on or about the Premises and/or the Project. Tenant shall at Tenant's cost obtain insurance coverage to the extent Tenant desires protection against such criminal acts.

34. **Force Majeure**. Neither Landlord nor Tenant shall be responsible or liable for delays in the performance of its obligations hereunder when caused by, related to, or arising out of acts of God, strikes, lockouts, or other labor disputes, embargoes, quarantines, weather, national, regional, or local disasters, calamities, or catastrophes, inability to obtain labor or materials (or reasonable substitutes therefor) at reasonable costs or failure of, or inability to obtain, utilities necessary for performance, governmental restrictions, orders, limitations, regulations, or controls, national emergencies, delay in issuance or revocation of permits, enemy or hostile governmental action, terrorism, insurrection, riots, civil disturbance or commotion, fire or other casualty, and other causes or events beyond the reasonable control of such party ("**Force Majeure**"); provided, however, that in no event shall Force Majeure excuse Tenant from performing any monetary obligation under this Lease.

35. **Brokers**. Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with this transaction and that no Broker brought about this transaction, other than CBRE and Scheer Partners, Inc. ("**SPI**"). CBRE shall be

paid by Landlord pursuant to a separate agreement between Landlord and CBRE, and SPI shall be paid by Landlord pursuant to a separate agreement between Landlord and SPI. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than CBRE and SPI, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

36. **Limitation on Landlord's Liability.** NOTWITHSTANDING ANYTHING SET FORTH HEREIN OR IN ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT TO THE CONTRARY: (A) LANDLORD SHALL NOT BE LIABLE TO TENANT OR ANY OTHER PERSON FOR (AND TENANT AND EACH SUCH OTHER PERSON ASSUME ALL RISK OF) LOSS, DAMAGE OR INJURY, WHETHER ACTUAL OR CONSEQUENTIAL TO: TENANT'S PERSONAL PROPERTY OF EVERY KIND AND DESCRIPTION, INCLUDING, WITHOUT LIMITATION TRADE FIXTURES, EQUIPMENT, INVENTORY, SCIENTIFIC RESEARCH, SCIENTIFIC EXPERIMENTS, LABORATORY ANIMALS, PRODUCT, SPECIMENS, SAMPLES, AND/OR SCIENTIFIC, BUSINESS, ACCOUNTING AND OTHER RECORDS OF EVERY KIND AND DESCRIPTION KEPT AT THE PREMISES AND ANY AND ALL INCOME DERIVED OR DERIVABLE THEREFROM; (B) THERE SHALL BE NO PERSONAL RECOURSE TO LANDLORD FOR ANY ACT OR OCCURRENCE IN, ON OR ABOUT THE PREMISES OR ARISING IN ANY WAY UNDER THIS LEASE OR ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT WITH RESPECT TO THE SUBJECT MATTER HEREOF AND ANY LIABILITY OF LANDLORD HEREUNDER SHALL BE STRICTLY LIMITED SOLELY TO LANDLORD'S INTEREST IN THE PROJECT OR ANY PROCEEDS FROM SALE OR CONDEMNATION THEREOF AND ANY INSURANCE PROCEEDS PAYABLE IN RESPECT OF LANDLORD'S INTEREST IN THE PROJECT OR IN CONNECTION WITH ANY SUCH LOSS; AND (C) IN NO EVENT SHALL ANY PERSONAL LIABILITY BE ASSERTED AGAINST ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS. UNDER NO CIRCUMSTANCES SHALL LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS BE LIABLE FOR INJURY TO TENANT'S BUSINESS OR FOR ANY LOSS OF INCOME OR PROFIT THEREFROM.

37. **Severability**. If any clause or provision of this Lease is illegal, invalid or unenforceable under present or future laws, then and in that event, it is the intention of the parties hereto that the remainder of this Lease shall not be affected thereby. It is also the intention of the parties to this Lease that in lieu of each clause or provision of this Lease that is illegal, invalid or unenforceable, there be added, as a part of this Lease, a clause or provision as similar in effect to such illegal, invalid or unenforceable clause or provision as shall be legal, valid and enforceable. This Lease, including the exhibits attached hereto, constitutes the entire agreement between Landlord and Tenant pertaining to the subject matter hereof and supersedes all prior agreements, understandings, letters of intent, negotiations, and discussions, whether oral or written, of the parties, and there are no warranties, representations, or other agreements, express or implied, made to either party by the other party in connection with the subject matter hereof except as specifically set forth herein or in the documents delivered pursuant hereto or in connection herewith.

38. **Signs; Exterior Appearance**. Tenant shall not, without the prior written consent of Landlord, which may be granted or withheld in Landlord's sole discretion: (i) attach any awnings, exterior lights, decorations, balloons, flags, pennants, banners, painting or other projection to any outside wall of the Project, (ii) use any curtains, blinds, shades or screens other than Landlord's standard window coverings, (iii) coat or otherwise sunscreen the interior or exterior of any windows, (iv) place any bottles, parcels, or other articles on the window sills, (v) place any equipment, furniture or other items of personal property on any exterior balcony, or (vi) paint, affix or exhibit on any part of the Premises or the Project any signs, notices, window or door lettering, placards, decorations, or advertising media of any type that can be viewed from the exterior of the Premises. Interior signs on doors and the directory tablet shall be inscribed, painted or affixed for Tenant by Landlord at the sole cost and expense of Tenant, and shall be of a size, color and type acceptable to Landlord. Nothing may be placed on the exterior of corridor walls

or corridor doors other than Landlord's standard lettering. The directory tablet shall be provided exclusively for the display of the name and location of tenants

(a) **Identification Signage**. Landlord shall, at its expense, place Tenant's name on the existing monument sign in front of the Building, the suite entry, and loading dock.

(b) **Façade Signage**. If and when Tenant leases more than 50% of the rentable square footage in the Building, Tenant shall have the exclusive right, at its sole cost and expense and in compliance with all applicable Legal Requirements, to install and affix to the façade of the Building facing Clopper Road a single sign bearing Tenant's name and its then current corporate logo ("**Identification Signage**"). Such Identification Signage right shall be personal to Kite Pharma, Inc. and the transferee under any Permitted Assignment. Landlord shall have the right to approve the place, size (the area of the Identification Signage shall be equal to Tenant's proportionate share of the Project in relation to the area of the Premises), and design of the Identification Signage, which approval shall not be unreasonably withheld, delayed, or conditioned, and shall in all cases comply with building standard signage requirements. On the expiration or earlier termination of this Lease, Tenant shall remove the Identification Signage at its sole cost and expense and in accordance with all applicable Legal Requirements.

39. [***]

(a) [***]

(i) [***]

(ii) [***]

(b) [***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

40. [***]

(a) [***]

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[***]

(c) [***]

(i) [***]

(ii) [***]

(iii) [***]

(d) [***]

(e) [***]

(f) [***]

(g) [***]

[***]

41. **Roof Equipment**. As long as Tenant is not in default under this Lease, Tenant shall have the right at its sole cost and expense, subject to compliance with all Legal Requirements, to install, maintain, and remove on the top of the roof of the Building (based on Tenant's proportionate share of the space available on the roof) directly above the Premises one or more satellite dishes, communication antennae, or other equipment (all of which having a diameter and height acceptable to Landlord) for the transmission or reception of communication of signals as Tenant may from time to time desire (collectively, the "**Roof Equipment**") at no rental charge to Tenant on the following terms and conditions:

(a) **Requirements**. Tenant shall submit to Landlord (i) the plans and specifications for the installation of the Roof Equipment, (ii) copies of all required governmental and quasi-governmental permits, licenses, and authorizations that Tenant will and must obtain at its own expense, with the cooperation of Landlord, if necessary for the installation and operation of the Roof Equipment, and

(iii) an insurance policy or certificate of insurance evidencing insurance coverage as required by this Lease and any other insurance as reasonably required by Landlord for the installation and operation of the Roof Equipment. Landlord shall not unreasonably withhold or delay its approval for the installation and operation of the Roof Equipment; provided, however, that Landlord may reasonably withhold its approval if the installation or operation of the Roof Equipment (A) may damage the structural integrity of the Building, (B) may void, terminate, or invalidate any applicable roof warranty, (C) may interfere with any service provided by Landlord or any tenant of the Building, (D) may reduce the leaseable space in the Building, or (E) is not properly screened from the viewing public.

(b) **No Damage to Roof**. If installation of the Roof Equipment requires Tenant to make any roof cuts or perform any other roofing work, such cuts shall only be made to the roof area of the Building located directly above the Premises and only in the manner designated in writing by Landlord; and any such installation work (including any roof cuts or other roofing work) shall be performed by Tenant, at Tenant's sole cost and expense by a roofing contractor designated by Landlord. If Tenant or its agents shall otherwise cause any damage to the roof during the installation, operation, and removal of the Roof Equipment such damage shall be repaired promptly at Tenant's expense and the roof shall be restored in the same condition it was in before the damage. Landlord shall not charge Tenant Additional Rent for the installation and use of the Roof Equipment. If, however, Landlord's insurance premium or Tax assessment increases as a result of the Roof Equipment, Tenant shall pay such increase as Additional Rent within 10 days after receipt of a reasonably detailed invoice from Landlord. Tenant shall not be entitled to any abatement or reduction in the amount of Rent payable under this Lease if for any reason Tenant is unable to use the Roof Equipment. In no event whatsoever shall the installation, operation, maintenance, or removal of the Roof Equipment by Tenant or its agents void, terminate, or invalidate any applicable roof warranty.

(c) **Protection**. The installation, operation, and removal of the Roof Equipment shall be at Tenant's sole risk. Tenant shall indemnify, defend, and hold Landlord harmless from and against any and all claims, costs, damages, liabilities and expenses (including, but not limited to, attorneys' fees) of every kind and description that may arise out of or be connected in any way with Tenant's installation, operation, or removal of the Roof Equipment.

(d) **Removal**. At the expiration or earlier termination of this Lease or the discontinuance of the use of the Roof Equipment by Tenant, Tenant shall, at its sole cost and expense, remove the Roof Equipment from the Building. Tenant shall leave the portion of the roof where the Roof Equipment was located in good order and repair, reasonable wear and tear excepted. If Tenant does not so remove the Roof Equipment, Tenant hereby authorizes Landlord to remove and dispose of the Roof Equipment and charge Tenant as Additional Rent for all costs and expenses incurred by Landlord in such removal and

disposal. Tenant agrees that Landlord shall not be liable for any Roof Equipment or related property disposed of or removed by Landlord.

(e) **No Interference**. The Roof Equipment shall not interfere with the proper functioning of any telecommunications equipment or devices that have been installed or will be installed by Landlord or for any other tenant or future tenant of the Building. Tenant acknowledges that other tenant(s) may have approval rights over the installation and operation of telecommunications equipment and devices on or about the roof, and that Tenant's right to install and operate the Roof Equipment is subject and subordinate to the rights of such other tenants. Tenant agrees that any other tenant of the Building that currently has or in the future takes possession of any portion of the Building will be permitted to install such telecommunication equipment that is of a type and frequency that will not cause unreasonable interference to the Roof Equipment.

(f) **Relocation**. Landlord shall have the right, at its expense and after 60 days prior notice to Tenant, to relocate the Roof Equipment to another site on the roof of the Building as long as such site reasonably meets Tenant's sight line and interference requirements and does not unreasonably interfere with Tenant's use and operation of the Roof Equipment.

(g) **Access**. Landlord grants to Tenant the right of ingress and egress on a 24 hour 7 day per week basis to install, operate, and maintain the Roof Equipment. Before receiving access to the roof of the Building, Tenant shall give Landlord at least 24 hours' advance written or oral notice, except in emergency situations, in which case 2 hours' advance oral notice shall be given by Tenant. Landlord shall supply Tenant with the name, telephone, and pager numbers of the contact individual(s) responsible for providing access during emergencies.

(h) **Appearance**. If permissible by Legal Requirements, the Roof Equipment shall be painted the same color as the Building so as to render the Roof Equipment virtually invisible from ground level.

(i) **No Assignment**. The right of Tenant to use and operate the Roof Equipment shall be personal solely to Kite Pharma, Inc. and the transferee under any Permitted Assignment, and (i) no other person or entity shall have any right to use or operate the Roof Equipment, and (ii) Tenant shall not assign, convey, or otherwise transfer to any person or entity any right, title, or interest in all or any portion of the Roof Equipment or the use and operation thereof.

42. **Termination Option**. Notwithstanding anything to the contrary contained herein, Tenant shall have a one-time option to terminate this Lease ("**Termination Option**") in accordance with the following terms and conditions:

(a) **Tenant Gives Notice**. If Tenant desires to exercise the Termination Option, Tenant shall give Landlord irrevocable written notice ("**Termination Notice**") of Tenant's exercise of the Termination Option. Landlord must receive the Termination Notice no later than the date that is 12 full months before the Termination Date. Time is of the essence with respect to Landlord's receipt of the Termination Notice and all other deadlines in this Section.

(b) **Termination Date**. If Tenant gives the Termination Notice and complies with all the provisions in this Section, this Lease shall terminate at midnight at the end of the 84th month after the Rent Commencement Date ("**Termination Date**").

(c) [***]

[***]
[***]

(d) **Tenant's Obligation Survives Termination**. Tenant's obligations to pay Base Rent and Additional Rent under this Lease, and to perform all other Lease obligations for the period up to and including the Termination Date, shall survive the termination of this Lease.

(e) **Landlord May Cancel and Void Termination if Tenant in Default**. Notwithstanding the foregoing provisions of this Section, if Tenant shall exercise the Termination Option (in accordance with paragraph (a) above) when it is in Default, then Landlord may elect, but is not obligated, to cancel and declare null and void Tenant's exercise of the Termination Option and this Lease shall continue in full force and effect for the full Term unaffected by Tenant's exercise of the Termination Option. If Landlord does not cancel Tenant's exercise of the Termination Option after such Default, Tenant shall cure any Default within the period of time specified in this Lease and this obligation shall survive the Termination Date.

(f) **Tenant Shall Surrender Space by Termination Date**. If Tenant exercises the Termination Option, Tenant shall surrender full and complete possession of the Premises to Landlord on or before the Termination Date vacant, broom-clean, in good order and condition, and in accordance with the provisions of this Lease (including, but not limited to, Section 28), and thereafter the Premises shall be free and clear of all leases, tenancies, and rights of occupancy of any entity claiming by, through, or under Tenant.

(g) **Failure to Surrender Makes Tenant a Holdover**. If Tenant shall fail to deliver possession of the Premises on or before the Termination Date in accordance with the terms hereof, Tenant shall be deemed to be a holdover tenant from and after the Termination Date, and in such event, Tenant shall be subject to the provisions of Section 8 relating to holdover tenancies.

(h) **Lease Ceases After Termination**. If Tenant properly and timely exercises the Termination Option and properly and timely satisfies all other monetary and non-monetary obligations under this Lease, this Lease shall cease and expire on the Termination Date with the same force and effect as if the Termination Date were the date originally provided in this Lease as the expiration date of the Term.

(i) **No Termination Option After Assignment**. If this Lease has been assigned other than pursuant to a Permitted Assignment, the Termination Option shall be deemed null and void and neither Tenant nor any assignee shall have the right to exercise the Termination Option during the term of such assignment.

43. **Miscellaneous**.

(a) **Notices**. All notices or other communications between the parties shall be in writing and shall be deemed duly given upon delivery or refusal to accept delivery by the addressee thereof if delivered in person, or upon actual receipt if delivered by reputable overnight guaranty courier, addressed and sent to the parties at their addresses set forth above. Landlord and Tenant may from time to time by written notice to the other designate another address for receipt of future notices.

(b) **Joint and Several Liability**. If and when included within the term "**Tenant**," as used in this instrument, there is more than one person or entity, each shall be jointly and severally liable for the obligations of Tenant.

(c) **Financial Information**. Tenant shall furnish Landlord with true and complete copies of (i) Tenant's most recent audited annual financial statements within 90 days of the end of each of Tenant's fiscal years during the Term, (ii) Tenant's most recent unaudited quarterly financial statements within 45 days of the end of each of Tenant's first three fiscal quarters of each of Tenant's fiscal years during the Term, and (iii) any other financial information or summaries that Tenant typically provides to its lenders or shareholders. The foregoing to the contrary notwithstanding, so long as Tenant's stock is listed for trading on the NASDAQ stock market or other public stock exchange and whose financial statements are publicly available within 3 months after the end of each calendar quarter, then Tenant's obligation to provide such financial statements and information shall be deemed satisfied by the availability of on-line access to U.S. Securities and Exchange Commission filings and other financial information of Kite Pharma, Inc. on its corporate website at http://www.kitepharma.com/.

(d) **Recordation**. Neither this Lease nor a memorandum of lease shall be filed by or on behalf of Tenant in any public record. Landlord may prepare and file, and upon request by Landlord Tenant will execute, a memorandum of lease.

(e) **Interpretation**. The normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Lease or any exhibits or amendments hereto. Words of any gender used in this Lease shall be held and construed to include any other gender, and words in the singular number shall be held to include the plural, unless the context otherwise requires. The captions inserted in this Lease are for convenience only and in no way define, limit or otherwise describe the scope or intent of this Lease, or any provision hereof, or in any way affect the interpretation of this Lease.

(f) **Not Binding Until Executed**. The submission by Landlord to Tenant of this Lease shall have no binding force or effect, shall not constitute an option for the leasing of the Premises, nor confer any right or impose any obligations upon either party until execution of this Lease by both parties.

(g) **Limitations on Interest**. It is expressly the intent of Landlord and Tenant at all times to comply with applicable law governing the maximum rate or amount of any interest payable on or in connection with this Lease. If applicable law is ever judicially interpreted so as to render usurious any interest called for under this Lease, or contracted for, charged, taken, reserved, or received with respect to this Lease, then it is Landlord's and Tenant's express intent that all excess amounts theretofore collected by Landlord be credited on the applicable obligation (or, if the obligation has been or would thereby be paid in full, refunded to Tenant), and the provisions of this Lease immediately shall be deemed reformed and the amounts thereafter collectible hereunder reduced, without the necessity of the execution of any new document, so as to comply with the applicable law, but so as to permit the recovery of the fullest amount otherwise called for hereunder.

(h) **Choice of Law**. Construction and interpretation of this Lease shall be governed by the internal laws of the state in which the Premises are located, excluding any principles of conflicts of laws.

(i) **Time**. Time is of the essence as to the performance of Tenant's obligations under this Lease.

(j) **OFAC**. Tenant, and all beneficial owners of Tenant, are currently (i) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "**OFAC Rules**"), (ii) not listed on, and shall not during the Term of this Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identifications List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any

authorizing statute, executive order, or regulation, and (iii) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

(k) **Incorporation by Reference**. All exhibits and addenda attached hereto are hereby incorporated into this Lease and made a part hereof. If there is any conflict between such exhibits or addenda and the terms of this Lease, such exhibits or addenda shall control.

(l) **No Accord and Satisfaction**. No payment by Tenant or receipt by Landlord of a lesser amount than the monthly installment of Base Rent or any Additional Rent will be other than on account of the earliest stipulated Base Rent and Additional Rent, nor will any endorsement or statement on any check or letter accompanying a check for payment of any Base Rent or Additional Rent be an accord and satisfaction. Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or to pursue any other remedy provided in this Lease.

(m) **Confidential Information**. Except as expressly permitted in this Section 43(m), neither party will, without the prior written consent of the other party, disclose any Confidential Information of the other party to any third party. Information will be considered "**Confidential Information**" of a party if either (i) it is disclosed by the party to the other party in tangible form and is conspicuously marked "Confidential", "Proprietary" or the like; or (ii) (A) it is disclosed by one party to the other party in non-tangible form and is identified as confidential at the time of disclosure; and (B) it contains the disclosing party's customer lists, customer information, technical information, pricing information, pricing methodologies, or information regarding the disclosing party's business planning or business operations; or (iii) it is disclosed to Tenant or its representatives, agents, or consultants in connection with the exercise of any audit right by Tenant under this Lease or the Work Letter, including, the audit right set forth in Section 5 of this Lease. In addition, notwithstanding anything in this Lease to the contrary, the terms of this Lease (but not its mere existence) will be deemed Confidential Information of each party. Tenant acknowledges and agrees that it will not take the position that this Lease is a material agreement for purposes of the Securities Exchange Act of 1934 or the Securities Act of 1933 or must be publicly filed with any governmental agency.

(i) **Confidential Information - Exceptions**. Other than the terms and conditions of this Lease, information will not be deemed Confidential Information hereunder if such information (i) is known to the receiving party prior to receipt from the disclosing party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (ii) becomes known (independently of disclosure by the disclosing party) to the receiving party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (iii) becomes publicly known or otherwise ceases to be secret or confidential, except through a breach of this Lease by the receiving party; or (iv) is independently developed by the receiving party. The terms and conditions of this Lease will cease being confidential if, and only to the extent that, they become publicly known, except through a breach of this Lease by the receiving party.

(ii) **Confidentiality - Exceptions**. Each party will secure and protect the Confidential Information of the other party (including, without limitation, the terms of this Lease) in a manner consistent with the steps taken to protect its own trade secrets and confidential information, but not less than a reasonable degree of care. Each party may disclose the other party's Confidential Information where (i) the disclosure is required by applicable Legal Requirement or by an order of a court or other governmental body having jurisdiction after giving reasonable notice to the other party with adequate time for such other party to seek a protective order; (ii) if in the reasonable opinion of counsel for such party, disclosure is advisable under any applicable securities laws regarding public disclosure of business information; (iii) the disclosure is reasonably necessary and is to that party's or its affiliates' employees, officers, directors, members, attorneys, accountants, lenders, underwriters, prospective purchasers, analysts, tax preparers, bank personnel, brokers, consultants and other advisors, or the disclosure is otherwise necessary for a party to exercise its rights and perform its obligations under this

Lease, so long as in all cases the disclosure is no broader than necessary and the disclosing party instructs the receiving party to maintain the confidentiality of the Confidential Information, or (iv) the disclosure is reasonably necessary in the course of operations of the Project or business of Landlord and its affiliates, including, without limitation, capital formation.

(n) **Hazardous Activities**. Notwithstanding any other provision of this Lease, Landlord, for itself and its employees, agents and contractors, reserves the right to refuse to perform any repairs or services in any portion of the Premises that, pursuant to Tenant's routine safety guidelines, practices or custom or prudent industry practices, require any form of protective clothing or equipment other than safety glasses. In any such case, Tenant shall contract with parties who are acceptable to Landlord, in Landlord's reasonable discretion, for all such repairs and services, and Landlord shall, to the extent required, equitably adjust Tenant's Share of Operating Expenses in respect of such repairs or services to reflect that Landlord is not providing such repairs or services to Tenant.

(o) [***]

(p) **Attorneys' Fees**. If any action is brought by either party against the other party, relating to or arising out of this Lease or the enforcement hereof, the prevailing party shall be entitled to recover from the other party reasonable attorneys' fees, costs and expenses incurred in connection with the prosecution or defense of such action. For purposes of this Lease, the term "**attorneys' fees**" or "**attorneys' fees and costs**" shall mean the fees and expenses of counsel to the parties hereto, which may include printing, photostating, duplicating and other expenses, air freight charges, and fees billed for law clerks, paralegals and other persons not admitted to the bar but performing services under the supervision of an attorney, and the costs and fees incurred in connection with the enforcement or collection of any judgment obtained in any such proceeding. Such expenses are recoverable at all levels, including appeals and post-judgment actions or proceedings. The provisions of this Section shall survive the entry of any judgment, and shall not merge, or be deemed to have merged, into any judgment.

[Signatures on next page]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease under seal as of the day and year first above written.

TENANT:

KITE PHARMA, INC.,
a Delaware corporation

By: /s/ Tim Moore (SEAL)
NAME: Tim More
Title: EVP Technical Operations

TECH PARK 270 III, LLC,
a Maryland limited liability company

By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company,
managing member

By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company,
managing member

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By: /s/ Eric S. Johnson (SEAL)
NAME: Eric S. Johnson
Title: Senior Vice President
RE Legal Affairs

ALEXANDRIA.

EXHIBIT A TO LEASE
DESCRIPTION OF PREMISES

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EXHIBIT B TO LEASE
DESCRIPTION OF PROJECT

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EXHIBIT C-1 TO LEASE
LANDLORD'S WORK

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EXHIBIT C-2 TO LEASE
WORK LETTER

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EXHIBIT D TO LEASE
ACKNOWLEDGMENT OF COMMENCEMENT DATE

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EXHIBIT F TO LEASE
TENANT'S PERSONAL PROPERTY

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THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

THIRD AMENDMENT TO LEASE AGREEMENT

THIS THIRD AMENDMENT TO LEASE AGREEMENT ("**this Third Amendment**") is made as of this 24 day of September, 2018 ("**Effective Date**"), between **TECH PARK 270 III, LLC**, a Maryland limited liability company, having an address at 385 E. Colorado Boulevard, Suite 299, Pasadena, California 91101 ("**Landlord**"), and **KITE PHARMA, INC.**, a Delaware corporation, having an address at Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301 ("**Tenant**").

RECITALS

A. Landlord and Tenant have entered into that certain Lease Agreement ("**Original Lease**") dated as of December 1, 2017, as amended by that certain First Amendment to Lease Agreement dated January 29, 2018 ("**First Amendment**"), and that certain Second Amendment to Lease Agreement dated February 26, 2018 ("**Second Amendment**"; together with the Original Lease and the First Amendment, the "**Lease**"), wherein Landlord leased to Tenant approximately [***] rentable square feet ("**Existing Premises**") located at Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301, as more particularly described in the Lease.

B. Landlord and Tenant desire to amend the Lease, among other things, to expand the Existing Premises by an additional 33,919 rentable square feet ("**Expansion Premises**") so that Tenant will lease the entire Building, to provide a tenant improvement allowance to Tenant, and to modify certain of Landlord and Tenant's maintenance and repair obligations.

AGREEMENT

Now, therefore, the parties hereto agree that, as of the Effective Date, the Lease is amended as follows:

1. **Definitions.** Terms used in this Third Amendment but not otherwise defined shall have the meanings set forth in the Lease.

2. **Expansion Premises.** Effective as of the Expansion Premises Commencement Date (as defined below), (a) the Existing Premises shall be expanded to include the Expansion Premises, and (b) **Exhibit A** to this Third Amendment, which depicts the Expansion Premises as the hatched area, is hereby added to **Exhibit A** to the Lease.

3. **Changes to Defined Terms.** Effective as of the Expansion Premises Commencement Date, the following amendments are hereby made to the definitions contained on page 1 of the Lease in the Basic Lease Provisions.

a. The defined term "**Premises**" shall be deleted in its entirety and replaced with the following:

"**Premises**: That portion of the Project, containing approximately 60,022 rentable square feet, as determined by Landlord, consisting of (a) approximately 26,103 rentable square feet of space shown as the hatched area on **Exhibit A** to this Lease ("**Existing Premises**"), and (b) approximately 33,919 rentable square feet of space shown on **Exhibit A** to this Lease and identified thereon as the "Expansion Premises" ("**Expansion Premises**"). Gaudreau, Inc., Landlord's architect, has measured the area of the Premises pursuant to the 1996 Standard Method of Measuring Floor Area in Office Buildings as adopted by the Building Owners and Managers Association (ANSI/BOMA Z65.1-1996) ("**BOMA Standards**"). Tenant acknowledges receipt of such measurement, and

Landlord and Tenant each confirm that such measurement shall be conclusive as to the area of the Premises.

b. The defined term "**Rentable Area of the Premises**" shall mean approximately 60,022 rentable square feet.

c. The defined term "**Tenant's Share of Operating Expenses**" shall mean 100%.

4. **Delivery of Expansion Premises**. On the Effective Date and as long as Tenant has delivered to Landlord the evidence of insurance required by the Lease with respect to the entire Premises, Tenant shall have full access to the Expansion Premises. The commencement date for the Expansion Premises shall be October 1, 2018 ("**Expansion Premises Commencement Date**").

a. Except as set forth in this Third Amendment, if applicable: (i) Tenant shall accept the Expansion Premises in their broom-clean "as is" condition as of the Expansion Premises Commencement Date, which condition shall be substantially similar in all material respects to the condition of the Expansion Premises as of the Effective Date, but Landlord shall be responsible for any costs to bring the Expansion Premises into compliance with applicable Legal Requirements as of the Expansion Premises Commencement Date as long as Tenant notifies Landlord in writing of such items that are not in compliance by no later than 6 months after the Expansion Premises Commencement Date (i.e., by no later than April 1, 2019); (ii) Landlord shall have no obligation for any defects in the Expansion Premises; and (iii) Tenant's taking possession of the Expansion Premises shall be conclusive evidence that Tenant accepts the Expansion Premises and that the Expansion Premises were in good condition at the time possession was taken.

b. Neither Landlord nor any of its agents has made any representation or warranty with respect to the condition of all or any portion of the Expansion Premises, and/or the suitability of the Expansion Premises for the conduct of Tenant's business, and Tenant waives any implied warranty that the Expansion Premises are suitable for the Permitted Use. Tenant shall use the Expansion Premises only for the Permitted Use under the Lease in compliance with the provisions of Section 7 of the Lease.

c. Except as set forth in this Third Amendment, Landlord shall have no obligation to perform any work at the Building in connection with Tenant's occupancy of the Expansion Premises or obtain any permits, approvals, or entitlements related to Tenant's specific use of the Expansion Premises or Tenant's business operations therein.

d. Notwithstanding the foregoing provisions of this Section 4, Tenant shall have a period of 6 months after the Expansion Premises Commencement Date (i.e., by no later than April 1, 2019) to reasonably identify in writing any (i) latent defects in the mechanical, electrical, and plumbing systems and the structural components serving the Expansion Premises, and (ii) HVAC system or component that is not in good working order. For purposes of this paragraph, "**latent defects**" means those material defects in such systems or components that could not have been identified or discovered through a reasonable inspection of such systems or components conducted by a qualified technician. Landlord will promptly repair such identified latent defects or HVAC system or component at Landlord's cost (and not as part of Operating Expenses), subject to Landlord's confirmation that such defects are, in fact, latent defects or that the HVAC system or component is not, in fact, in good working order.

e. Tenant acknowledges receipt of the Focused Tenant Exit Audit dated as of March 16, 2017 relating to the prior tenant's operations at the Expansion Premises. By no later than the Expansion Premises Commencement Date, Tenant shall have the right, at its expense, to engage a qualified environmental engineering firm to inspect the Expansion Premises before the Expansion Premises Commencement Date to determine whether, as of the date of such

inspection, the Premises is in violation of any applicable Environmental Requirements. If such report indicates any such violation, Tenant shall provide a copy to Landlord and Landlord shall, at its expense (and not as an Operating Expense), take such action as is necessary to correct such violation. Tenant shall provide such access to Landlord and its agents as may be necessary to allow Landlord to correct such violation.

f. Landlord shall be responsible for the compliance of the Expansion Premises with the ADA as of the Expansion Premises Commencement Date. Thereafter, Tenant shall be responsible for the compliance of the Expansion Premises with the ADA.

g. Tenant acknowledges receipt of the letter dated August 23, 2018 addressed to Tenant from Jennerik Engineering, Inc. stating that the HVAC equipment serving the Expansion Premises is in good working order.

5. **Base Rent for Expansion Premises**. Tenant shall continue to pay Base Rent with respect to the Existing Premises at the rates set forth in the Lease. The Base Rent for the Expansion Premises shall be phased in as follows:

a. Commencing on the Expansion Premises Commencement Date through September 30, 2019, Base Rent for the Expansion Premises shall be payable at the rate of $40,249.58 per month (i.e., $29/rentable square foot ("**rsf**") per annum x 16,655 rsf).

b. Commencing on October 1, 2019 (i.e., the first anniversary of the Expansion Premises Commencement Date), Base Rent for the Expansion Premises shall be payable at the rate of $84,430.04 per month (i.e., $29.87/rsf per annum x 33,919 rsf). The Base Rent for this period reflects the first annual increase in the Base Rent for the Expansion Premises based on the Rent Adjustment Percentage as set forth in the Basic Lease Provisions. On each anniversary of the Expansion Premises Commencement Date occurring after October 1, 2019 (i.e., October 1, 2020 and each October 1 thereafter), the Base Rent for the Expansion Premises shall be increased by multiplying the Base Rent payable for the Expansion Premises immediately before such date by the Rent Adjustment Percentage (i.e., 3%) and adding the resulting amount to the Base Rent payable for the Expansion Premises immediately before such date. Base Rent for the Expansion Premises, as so adjusted, shall thereafter be due as provided in the Lease.

6. **Tenant's Share of Operating Expenses**. Tenant shall continue to pay Tenant's Share of Operating Expenses with respect to the Existing Premises as set forth in the Lease. Commencing on the Expansion Premises Commencement Date and during the balance of the Term, Tenant's Share of Operating Expenses for the Expansion Premises shall be 56.5% based on 33,919 rsf. As a result, commencing on the Expansion Premises Commencement Date and during the balance of the Term, Tenant's Share of Operating Expenses for the Premises shall be 100%.

7. **Electrical Submeter Installation**. By no later than the Expansion Premises Commencement Date, Landlord shall, at its sole cost, install separate electrical submeters in the Expansion Premises.

8. **Identification Signage**. Section 38(b) of the Lease provides that if and when Tenant leases more than 50% of the rentable square footage in the Building, Tenant shall have the exclusive right, at its sole cost and expense and in compliance with all applicable Legal Requirements, to install and affix to the Identification Signage to the façade of the Building facing Clopper Road. Pursuant to Section 38(b) of the Lease, from and after the Expansion Premises Commencement Date, Tenant shall have the right to install and affix the Identification Signage as provided in Section 38(b) of the Lease.

9. **Expansion Premises TI Allowance**. Landlord shall provide to Tenant an additional tenant improvement allowance in an amount equal to **$30** per rentable square foot of the Expansion Premises (i.e., **$1,017,570**) ("**Expansion Premises TI Allowance**") to be used by Tenant as set forth in

this Section. Other than funding the Expansion Premises TI Allowance, Landlord shall have no other obligation whatsoever with respect to making any leasehold or other improvements to the Expansion Premises. Landlord's obligations with respect to the Expansion Premises TI Allowance shall cease upon disbursement in full of the Expansion Premises TI Allowance to or on behalf of Tenant. The Expansion Premises TI Allowance shall be used to reimburse Tenant only for the design, permits, and construction (including, without limitation, construction management and engineering fees) of modifications of or improvements to the Premises (including, without limitation, modifications of or improvements to the Tenant Improvements under the Original Lease) of a fixed and permanent nature desired by Tenant to the Premises ("**Third Amendment Improvements**"), but shall not be used to purchase any personal property or other non-Building Systems materials or equipment. Notwithstanding anything to the contrary, Landlord shall be solely responsible for, and the Expansion Premises TI Allowance shall not be reduced by, costs incurred to remove Hazardous Materials from the Expansion Premises that existed before the Expansion Premises Commencement Date or, except to the extent required as a result of the specialized nature of Tenant's improvements, costs to bring the Expansion Premises into compliance with Legal Requirements.

a. **Third Amendment Improvements; Insurance**. Title to the Third Amendment Improvements shall remain in the sole name of Landlord and shall not be subject to any liens or encumbrances. Landlord's approval of the Third Amendment Improvements and Tenant's contractors and architect for the Third Amendment Improvements shall not be unreasonably withheld, delayed, or conditioned. Tenant shall have no right to the use or benefit (including any reduction to Base Rent) of any portion of the Expansion Premises TI Allowance not required for the Third Amendment Improvements (as approved by Landlord pursuant to this Section). Before the commencement of the Third Amendment Improvements, Tenant shall deliver to Landlord a copy of any contract with Tenant's contractors (including any architect), and certificates of insurance from any contractor performing any part of the Third Amendment Improvements evidencing industry standard commercial general liability, automotive liability, "builder's risk", and workers' compensation insurance. Tenant shall cause the general contractor, if any, to provide a certificate of insurance naming Landlord, Alexandria Real Estate Equities, Inc., and Landlord's lender (if any) as additional insureds for the general contractor's liability coverages required above.

b. **Reimbursement**. Upon submission by Tenant to Landlord of a draw request in Landlord's standard form, containing such certifications, lien waivers (including a conditional lien release for each progress payment and unconditional lien releases for the prior month's progress payments), inspection reports, and other matters as Landlord customarily obtains for the expenses incurred by Tenant with respect to the Third Amendment Improvements, Landlord shall promptly reimburse Tenant for such expenses from the Expansion Premises TI Allowance, but only to the extent of the Expansion Premises TI Allowance. Landlord shall make the Expansion Premises TI Allowance available to Tenant for any expenses incurred for the Third Amendment Improvements made for a period of [***] after the Expansion Premises Commencement Date, i.e., such period shall end on [***] subject to extension for Force Majeure Delays to a maximum of [***] in the aggregate. Tenant shall not make more than one such submission each month to Landlord.

10. **Amendment to Basic Lease Provisions (Tenant's Notice Address)**. Tenant's Notice Address under the Lease is hereby changed to the following:

Tenant's Notice Address:

Kite Pharma, Inc.
930 Clopper Road
Gaithersburg, MD 20878-1301
Attention: Head of Facilities

and

Kite Pharma, Inc.
2400 Broadway
Santa Monica, CA 90404
Attention: VP of Facilities

With a copy to:

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
Attention: General Counsel

11. **Amendment to Section 1 (Lease of Premises)**. Effective as of the Expansion Premises Commencement Date, Tenant shall lease the entire Premises and, as a result, there shall be no Common Areas as of that date. Accordingly, Section 1 of the Lease is hereby amended by adding the following sentence at the end thereof: "Notwithstanding any contrary provision contained in this Lease, as of the Expansion Premises Commencement Date there shall be no Common Areas."

12. **Amendment to Section 7 (Use)**. Effective as of the Expansion Premises Commencement Date, Section 7 of the Lease is hereby amended as follows: (i) delete the 7th sentence stating "Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations from the Premises from extending into Common Areas, or other space in the Project[.]", and (ii) delete the 8th sentence and replace it with the following new sentence stating "Tenant shall not place any machinery or equipment weighing 500 pounds or more in or upon the Premises."

13. **Amendment to Section 7(a) (Modifications to Common Areas)**. Effective as of the Expansion Premises Commencement Date, Section 7(a) of the Lease is hereby amended as follows: (i) delete the first sentence in its entirety and replace it with the following: "Landlord shall be responsible for the compliance of the Building exterior and all areas of the Project outside of the Building with the ADA and other Legal Requirements as of the Commencement Date (and shall not include such costs in Operating Expenses)[.]"; and (ii) delete the phrase "Common Areas or the exterior of the Building" in the 2nd sentence and replace the same with "the Building exterior and all areas of the Project outside of the Building".

14. **Amendment to Section 10 (Parking)**. Effective as of the Expansion Premises Commencement Date, Section 10 of the Lease shall be deleted and replaced with the following new Section 10:

> **10. Parking**. Subject to all Legal Requirements, Force Majeure, a Taking (as defined in Section 19 below) and the exercise by Landlord of its rights hereunder, Tenant shall have the exclusive right to park in those areas of the Project designated for parking, subject to Landlord's reasonable rules and regulations at no cost to Tenant. Landlord shall not be responsible for enforcing Tenant's parking rights against any third parties. As of the Commencement Date, the current parking ratio is 3.3 standard sized spaces per 1,000 leased rentable square feet.

15. **Amendment to Section 11(a) (General)**. Effective as of the Expansion Premises Commencement Date, Section 11(a) of the Lease is hereby amended as follows: (i) delete the phrase "janitorial services to the Common Areas," and (ii) delete the penultimate sentence stating "Tenant agrees to limit use of water and sewer with respect to Common Areas to normal restroom use."

16. **Amendment to Section 11—New Section 11(d) (Generator)**. Effective as of the Expansion Premises Commencement Date, Section 11 of the Lease is hereby amended by adding the

following new Section 11(d):

(d) **Generator**. An emergency electricity generator ("**Generator**") and fuel supply system ("**Fuel System**"; together with the Generator, the "**Generator Equipment**") serve the Building as of the Commencement Date. From and after the Expansion Premises Commencement Date, Tenant shall, at its sole cost and expense, properly maintain and repair the Generator Equipment. At the expiration or earlier termination of the Term, the Generator Equipment shall remain at the Project and Tenant shall return the Generator Equipment to Landlord in the condition it was in on the Expansion Premises Commencement Date, ordinary wear and tear excepted. Tenant shall pay all governmental fees, charges, and taxes and all hook-up and disconnection fees associated with Tenant's use of the Generator Equipment and Landlord shall have no liability therefor. All of the provisions of this Lease, including, without limitation, the insurance, maintenance, repair, and indemnification provisions set forth in this Lease shall apply and be applicable to Tenant's operation, maintenance, replacement, and removal of the Generator Equipment. Without limiting any other obligations of Tenant set forth in this Lease, Tenant shall, at its sole cost and expense, maintain and repair the Generator Equipment and keep it in good order and operating condition.

(i) **Insurance**. If the presence of the Generator Equipment is the sole cause of an increase in Landlord's property or liability insurance premiums for the Building, Landlord shall so inform Tenant in writing and Tenant shall pay to Landlord as Additional Rent within 10 days after demand therefor an amount equal to such increase.

(ii) **Compliance**. Tenant shall, at its sole cost and expense, comply with all Legal Requirements that may now or hereafter be applicable to the area in which the Generator Equipment is located or to the use, operation, repair, maintenance, and replacement of the Generator Equipment. The Legal Requirements include, but are not limited to, Legal Requirements (A) requiring that Tenant obtain the necessary permits and approvals for the use, operation, repair, maintenance, and replacement of the Generator Equipment, (B) prohibiting any form of pollution, (C) requiring the person discharging or permitting the discharging of Hazardous Materials or participating in the discharge or spilling of Hazardous Materials to report such discharge or spill to the proper Governmental Authorities, (D) requiring certain inspections, gauging, and recordkeeping. Tenant shall pay all costs, expenses, claims, fines, penalties, and damages that may in any manner arise out of or be imposed because of the failure of Tenant to comply with this Section. Tenant shall indemnify, defend, and hold harmless Landlord and its officers, members, directors, employees, managers, employees, agents, and contractors from all claims, injuries, damages, costs, expenses, losses, and liabilities (including, but not limited to, attorneys' fees) arising from Tenant's failure to comply with this Section. Each party shall promptly give notice to the other of any notice of violation received by each party.

17. **Amendment to Sections 13 (Landlord's Repairs) and 14 (Tenant's Repairs)**. Effective as of the Expansion Premises Commencement Date, Sections 13 and 14 of the Lease are hereby deleted in their entirety and replaced with the following new Sections 13 and 14:

13. Landlord's Repairs. Landlord, as an Operating Expense, shall maintain the following in good repair, reasonable wear and tear and uninsured losses and damages caused by Tenant, or by any of Tenant's agents, servants, employees, invitees

and contractors (collectively, "**Tenant Parties**") excluded: (a) all of the exterior structural portions of the Building, (b) roof, roof membrane, and roofing and covering materials (including performing roof surveys), (c) foundations, (d) exterior demising walls and Building façade, (e) all landscaping, sidewalks, and parking areas contained in or about the Project, including all areas covered by asphalt and concrete; (f) exterior lighting (including parking lot lighting), (g) exterior signage at the Project (excluding, however, the Identification Signage), (h) patio and patio furniture, and (i) elevators. Landlord, as an Operating Expense, shall perform snow removal, exterior washing of windows, and exterior window repair. Losses and damages caused by Tenant or any Tenant Party shall be repaired by Landlord, to the extent not covered by insurance, at Tenant's sole cost and expense, subject to the terms of Section 17 below regarding each party's waiver of subrogation. Landlord reserves the right to stop the elevators and Building Systems (as defined in Section 14) services when necessary (i) by reason of accident or emergency, or (ii) for planned repairs, alterations or improvements, which are, in the judgment of Landlord, desirable or necessary to be made, until said repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply elevator and Building Systems services during any such period of interruption; provided, however, that Landlord shall, except in case of emergency, make a commercially reasonable effort to give Tenant 48 hours advance notice of any planned stoppage of elevator and Building Systems services for routine maintenance, repairs, alterations or improvements. Tenant shall promptly give Landlord written notice of any repair required by Landlord pursuant to this Section, after which Landlord shall have a reasonable opportunity to effect such repair. Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after Tenant's written notice of the need for such repairs or maintenance. Tenant waives its rights under any Legal Requirement to terminate this Lease or to make such repairs at Landlord's expense and agrees that the parties' respective rights with respect to such matters shall be solely as set forth herein. Repairs required as the result of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction shall be controlled by Section 18.

14. **Tenant's Repairs**. Except as expressly provided in Section 13 above or in this Section, Tenant, at its expense, shall repair, replace and maintain in good condition all portions and components of the interior of the Premises, including, without limitation, (i) entries, (ii) doors, (iii) ceilings (including structural portions of the floor/ceiling slabs), (iv) interior windows, (v) interior walls, (vi) the interior side of demising walls, (vii) HVAC, mechanical, electrical, life safety, plumbing, pipes and conduits, fire sprinklers, and all other building systems serving the Premises and other portions of the Project ("**Building Systems**"), (viii) shafts (including elevator shafts), (ix) columns and beams, (x) emergency electrical generator ("**Generator**") and related fuel supply system and infrastructure, and (xi) security cameras and related hardware installed by Landlord and used by Tenant (Tenant shall have the right to request Landlord to disconnect [but not remove] the Landlord-installed security cameras and related hardware serving the Building, which work Landlord shall promptly perform at its expense; if disconnected, such cameras and related hardware shall remain in place and maintained in such state by Tenant). Such repair and replacement may include capital expenditures and repairs whose benefit may extend beyond the Term; provided, however, that the cost to replace any HVAC system shall be allocated as set forth in Section 14(c) below. Should Tenant fail to make any such repair or replacement or fail to maintain the Premises, Landlord shall give Tenant notice of such failure. If Tenant fails to commence cure of such failure within 10 days of Landlord's notice, and thereafter diligently prosecute such cure to completion, Landlord may perform such work and shall be reimbursed the actual, reasonable cost thereof by Tenant within 10 days after demand therefor; provided, however, that if such failure by Tenant creates or could create an emergency, Landlord may immediately commence cure of such failure and shall thereafter be entitled to

recover the actual, reasonable costs of such cure from Tenant. Subject to Sections 17 and 18, Tenant shall bear the full uninsured cost of any repair or replacement to any part of the Project that results from damage caused by Tenant or any Tenant Party and any repair that benefits only the Premises.

(a) **Maintenance Contracts**. Tenant, at its expense, shall at all times during the Term maintain with qualified contractors maintenance and repair contracts ("**Maintenance Contracts**") for all Building Systems and the Generator. The Maintenance Contracts shall be in form and content reasonably satisfactory to Landlord. Landlord shall be a third party beneficiary of the Maintenance Contracts and, within 30 days after Landlord's request, Tenant shall deliver a copy of the Maintenance Contracts to Landlord.

(b) [***]

(c) [***]

(d) **Performance Audits**. Landlord shall have the ongoing right to inspect, perform maintenance audits (not to exceed twice per calendar year), and contract for an independent facility condition assessment (not to exceed once every 3 calendar years) to monitor Tenant's maintenance and repair obligations under this Lease, the reasonable costs of which may be included in Operating Expenses. Landlord shall have the right to review Tenant's certification records or maintenance records upon Landlord's written request (but not to exceed once per calendar year). All repairs made by Tenant shall be at least equal in quality to the original work, and shall be made only by a licensed, bonded (if required by Landlord in its sole discretion) contractor approved in advance by Landlord, which approval shall not be unreasonably withheld, delayed, or conditioned.

(e) **Lab Systems**. Tenant acknowledges that (i) the Expansion Premises contains an autoclave, glass washer, ice maker, RO water system, compressed air system, and vacuum system (collectively, "**Lab Systems**"), (ii) Tenant will not use the Lab Systems during the Term, and (iii) the Lab Systems shall remain in their current location within the Expansion Premises during the Term and shall not be removed from the Expansion Premises or

relocated within the Expansion Premises. By no later than the Expansion Premises Commencement Date, Landlord shall take such action as it deems necessary to secure the Lab Systems. From and after the Expansion Premises Commencement Date, Tenant shall have no obligation to maintain service contracts on the Lab Systems, but shall be responsible for repairing or replacing any Lab Systems damaged by Tenant or any Tenant Party. On the expiration or earlier termination of the Term, Tenant shall surrender the Lab Systems to Landlord in their then current condition, ordinary wear and tear and damage by Tenant or any Tenant Party excluded.

18. **Amendment to Sections 16(b) and 30(i) (Pre-Existing Environmental Conditions).** Sections 16(b) and 30(i) of the Lease shall remain in full force and effect, but as to the Expansion Premises, Pre-Existing Environmental Conditions shall mean the presence of Hazardous Materials in, on, under, or about the Expansion Premises before the Expansion Premises Commencement Date.

19. **Amendment to Sections 21(c) and (d) (Default Remedies).** Sections 21(c) and 21(d) of the Lease are each hereby amended by inserting "Upon a Default by Tenant hereunder," at the beginning of the first sentence thereof.

20. **Amendment to Section 21(e) (Suspension of Funding/Performance).** Section 21(e) of the Lease is hereby amended by deleting that provision in its entirety and replacing it with the following new Section 21(e):

(e) **Suspension of Funding/Performance.** Upon a Default by Tenant hereunder and during the continuance thereof, Landlord shall have the right to suspend funding of any TI Allowance, the Expansion Premises TI Allowance, or the performance of Landlord's Work (and such suspension shall constitute a Tenant Delay [as defined in **Exhibit C-1** attached hereto]).

21. **Amendment to Section 27 (Subordination).** The reference to the "Commencement Date" in the first sentence of Section 27 of the Lease shall be deemed a reference to the "Commencement Date and the Expansion Premises Commencement Date".

22. **Amendment to Section 39 (Right of First Offer).** Effective as of the Expansion Premises Commencement Date, Section 39 of the Lease is hereby deleted in its entirety and replaced with the words "Reserved."

23. [***]

24. [***]

(c) [***]

[***]

25. [***]

26. **Tenant's Property.** Notwithstanding anything to the contrary in the Lease, all alterations and improvements that may be installed or placed in or about the Premises, including, without limitation, the Tenant Improvements and the Third Amendment Improvements, to the extent paid for by Tenant, shall be Tenant's property during the Term of the Lease. As such, prior to the expiration or earlier termination of the Lease, Tenant shall be entitled to all depreciation, amortization, and other tax benefits with respect thereto. All such alterations and improvements shall be and become the property of Landlord upon the expiration or earlier termination of the Lease, except to the extent Tenant is required to remove the same pursuant to the terms of the Lease.

27. **No Liens.** Landlord hereby waives each and every lien for rent or right of distress, whether statutory, common law, contractual, or otherwise, with respect to Tenant's personal property in the Premises.

28. **Miscellaneous.**

a. This Third Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Third Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Third Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

c. This Third Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000), or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Third Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Tenant represents and warrants to Landlord that Tenant has not dealt with any broker, agent, or other person (collectively, "**Broker**") in connection with this Third Amendment and that no Broker brought about this transaction, other than CBRE, Inc. ("**CBRE**") and Scheer Partners, Inc. ("**SPI**"). CBRE, acting as Tenant's broker, shall be paid by Landlord pursuant to a separate agreement between Landlord and CBRE. SPI, acting as Landlord's broker, shall be paid by Landlord pursuant to a separate agreement between Landlord and SPI. Tenant hereby agrees to indemnify and hold Landlord harmless from and against any claims by any Broker (other than CBRE and SPI) claiming a commission or other form of compensation by virtue of having dealt with Tenant with regard to this Third Amendment.

e. Except as amended and/or modified by this Third Amendment, the Lease is

hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Third Amendment. In the event of any conflict between the provisions of this Third Amendment and the provisions of the Lease, the provisions of this Third Amendment shall prevail. Regardless of whether specifically amended by this Third Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Third Amendment.

[SIGNATURES APPEAR ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Third Amendment under seal as of the day and year first above written.

TENANT:

KITE PHARMA, INC.,
a Delaware corporation

By:_____(SEAL)
Name:_____
Title:_____

GILEAD
Approved by Legal Department

LANDLORD:

TECH PARK 270 III, LLC,
a Maryland limited liability company

By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company,
managing member

By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company,
managing member

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By:_____(SEAL)
Name:_____
Title: Jennifer Banks
Co-Chief Operating Officer
& General Counsel

EXHIBIT A
EXPANSION PREMISES

Expansion Premises

[***]

EXHIBIT A--continued
EXPANSION PREMISES

Expansion
Premises

[***]

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

FOURTH AMENDMENT TO LEASE AGREEMENT

THIS FOURTH AMENDMENT TO LEASE AGREEMENT ("**this Fourth Amendment**") is made as of this 23 day of May, 2019 ("**Effective Date**"), between **TECH PARK 270 III, LLC**, a Maryland limited liability company, having an address at 385 E. Colorado Boulevard, Suite 299, Pasadena, California 91101 ("**Landlord**"), and **KITE PHARMA, INC.**, a Delaware corporation, having an address at Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301 ("**Tenant**").

RECITALS

A. Landlord and Tenant have entered into that certain Lease Agreement ("**Original Lease**") dated as of December 1, 2017, as amended by that certain First Amendment to Lease Agreement dated January 29, 2018 ("**First Amendment**"), that certain Second Amendment to Lease Agreement dated February 26, 2018 ("**Second Amendment**"), and that certain Third Amendment to Lease Agreement dated September 24, 2018 ("**Third Amendment**"; together with the Original Lease, the First Amendment, and the Second Amendment, the "**Lease**"), wherein Landlord leased to Tenant approximately [***] rentable square feet ("**Premises**") located at Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301, as more particularly described in the Lease.

B. Landlord and Tenant desire to amend the Lease, among other things, to modify the provisions governing the costs to replace certain HVAC systems serving the Premises and to allow for the removal from the Premises of certain Lab Systems.

AGREEMENT

Now, therefore, the parties hereto agree that, as of the Effective Date, the Lease is amended as follows:

1. **Amendments to Certain Provisions of Section 14 (Tenant's Repairs)**. Effective as of the Effective Date, Sections 14(b) (HVAC System Condition), 14(c) (HVAC System Replacement), and 14(e) (Lab Systems) of the Lease are hereby deleted in their entirety and replaced with the following new Sections 14(b) (HVAC System Condition), 14(c) (Replacement of Certain Existing HVAC/Water Equipment), 14(e) (Lab Systems), and a new Section 14(f) (Boiler):

(b) **HVAC System Condition**. Tenant confirms that (i) Landlord previously obtained and provided to Tenant a copy of a report prepared by Jennerik Engineering, Inc. dated August 23, 2018 and addressed to Tenant evaluating the condition of the base building HVAC system serving the Premises, and (ii) Landlord has, at its sole cost and expense, replaced the HVAC unit known as RTU-14 (Carrier Model 48GX-024040301; serial number 2501G1152) with a new HVAC unit ("**Replaced HVAC Unit**"). Subject to the provisions of Section 14(c) below, Tenant shall thereafter maintain, repair, and replace the Replaced HVAC Unit, the Existing HVAC/Water Equipment (as defined below), and the New HVAC/Water Equipment (as defined below) as provided in this Section 14.

(c) **Replacement of Certain Existing HVAC/Water Equipment**. Notwithstanding any contrary provision contained in Section 5 (Operating Expense Payment) or Section 13 (Landlord's Repairs) or this Section 14, the cost to replace certain of the existing HVAC units, exhaust fans, air handling units, boilers, and water pumps serving the Premises shall be governed by the provisions of this Section. For purposes of this Lease, "**Existing HVAC/Water Equipment**" means the following HVAC units, exhaust fans, air handling units, boilers, and water pumps serving the Premises:

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(iii) **Other HVAC Systems**. Landlord shall, as an Operating Expense, promptly replace when operationally required any HVAC system that is not a Replaced HVAC Unit, an item of the Existing HVAC/Water Equipment, or an item of the New HVAC/Water Equipment ("**Other HVAC Systems**") with a new HVAC system of comparable tonnage. The cost of the Other HVAC System shall be amortized over the useful life of the Other HVAC System.

* * * * * * * * * * *

(e) **Lab Systems**. Tenant acknowledges that (i) room 330 in the Expansion Premises contains 2 autoclaves, glass washer, ice maker, RO water system, compressed air system, and vacuum system (collectively, "**Lab Systems**"), (ii) Tenant will not use the Lab Systems during the Term, and (iii) the Lab Systems shall remain in their current location within the Expansion Premises during the Term and shall not be removed from the Expansion Premises or relocated within the Expansion Premises except as otherwise stated in this paragraph. By no later than the Expansion Premises Commencement Date, Landlord shall take such action as it deems necessary to secure the Lab Systems. From and after the Expansion Premises Commencement Date, Tenant shall have no obligation to maintain service contracts on the Lab Systems, but shall be responsible for repairing or replacing any Lab Systems damaged by Tenant or any Tenant Party. On the expiration or earlier termination of the Term, Tenant shall surrender the Lab Systems to Landlord in their then current condition, ordinary wear and tear and damage by Tenant or any Tenant Party excluded; provided, however, that (A) Tenant shall have the right, at Tenant's expense and upon not less than 120 days' advance notice to Landlord, to remove and dispose of all or some of the Lab Systems, which removal and disposal shall be performed in a good and workmanlike manner in accordance with applicable Legal Requirements, and (B) during such 120 day period, Landlord shall have the superior right to sell all or any of the Lab Systems and, in the event of any such sale, Landlord and its agents shall at Landlord's expense remove such Lab Systems (such removal shall be performed in a good and workmanlike manner in accordance with applicable Legal Requirements), and Landlord shall at its expense promptly repair any damage caused by or occasioned as a result of such removal, including capping off any connections behind the walls of the Premises and repairing any holes. If Tenant exercises its right to remove and dispose of all or any of the Lab Systems as described in this paragraph, Tenant shall at its expense promptly repair any damage caused by or occasioned as a result of such removal, including capping off any connections behind the walls of the Premises and repairing any holes.

(f) [***]

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2. **Amendment to Section 21(e) (Suspension of Funding/Performance)**. Section 21(e) of the Lease is hereby amended by deleting that provision in its entirety and replacing it with the following new Section 21(e):

(e) **Suspension of Funding/Performance**. Upon a Default by Tenant hereunder and during the continuance thereof, Landlord shall have the right to suspend funding of any TI Allowance, the Expansion Premises TI Allowance, the HVAC Allowance, or the performance of Landlord's Work (and such suspension shall constitute a Tenant Delay [as defined in **Exhibit C-1** attached hereto]).

3. [***]
[***]
[***]

(c) [***]
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4. **Miscellaneous**.

a. This Fourth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Fourth Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Fourth Amendment is binding upon and shall inure to the benefit of the parties

hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

c. This Fourth Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000), or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Fourth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Tenant represents and warrants to Landlord that Tenant has not dealt with any broker, agent, or other person (collectively, "**Broker**") in connection with this Fourth Amendment and that no Broker brought about this transaction. Tenant hereby agrees to indemnify and hold Landlord harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Tenant with regard to this Fourth Amendment.

e. Except as amended and/or modified by this Fourth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Fourth Amendment. In the event of any conflict between the provisions of this Fourth Amendment and the provisions of the Lease, the provisions of this Fourth Amendment shall prevail. Regardless of whether specifically amended by this Fourth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Fourth Amendment.

[SIGNATURES APPEAR ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Fourth Amendment under seal as of the day and year first above written.

TENANT:

KITE PHARMA, INC.,
a Delaware corporation

By: /s/ Tim Moore (SEAL)
Name: Tim Moore
Title: EVP Technical Operations

GILEAD
Approved by Legal Department
By: /s/ Illegible

LANDLORD:

TECH PARK 270 III, LLC,
a Maryland limited liability company

By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company,
managing member

By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company,
managing member

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By: /s/ Jackie Clem (SEAL)
Name: Jackie Clem
Title: Senior Vice President
RE Legal Affairs

Signature:

Email: [***]

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

NON-EXCLUSIVE LICENSE AGREEMENT

by and between

ACUITAS THERAPEUTICS, INC.

and

BIONTECH RNA PHARMACEUTICALS GMBH

dated

April 7, 2020

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License Agreement

This License Agreement ("License Agreement"), dated as of April 7, 2020 (the "License Agreement Effective Date"), is made by and between Acuitas Therapeutics Inc., a British Columbia corporation ("Acuitas"), and BioNTech RNA Pharmaceuticals GmbH, a German corporation ("BioNTech"). Each of Acuitas and BioNTech may be referred to herein as a "Party" or together as the "Parties."

WHEREAS, Acuitas has proprietary LNP Technology (as defined below);

WHEREAS, BioNTech has expertise and intellectual property relating to mRNA Constructs (as defined below) as well as to formulation development including non-clinical testing and GMP manufacturing;

WHEREAS, Acuitas and BioNTech are parties to that certain Development and Option Agreement (dated July 10, 2017) (the "Development and Option Agreement") pursuant to which BioNTech has options to take licenses under the Acuitas LNP Technology (as defined below) with respect to BioNTech's mRNA Constructs; and

WHEREAS, pursuant to the terms of the Development and Option Agreement, BioNTech has exercised an option with respect to the Target (as defined below) and the Parties are now entering into a licensing arrangement whereby BioNTech will have a license under the Acuitas LNP Technology to develop and commercialize Licensed Products (as defined below) based on such Target.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Definitions.

The following terms and their correlatives will have the following meanings:

1.1 "Acuitas LNP Technology" means any and all LNP Technology Controlled by Acuitas or any of its Affiliates as of the License Agreement Effective Date or at any time during the Term, including Acuitas' right and interest in any Technology created, conceived or reduced to practice under the Development and Option Agreement and necessary or useful for the research, development, manufacturing and commercialization of Licensed Products. Unless otherwise set forth herein, Acuitas LNP Technology will exclude Jointly Owned Patents and Dual Improvement Patents.

1.2 "Acuitas Indemnitiees" has the meaning set forth in Section 9.6(a).

1.3 "Affiliate" of a person or entity means any other entity which (directly or indirectly) is controlled by, controls or is under common control with such person or entity. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to an entity will mean (i) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors or (ii) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%) of the equity interests with the voting power to direct the management and policies of such entity, provided that if local Law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local Law, be owned by foreign interests.

1.4 [***]

1.5 "cGMP" means current Good Manufacturing Practices as specified in the U.S. C.F.R., ICH Guideline Q7A, or equivalent Laws of an applicable Regulatory Authority at the time of manufacture.

1.6 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.7 "Change of Control" with respect to Acuitas, shall be deemed to have occurred if during the Term (i) any person or entity is or becomes the "beneficial owner", directly or indirectly, of shares of capital stock or other interests (including partnership interests) of Acuitas then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions of Acuitas representing fifty percent (50%) or more of the total voting power of all outstanding classes of voting stock of Acuitas or has the power, directly or indirectly, to elect a majority of the members of the Acuitas' board of directors, or similar governing body; or (ii) Acuitas enters into a merger, consolidation or similar transaction with another person or entity; or (iii) Acuitas sells or transfers to any Third Party, in one (1) or more related transactions, properties or assets representing all or substantially all of Acuitas' consolidated total assets to which this Agreement relates; or (iv) the holders of capital stock of Acuitas approve a plan or proposal for the liquidation or dissolution of Acuitas."

1.8 "Combination Product" means a Licensed Product that is combined and sold together (but not, for avoidance of doubt, formulated together) with at least one additional active ingredient/product other than a Licensed Product. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7) or equivalent Laws in other jurisdictions, provided however, **[***]**

1.9 "Competitive Product" shall mean a product that is, or can reasonably be, used for the same Indication as a Licensed Product.

1.10 "Indication" shall mean an individual disease or clinical condition with respect to which at least one adequate and well controlled study is required to support inclusion of such disease or condition in the indication statement of an FDA approved package insert for a Licensed Product.

1.11 "Confidential Information" has the meaning set forth in Section 8.1.

1.12 "Control" or "Controlled" means, with respect to any Know-How or Patent, the possession (whether by ownership or license, other than by a license or sublicense granted pursuant to this License Agreement or the Development and Option Agreement) by Acuitas or its Affiliates of the ability to grant to BioNTech a license or access to such Know-How or Patent as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party and without owing any milestone, royalty or other monetary obligations to a Third Party.

1.13 "Covered Product" means a Licensed Product covered by one or more Valid Claims of the Acuitas LNP Technology.

1.14 "Covers", with reference to (a) a Patent, means that the manufacture, development or commercialization of a Licensed Product would infringe a Valid Claim of such Patent in the country in which such activity occurs; and (b) Know-How, means that the manufacture, development or commercialization of a Licensed Product incorporates or embodies such Know-How.

1.15 "Development and Option Agreement" has the meaning set forth in the Preamble.

1.16 "Disclosing Party" has the meaning set forth in Section 8.1

1.17 "Dual Improvement Patents" means the Patents listed in Appendix 1.17 hereto, as amended from time to time.

1.18 "Field of Use" means use of Licensed Product for human therapeutic and prophylactic applications.

1.19 "First Commercial Sale" means the first sale for use or consumption of any Licensed Product in a country after all required Regulatory Approvals for commercial sale of such Licensed Product have been obtained in such country.

1.20 "Fusion Protein" [***]

1.21 "Indemnification Claim Notice" has the meaning set forth in Section 9.6(c).

1.22 "Indemnified Party" has the meaning set forth in Section 9.6(c).

1.23 "Jointly Owned Patents" means the Patents listed in Appendix 1.23 hereto, as amended from time to time.

1.24 "Know-How" means all commercial, technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical,

pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, provided it is confidential and proprietary, and regardless of whether patentable, in written, electronic or any other form.

1.25 "Law" or "Laws" means all laws, statutes, rules, regulations, orders, judgments, or ordinances having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

1.26 "License Agreement" has the meaning set forth in the Preamble.

1.27 "License Agreement Effective Date" has the meaning set forth in the Preamble.

1.28 "Licensed Product(s)" means [***] product(s) consisting of Lipid Nanoparticles (LNP) containing [***] mRNA Constructs [***] where such product is derived from, is based on, or utilizes any Acuitas LNP Technology. For the avoidance of doubt, the term "Licensed Product" in respect of the Target [***].

1.29 "LNP Technology" means Technology that claims, embodies or incorporates delivery systems (and components thereof) based on or incorporating lipid nanoparticles (LNP).

1.30 "LNP Technology Patent(s)" means Patents comprised in the Acuitas LNP Technology, including any future Patent which will become part of the Acuitas LNP Technology during the Term and further including Acuitas' rights in the Jointly Owned Patents, unless otherwise set forth herein.

1.31 "Losses" has the meaning set forth in Section 9.6(a).

1.32 "Major Market Countries" means Canada, United States, Japan, France, Germany, Spain, Italy, or United Kingdom.

1.33 "mRNA Construct" [***]

1.34 "mRNA Technology" means Technology that claims, embodies or incorporates expression systems (and components thereof), based on or incorporating mRNA.

1.35 "Milestones" means the milestones payable pursuant to Section 4.

1.36 "Milestone Event" has the meaning set forth in Section 4.1.

1.37 "Milestone Payment" has the meaning set forth in Section 4.1.

1.38 "Net Sales" means, with respect to any Licensed Product, [***]

(a) [***]

(b) [***]

(c) [***]

(d) [***]

(e) [***]

(f) [***]

(g) [***]

[***]
[***]

[***]

[***]

1.39 "Patent(s)" means an (i) issued patent, a patent application, and a future patent issued from any such patent application, (ii) a future patent issued from a patent application filed in any country worldwide which claims priority from a patent or patent application of (i), and (iii) any additions, divisions, continuations, continuations-in-part, invention certificates, substitutions, reissues, reexaminations, extensions, registrations, utility models, supplementary protection certificates and renewals based on any patent or patent application under (i) or (ii), but not including any rights that give rise to regulatory

exclusivity periods (other than supplementary protection certificates, which will be treated as "Patents" hereunder).

1.40 "Patent Costs" means the reasonable, documented, out-of-pocket costs and expenses paid to outside legal counsel, and filing and maintenance expenses, actually and reasonably incurred by a Party in prosecuting and maintaining Patents and enforcing and defending them.

1.41 "Phase 1 Study" means a human clinical trial of a Licensed Product in any country, the primary purpose of which is the determination of safety and which may include the determination of pharmacokinetic and/or pharmacodynamic profiles in healthy individuals or a diseased patient population. A Phase 1 Study in a diseased patient population may include, in addition to primary determination of safety, dose exploration and a determination of preliminary efficacy of a product in the target patient population. For clarity, a particular human clinical trial of a Licensed Product will not be considered both a Phase 1 Study and a Phase 2 Study for the purposes of Milestone payments under Section 4.1.

1.42 "Phase 2 Study" means a human clinical trial of a Licensed Product in any country, and which is: (a) a human clinical trial (other than a Phase 1 Study) in which the primary purpose is dose exploration, dose response, duration of effect, kinetics or preliminary efficacy and safety of a product in the target patient population, or (b) a controlled dose-ranging clinical trial to evaluate further the efficacy and safety of such product in the target patient population and to define the optimal dosing regimen.

1.43 "Phase 3 Study" means a human clinical trial of a Licensed Product in any country, and which is: (a) a controlled study of a product in the target patient population of the efficacy and safety of such product which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to obtain Regulatory Approval to market such product.

1.44 "Pre-Existing Restrictions" means, with respect to a Target, that (a) [***] ("Pre-Existing Third Party Restrictions"), or (b) [***] ("Pre-Existing Internal Restrictions").

1.45 "Receiving Party" has the meaning set forth in Section 8.1.

1.46 "Regulatory Approval" means, with respect to a country or extra-national territory, any and all approvals (including BLAs and MAAs), licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a product in such country or some or all of such extra-national territory, including any pricing or reimbursement approvals.

1.47 "Regulatory Authority" means any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental authority, in any jurisdiction in the world, involved in the granting of Regulatory Approval.

1.48 "[***] Target" means the [***]

1.49 "Royalty Term" has the meaning set forth in Section 4.2(d).

1.50 "BioNTech Indemnitees" has the meaning set forth in Section 9.6(b).

1.51 "Solely Owned IP" has the meaning set forth in Article 5.

1.52 "Sublicensee" means any Third Party that is granted a sublicense as permitted by Section 2.2, either directly by BioNTech or its Affiliates or indirectly by any other Sublicensee hereunder.

1.53 "Target" means the proteins described in Appendix 1.53 and includes: (a) [***] naturally occurring human protein [***].

1.54 "Technology" means collectively Patents and Know-How.

1.55 "Term" has the meaning set forth in Section 10.1.

1.56 "Territory" means worldwide.

1.57 "Third Party" means any person or entity other than BioNTech, Acuitas and their respective Affiliates.

1.58 "Third Party Claims" has the meaning set forth in Section 9.6(a).

1.59 "Vaccine" means any product primarily intended (i) to elicit an adaptive immune response in the recipient against a specific disease-causing organism or malignancy as the result of presentation of antigen(s) associated with the disease-causing organism or malignancy; or (ii) to provide passive immune protection against a specific disease-causing organism.

1.60 "Vaccine Target" means Covid-19 Target as described in Appendix 1.53.

1.61 "Valid Claim" means, with respect to a particular country, any claim of (i) an issued and unexpired Patent; or (ii) a pending Patent claim, [***]

2. License Grants; Technology Transfer.

2.1 Licenses by Acuitas. Subject to the terms and conditions of this License Agreement, Acuitas hereby grants to BioNTech and its Affiliates (i) a non-exclusive, non-transferrable license, with the right to sublicense only as permitted by Section 2.3(b), under the Acuitas LNP Technology, to develop, have developed, make, have made, use and have used, sell, offer for sale, have sold and import and have imported Licensed Products in the Field of Use in the Territory and (ii) an exclusive, non-transferrable license, with the right to sublicense only as permitted by Section 2.3(b), under the Jointly Owned Program Patents, and any Dual Improvement Patents owned by Acuitas, to develop, have developed, make, have made, use and have used, sell, offer for sale, have sold and import and have imported Licensed Products within the scope of allowed and/or issued claims within any Major Market Country (whether or not expired) within the BioNTech mRNA Technology in the Field of Use in the Territory. [***]

2.2 Option to Convert Non-exclusive License. BioNTech will have a limited option to convert the non-exclusive license granted pursuant to Section 2.1 to an exclusive license. BioNTech will notify Acuitas and the Escrow Agent in writing of its desire to exercise the exclusive license option ("Conversion Option Notice") and pay to Acuitas an escrow fee of [***] dollars (U.S.$ [***]). The Escrow Agent - on behalf of Acuitas - will review the Conversion Option Notice provided by BioNTech hereunder to determine whether or not any such proposed Target is on the Restricted Target List as of the date of such Option Conversion Notice. If the Target is subject to Pre-existing Restrictions, the Escrow Agent will notify BioNTech that the license set forth in Section 2.1 may not be converted to an exclusive license. If the Target is not subject to Pre-existing Restrictions, the Escrow Agent will notify BioNTech that the license set forth in Section 2.1 may be converted to an exclusive license upon BioNTech's delivery of a signed Exclusive License Agreement in the form attached hereto as Exhibit 2.2 and payment of a conversion fee equal to (the difference between the nonexclusive and exclusive option fee under the Development and Option Agreement ([***] dollars (U.S.$ [***])) plus (the difference between any milestone fees paid under the nonexclusive license prior to the Conversion Option Notice and the milestone fees for such events under an exclusive license).

2.3 Sublicensing Rights.

(a) Transfer. The license granted in Section 2.1 [and option set forth in Section 2.2] is transferable only upon a permitted assignment of this License Agreement in accordance with Section 11.11.

(b) BioNTech Sublicenses. The licenses granted in Section 2.1 may be sublicensed (with the right to sublicense through multiple tiers), in full or in part, by BioNTech, its Affiliates or Sublicensees to Third Parties provided, that for any sublicense to Third Parties:

(i) Each sublicense will be in writing and on terms consistent with and subject to the terms of this License Agreement,

(ii) BioNTech will provide Acuitas with a copy of any sublicense agreement with a Sublicensee within [***] days of execution thereof, which sublicense agreement may be redacted as

necessary to protect commercially sensitive information and shall be treated as BioNTech Confidential Information hereunder;

(iii) BioNTech will be responsible for any and all obligations of such Sublicensee as if such Sublicensee were BioNTech hereunder; and

(iv) Any sublicense granted by BioNTech to any rights licensed to it hereunder shall terminate immediately upon the termination of the license from Acuitas to BioNTech and its Affiliates with respect to such rights, provided that such sublicensed rights shall not terminate if, as of the effective date of such termination pursuant to Sections 10.2, 10.3(a) or 10.4, a Sublicensee is not in material default of its obligations under its sublicense agreement, and within [***] days of such termination and a written notice by Acuitas and disclosure of this License Agreement to the Sublicensee, the Sublicensee agrees in writing to be bound directly to Acuitas under a license agreement substantially similar to this License Agreement with respect to the rights sublicensed hereunder, substituting such Sublicensee for BioNTech.

(c) Subcontractors. For clarity purposes, BioNTech is entitled to engage contract research organizations and contract manufacturing organizations for the development and manufacture of Licensed Products on behalf of BioNTech. To the extent such contract organizations require a license to perform such subcontracted activities under applicable Laws, BioNTech is entitled to grant a limited license without an obligation to meet the conditions of Section 2.2 (b)(ii) and (iv).

2.4 Technology Transfer. After the License Agreement Effective Date Acuitas will conduct a single full transfer of Acuitas LNP Technology to BioNTech and/or its designee(s) (which designee(s) may be an Affiliate or a Third Party cGMP manufacturer) as required for the applicable transferee of the then-current process. The technology transfer activities, the rights and obligations of the Parties, the reimbursement of Acuitas for the technology transfer activities, and the rights and licenses to any Technology generated in the course of the technology transfer will be as set forth in the Technology Transfer Agreement becoming effective on the License Agreement Effective Date and included in Appendix 2.4.

2.5 Updates to Appendix 1.1. Acuitas shall notify BioNTech at least once every [***] months of Patents that are added to the Acuitas LNP Technology following the License Agreement Effective Date or any Patents that have been abandoned or discontinued in accordance with the terms of this License Agreement. Appendix 1.1 shall be automatically updated to include any such added or deleted Patents.

2.6 Documents and Declarations. Acuitas shall execute all documents, give all declarations regarding the licenses granted hereunder and reasonably cooperate with BioNTech to the extent such documents, declarations and/or cooperation are required for the recording or registration of the licenses granted hereunder at the various patent offices in the Territory for the benefit of BioNTech, its Affiliates or their Sublicensees.

3. License Limitations. No licenses or other rights are granted by Acuitas hereunder to use any trademark, trade name, trade dress or service mark owned or otherwise Controlled by Acuitas or any of its Affiliates. All licenses and other rights are or shall be granted only as expressly provided in this License Agreement, and no other licenses or other rights is or shall be created or granted by either Party hereunder by implication, estoppel or otherwise.

4. Payments and Royalties.

4.1 Milestone Payments. BioNTech will make milestone payments (each, a "Milestone Payment") to Acuitas upon the first occurrence of each of the milestone events (each, a "Milestone Event") by a Licensed Product as set forth below in this Section 4.1. BioNTech will notify Acuitas of the

achievement of each Milestone Event within [***] business days of such achievement. Each Milestone Payment will be payable to Acuitas by BioNTech within [***] days of the achievement of the specified Milestone Event and such payments when owed or paid will be non-refundable and non-creditable. If one or more of the Milestone Events set forth below are not achieved or not required for any reason, the payment for such skipped Milestone Event will be due at the same time as the payment for the next achieved Milestone Event.

Milestone Event	Milestone Payment For Covered Products
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***]

4.2 Royalties.

(a) Royalty. Subject to the remainder of this Section 4.2, on a country-by-country basis and a Licensed Product-by-Licensed Product basis,

(i) [***] BioNTech will pay to Acuitas a royalty of [***]% Net Sales.

[***]

(b) Third Party Royalty Payments. If BioNTech or its Affiliate or Sublicensee, in its reasonable judgment, considers it necessary or useful to obtain a license from any Third Party that Covers a Licensed Product in order to develop, manufacture or commercialize such Licensed Product the amount of BioNTech's royalty obligations under Sections 4.1(a) will be reduced by [***] percent ([***]%) of the amount of the royalty payments made to such Third Party ("Third Party Royalty Payments"), provided, however, [***] For avoidance of doubt, Third Party Royalty Payments will include payments by BioNTech in connection with Acuitas sublicenses under Section 2.2.

(c) [***]

(d) Term. The royalty term ("Royalty Term") shall expire on a country-by-country

and Licensed Product-by-Licensed Product basis, on the last to occur of (i) expiration of the last to expire Valid Claim in the Acuitas LNP Technology that, but for the license described herein from Acuitas to BioNTech for the applicable Licensed Product, is infringed by the making, using or sale of such Licensed Product, (ii) expiration of any period of data exclusivity, market exclusivity or supplemental protection certificates covering the Licensed Product in such country; and (iii) [***] years after First Commercial Sale of Licensed Product in such country, provided [***]. For the avoidance of doubt, upon exhaustion of the obligation to pay Royalties to Acuitas as set forth above the continued use of Acuitas Know-How comprised in the LNP Technology for the development, manufacture and/or sale of the Licensed Product shall not, in and of itself, obligate BioNTech to pay further royalties to Acuitas. Thereafter, BioNTech's license under Section 2.1 will become irrevocable, fully paid-up and royalty-free on a country-by-country and Licensed Product-by-Licensed Product basis.

(e) [***]

4.3 Payment Terms.

(a) Manner of Payment. All payments to be made by BioNTech hereunder will be made in U.S. dollars by wire transfer to such bank account as Acuitas may designate.

(b) Records and Audits. BioNTech shall keep, and shall cause each of its Affiliates and Sublicensees, as applicable, to keep adequate books and records of accounting for the purpose of calculating all royalties payable to Acuitas hereunder. For the [***] years next following the end of the calendar year to which each shall pertain, such books and records of accounting (including those of BioNTech's Affiliates) shall be kept at each of their principal places of business and shall be open for inspection at reasonable times and upon reasonable notice by an independent certified accountant selected by Acuitas, and which is reasonably acceptable to BioNTech, for the sole purpose of inspecting the royalties due to Acuitas under this License Agreement. In no event shall such inspections be conducted hereunder more frequently than once every [***] months. Such accountant must have executed and delivered to BioNTech and its Affiliates, a confidentiality agreement as reasonably requested by BioNTech, which shall include provisions limiting such accountant's disclosure to Acuitas to only the results and basis for such results of such inspection. The results of such inspection, if any, shall be binding on both Parties. Any underpayments shall be paid by BioNTech within [***] days of notification of the results of such inspection. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods. Acuitas shall pay for such inspections, except that in the event there is any upward adjustment in aggregate royalties payable for any calendar year shown by such inspection of more than [***] percent ([***]%) of the amount paid, BioNTech shall reimburse Acuitas for any reasonable out-of-pocket costs of such accountant.

(c) Reports and Royalty Payments. For as long as royalties are due under Section 4.2, BioNTech shall furnish to Acuitas a written report for each Calendar Quarter, showing the amount of Net Sales of Licensed Products and royalty due for such Calendar Quarter. Reports shall be provided within [***] ([***]) days of the end of the Calendar Quarter for Net Sales generated by BioNTech and its Affiliates, and within [***] ([***]) days of the end of the Calendar Quarter for Net Sales generated by Sublicensees. Royalty payments for each Calendar Quarter shall be due at the same time as the last such written report for the Calendar Quarter. The report shall include, at a minimum, the following information for the applicable Calendar Quarter, each listed by Licensed Product and by country of sale: (i) [***] (ii) [***] (iii) [***] (iv) [***] and (v) [***]. All such reports shall be treated as Confidential Information of BioNTech. [***].

(d) Currency Exchange. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due to Acuitas hereunder will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on standard methodologies employed by BioNTech or its Affiliates or Sublicensees for consolidation purposes for the Calendar Quarter for which remittance is made for royalties.

(e) Withholding Taxes. BioNTech may withhold from payments due to Acuitas amounts for payment of any withholding tax that is required by Law to be paid to any taxing authority with respect to such payments. BioNTech will provide Acuitas all relevant documents and correspondence, and will also provide to Acuitas any other cooperation or assistance on a reasonable basis as may be necessary to enable Acuitas to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. BioNTech will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include BioNTech making payments from a single source in the U.S., where possible. Apart from any such permitted withholding and those deductions expressly included in the definition of Net Sales, the amounts payable by BioNTech to Acuitas hereunder will not be reduced on account of any taxes, charges, duties or other levies.\

(f) Taxes on Income. Except as otherwise set forth in this Section 4.3, each Party shall be solely responsible for the payment of all taxes imposed on such Party's income arising directly or indirectly from the activities of the Parties under this Agreement.

(g) Blocked Payments. In the event that, by reason of applicable law in any country, it becomes impossible or illegal for BioNTech or its Affiliates or Sublicensees to transfer, or have transferred on its behalf, payments owed to Acuitas hereunder, BioNTech will promptly notify Acuitas of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Acuitas in a recognized banking institution designated by Acuitas or, if none is designated by Acuitas within a period of [***] days, in a recognized banking institution selected by BioNTech or its Affiliate or Sublicensee, as the case may be, and identified in a written notice given to Acuitas.

(h) Interest Due. If any payment due to Acuitas under this License Agreement is overdue (and is not subject to a good faith dispute), then BioNTech will pay interest thereon (before and after any judgment) at an annual rate of the lesser of [***] percent ([***]%) above the prime rate as reported in The Wall Street Journal, Eastern Edition, and [***], such interest to run from the date upon which payment of such sum became due until payment thereof in full together with such interest.

(i) Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Acuitas.

5. Ownership and Inventorship of IP. As between the Parties, each Party will own and retain all right, title and interest in and to any and all Know-How and Patents arising therefrom that are discovered, created, conceived, developed or reduced to practice solely by or on behalf of such Party under or in connection with this License Agreement ("Solely Owned IP"). Subject to the licenses hereunder and the other terms and conditions of this License Agreement or any other agreement between the Parties, each Party will be solely responsible for the prosecution and maintenance, and the enforcement and defense, of any Patents within its Solely Owned IP.

6. Patent Prosecution and Maintenance.

6.1 Generally. As between the Parties and subject to Section 6.2 below, Acuitas (or its Third Party licensor, if any) will have the sole right, at its sole costs, to prosecute and maintain Acuitas LNP Technology Patents. Upon filing, Acuitas will provide BioNTech with copies of all applications for all such LNP Technology Patents, and will keep BioNTech timely updated about patent applications intended for grant. If BioNTech deems it necessary to file a divisional application before grant of the patent but Acuitas elects not to file such a divisional application, BioNTech will have the right to request the filing on its own costs under the provisions of Section 6.2(a). The Parties will enter into a joint patent prosecution and maintenance agreement with respect to prosecution and maintenance any and all Jointly Owned Patents and the Parties will share equally all costs in connection with such efforts.

6.2 Election Not to Prosecute or Maintain or Pay Patent Costs.

(a) By Acuitas. If Acuitas elects not (i) to file, prosecute or maintain any LNP Technology Patents (including filing a divisional application for any LNP Technology Patents)for which it is responsible under Section 6.1 in any particular country before the applicable filing deadline or continue such activities once filed in a particular country, or (ii) to pay the Patent Costs associated with prosecution or maintenance of any such LNP Technology Patents then in each such case Acuitas will so notify BioNTech, promptly in writing and in good time to enable Acuitas to meet any deadlines by which an action must be taken to preserve such LNP Technology Patent in such country, if BioNTech so requests. Upon receipt of each such notice by Acuitas, BioNTech will have the right, but not the obligation, to notify Acuitas in writing on a timely basis that Acuitas should continue the prosecution and/or maintenance and/or file divisional application of such LNP Technology Patent in the respective country, and thereafter, Acuitas would prosecute and maintain such LNP Technology Patent in such country at the sole direction of BioNTech, Acuitas would make available to BioNTech all documentation and correspondence with respect to such Acuitas LNP Technology Patent, and BioNTech would compensate the reasonable Patent Costs incurred by Acuitas in connection with such efforts, i.e., Patent Costs which Acuitas would not have had incurred if it had elected not to file, prosecute or maintain the respective Acuitas LNP Technology Patent. BioNTech's license to such Acuitas LNP Technology Patent hereunder under Section 2.1 will be, irrevocable and royalty free, and such Acuitas LNP Technology Patent will thereafter no longer be part of the Acuitas LNP Technology in such country for purposes of this License Agreement. BioNTech is entitled to discontinue the payment of Patent Costs for any LNP Technology Patents at any time, provided that it will so notify Acuitas in writing in time for such discontinuance.

(b) By BioNTech. If BioNTech elects not (i) to file, prosecute or maintain any Jointly Owned Patents for which it is responsible under Section 6.1 in any particular country before the applicable filing deadline or continue such activities once filed in a particular country, or (ii) to pay the Patent Costs associated with prosecution or maintenance of any Jointly Owned Patents then in each such case BioNTech will so notify Acuitas, promptly in writing and in good time to enable BioNTech to meet any deadlines by which an action must be taken to preserve such Jointly Owned Patent in such country at Acuitas' expense, if Acuitas so requests. Upon receipt of each such notice by BioNTech, Acuitas will have the right, but not the obligation, to notify BioNTech in writing on a timely basis that BioNTech should transfer the prosecution or maintenance of such Jointly Owned Patent to Acuitas and at Acuitas' sole expense and such LNP Technology Patent will thereafter no longer be part of the Acuitas LNP Technology in such country for purposes of this License Agreement. Acuitas is entitled to discontinue the payment of Patent Costs for any Jointly Owned Patents at any time, provided that it will so notify BioNTech in writing in time for such discontinuance.

6.3 Regulatory Exclusivity Periods. With respect to any Patent listings required for any regulatory exclusivity periods for Licensed Products the Parties will discuss and seek to reach mutual agreement, subject to Applicable Law, on which Acuitas LNP Technology Patents to list. Except where required under Applicable Law, without the written consent of BioNTech, Acuitas will not apply for, and

is not authorized under this Agreement to apply for, any Patent listings required for any regulatory exclusivity periods for any Licensed Product. For the avoidance of doubt, Acuitas is not restricted from applying for any Patent listings required for any regulatory exclusivity periods for any product but the Licensed Products.

6.4 Cooperation. Each Party will reasonably cooperate with the other Party in those activities involving the Acuitas LNP Technology Patents set forth in Sections 6.1 to 6.3. Such cooperation includes promptly executing all documents, or requiring inventors, subcontractors, employees and consultants and agents of BioNTech and Acuitas and their respective Affiliates and Sublicensees to execute all documents, as reasonable and appropriate so as to enable such activities in respect of any such Acuitas LNP Technology Patents in any country.

7. Patent Enforcement and Defense.

7.1 Notice. To the extent not in breach of an obligation of confidentiality, each Party will promptly notify, in writing, the other Party upon learning of any actual or suspected infringement of any Acuitas LNP Technology Patents by a Third Party, or of any claim of invalidity, unenforceability, or non-infringement of any Acuitas LNP Technology Patents, and will, along with such notice, supply the other Party with any evidence in its possession pertaining thereto.

7.2 Enforcement and Defense.

(a) Enforcement. As between the Parties, Acuitas (or its Third Party licensor, or licensee if any) will have the first right, but not the obligation, to seek to abate any infringement of the Acuitas LNP Technology Patents by a Third Party, or to file suit against any such Third Party for such infringement provided that (i) Acuitas shall bear all the expense of such suit or abatement of infringement, and (ii) BioNTech shall have the first right but not the obligation to take action or bring suit against such Third party infringer with respect to: (A) Jointly Owned Patents; and/or (B) any other LNP Technology Patents that, on the date of first notice of such infringement, are necessary or useful for the research, development, manufacturing and commercialization of Licensed Product but not necessary or useful for the research, development, manufacturing and commercialization of any LNP-comprising product that is exclusively licensed or optioned to a Third Party or is under late stage development by Acuitas; provided that BioNTech shall bear all the expense of such suit or abatement of infringement. If the Party first responsible for such enforcement elects not to take action or to bring suit to prosecute such infringement or to continue such action or suit, it shall notify the other Party of such election within [***] days after become aware of or receipt of the notice of the infringement or after the election to stop any such action or suit. If after the expiration of the [***] days period (or, if earlier, the date upon which the responsible Party provides written notice that it does not plan to bring such action) the responsible Party has neither obtained a discontinuance of infringement nor filed suit against any such Third Party infringer of such Patent, then (i) in the case of an election by Acuitas (or its Third Party licensor, or licensee if any) not to prosecute an infringement of an LNP Technology Patent, BioNTech shall have the right, but not the obligation, to take action or bring suit against such Third Party infringer of such Patents, provided the infringement is with respect to a product related to the Target(s) being the subject of this License Agreement, and further provided that BioNTech shall bear all the expenses of such suit and (ii) in the case of a BioNTech election not to prosecute an infringement of a Jointly Owned Patents or LNP Technology Patent, Acuitas shall have the right, but not the obligation, to take action or bring suit against such Third Party infringer of such Patents, provided that Acuitas shall bear all the expenses of such suit.

(b) Defense. As between the Parties, Acuitas (or is Third Party licensor or licensee, if any) will have the first right, but not the obligation, at its sole costs, to defend against a declaratory judgment action or other action challenging any Acuitas LNP Technology Patents, other than: (i) Jointly Owned

Patents; and (ii) any other LNP Technology Patents that, on the date of first notice of such action, are not necessary or useful for the research, development, manufacturing and commercialization of any LNP-comprising product that is exclusively licensed or optioned to a Third Party or is under Late Stage Development by Acuitas, and as between the Parties, BioNTech will have the first right, but not the obligation, at its sole costs, to defend against a declaratory judgment action or other action challenging Jointly Owned Patents and/or such other LNP Technology Patents. If the Party first responsible for such defense does not take steps to defend within a commercially reasonably time, or elects not to continue any such defense (in which case it will promptly provide notice thereof to the other Party), then (i) in the case of an election by Acuitas (or its Third Party licensor, or licensee if any) not to defend an LNP Technology Patent, BioNTech shall have the right, but not the obligation, to take defend any LNP Technology Patents that cover Licensed Product and no other product licensed or optioned by Acuitas to a Third Party or commercialized by Acuitas provided that BioNTech shall bear all the expenses of such suit and (ii) in the case of a BioNTech election not to defend the Jointly Owned Patents, Acuitas shall have the right, but not the obligation, to take action or bring suit to defend such Patents, provided that Acuitas shall bear all the expenses of such suit.

(c) Notwithstanding the foregoing, any response to a Third Party infringer's counterclaim of invalidity or unenforceability of any Acuitas LNP Technology Patents shall be controlled by the Party who controls the relevant enforcement proceeding pursuant to Section 7.2 (a) unless otherwise mutually agreed by the Parties.

(d) Withdrawal, Cooperation and Participation. With respect to any infringement or defensive action identified above in this Section 7.2 which may be controlled by either BioNTech or Acuitas:

(i) If the controlling Party ceases to pursue or withdraws from such action, it will promptly notify the other Party (in good time to enable the other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and such other Party may substitute itself for the withdrawing Party, shall be granted the right and standing to sue in the other Party's name, and proceed under the terms and conditions of this Section 7.2.

(ii) The non-controlling Party will cooperate with the Party controlling any such action (as may be reasonably requested by the controlling Party), including (A) providing access to relevant documents and other evidence, (B) making its and its Affiliates and licensees and Sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (C) if necessary, by being joined as a party, subject for this clause (C) to the controlling Party agreeing to indemnify such non-controlling Party for its involvement as a named party in such action and paying those Patent Costs incurred by such Party in connection with such joinder. The Party controlling any such action will keep the other Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.

(iii) Each Party will have the right to participate or otherwise be involved in any such action controlled by the other Party, in each case at the participating (i.e., non-controlling) Party's sole cost and expense. If a Party elects to so participate or be involved, the controlling Party will provide the participating Party and its counsel with an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the controlling Party will

take into account reasonable requests of the participating Party regarding such enforcement or defense.

(e) Settlement. Neither Party will settle or consent to an adverse judgment in any action described in this Section 7.2 and controlled by such Party, including any judgment which affects the scope, validity or enforcement of any Acuitas LNP Technology Patents involved therewith, without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).

(f) Damages. Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action which may be controlled by either BioNTech or Acuitas and described in Section 7.2(a) or 7.2(b) in each case will be used first to reimburse the controlling Party, and thereafter the non-controlling Party, for each of their out-of-pocket costs and expenses relating to the action, with the balance of any such recovery to be divided as follows:

(i) To the extent such recovery reflects lost profits damages, BioNTech will retain such lost profits recovery, less the amount of royalties payable to Acuitas by treating such lost profits recovery as "Net Sales" hereunder; and

(ii) To the extent such recovery reflects reasonable royalty damages, [***] percent ([***]%) to the Party controlling the action and [***] percent ([***]%) to the other Party.

8. Confidentiality.

8.1 Confidential Information. Each Party ("Disclosing Party") may disclose to the other Party ("Receiving Party"), and Receiving Party may acquire during the course and conduct of activities under this License Agreement, certain proprietary or confidential information of Disclosing Party in connection with this License Agreement. The term "Confidential Information" means all information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, that are disclosed or made available by or on behalf of the Disclosing Party to the Receiving Party in connection with this License Agreement.

8.2 Restrictions. During the Term and for [***] years thereafter, Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information, but in no event less than reasonable care. Receiving Party will not use Disclosing Party's Confidential Information except for in connection with the performance of its obligations and exercise of its rights under this License Agreement. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent to Receiving Party's Affiliates, and each of their employees, subcontractors, consultants and agents who have a need to know such Confidential Information in order to perform their obligations and exercise their rights under this License Agreement and who are under written obligation to comply with the restrictions on use and disclosure that are no less restrictive than those set forth in this Section 8.2. Receiving Party assumes responsibility for such entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.

8.3 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to a specific portion of the Disclosing Party's Confidential Information to the extent that Receiving Party can demonstrate that such portion: (i) was known to Receiving Party or any of its Affiliates prior to the time of disclosure by the Disclosing Party without obligation of confidentiality; (ii) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (iii) is obtained on a non-confidential basis by

Receiving Party or any of its Affiliates from a Third Party who to Receiving Party's knowledge is lawfully in possession thereof and under no obligation of confidentiality to Disclosing Party; or (iv) has been independently developed by or on behalf of Receiving Party or any of its Affiliates without the aid, application or use of Disclosing Party's Confidential Information.

8.4 Permitted Disclosures. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(a) in order and to the extent required to comply with applicable Law (including any securities Law or regulation or the rules of a securities exchange) or with a legal, regulatory or administrative proceeding;

(b) in connection with prosecuting or defending litigation, and filing, prosecuting and enforcing LNP Technology Patents in connection with Receiving Party's rights and obligations pursuant to this License Agreement; and

(c) to acquirers or permitted assignees; investment bankers, investors and lenders, including potential acquirers, assignees, investment bankers, and lenders;

(d) in the case of BioNTech, to (i) subcontractors; or (ii) potential licensees or collaboration partners, but in case (ii) only such information that is reasonably necessary or useful for the potential licensee or partner to evaluate the applicable Licensed Product, and LNP/Licensed Product manufacturing processes, but excluding the particular chemical structure and formulation of any LNPs (which excluded information may be disclosed to such potential licensee or partner upon Acuitas' prior written consent);

provided that (1) where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant to subsections (a) and (b) sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to subsections (c) and (d), each of those entities are required to comply with the restrictions on use and disclosure in Section 8.2 (other than investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality).

8.5 Return of Confidential Information. Upon expiry or earlier termination of this License Agreement, upon written request of a Party (such request, if made, to be made within [***] months of such expiry or termination) the other Party will destroy or return (as shall be specified in such request) to the requesting Party all copies of the Confidential Information of the requesting Party; provided that the Party may retain: (i) one copy of such Confidential Information for record-keeping purposes, for the sole purpose of ensuring compliance with this Agreement; (ii) any copies of such Confidential Information as is required to be retained under applicable Law; (iii) any copies of such Confidential Information as is necessary or useful for such Party to exercise a right or fulfill an obligation under another License Agreement, if any, or as set forth in this License Agreement; and (iv) any copies of any computer records and files containing Confidential Information that have been created by such Party's routine archiving/backup procedures.

8.6 Publications. Notwithstanding anything in this License Agreement to the contrary, BioNTech is permitted to publish the results of its development under this License Agreement, provided, however, that it will not disclose Acuitas Confidential Information in any publication by BioNTech of the

results of any Licensed Product development by BioNTech without Acuitas' prior written consent, which will not be unreasonably withheld, conditioned or delayed.

8.7 Terms of this License Agreement; Publicity. The Parties agree that the existence and terms of the Parties' relationship and this License Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 8.4. Except as required by Law, each Party agrees not to issue any press release or public statement disclosing information relating to the existence of this License Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party.

9. Warranties; Limitations of Liability; Indemnification.

9.1 Representations and Warranties. Each Party represents and warrants to the other as of the License Agreement Effective Date that:

(a) it is a corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated,

(b) it has the legal right and power to enter into this License Agreement, to extend the rights and licenses granted or to be granted to the other in this License Agreement, and to fully perform its obligations hereunder,

(c) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this License Agreement and the performance of its obligations hereunder and

(d) this License Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

9.2 Additional Representations of Acuitas. Except as set forth on Appendix 9.2, Acuitas hereby represents and warrants to BioNTech as of the License Agreement Effective Date as follows:

(a) Impairment. Neither Acuitas nor any of its Affiliates has entered into any agreement or otherwise licensed, granted, assigned, transferred, conveyed or otherwise encumbered or disposed of any right, title or interest in or to any of its assets, including any intellectual property rights including Know-How, that would in any way conflict with or impair the scope of any rights or licenses granted to BioNTech hereunder, including under any of the agreements which Acuitas has identified to BioNTech prior to the License Agreement Effective Date.

(b) Patents. Appendix 1.1 sets forth a complete and accurate list of all LNP Technology Patents. Acuitas Controls, and will Control during the Term, the LNP Technology Patents listed on Appendix 1.1 and the Know-How within the Acuitas LNP Technology, and is entitled to grant the licenses specified herein. To Acuitas' knowledge, the LNP Technology Patents have been procured or are being procured from the respective patent offices in accordance with applicable Law. None of the LNP Technology Patents is or has been involved in any opposition, cancellation, interference, reissue or reexamination proceeding, and to Acuitas' knowledge as of the License Agreement Effective Date, no Acuitas LNP Technology is the subject of any judicial, administrative or arbitral order, award, decree, injunction, lawsuit, proceeding or stipulation. Neither Acuitas nor any of its Affiliates has received any notice alleging that the LNP Technology Patents are invalid or unenforceable, or challenging Acuitas' ownership of or right to use any such rights before the Effective Date.

(c) Entire LNP Technology. The Acuitas LNP Technology licensed to BioNTech under this License Agreement comprises all Technology Controlled by Acuitas which is required to develop, manufacture and commercialize the Licensed Products.

(d) Encumbrances. Acuitas and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this License Agreement. Until the License Agreement Effective Date, neither Acuitas nor any of its Affiliates has granted any license or security interests on the Acuitas LNP Technology, and the Acuitas LNP Technology as licensed hereby is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien or charge of any kind.

(e) Defaults. The execution, delivery and performance by Acuitas of this License Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any understanding, contract or agreement to which Acuitas is a party or by which it is bound, including each of the agreements which Acuitas has identified to BioNTech prior to the License Agreement Effective Date, in each case as would reasonably be expected to have a material adverse effect on the rights granted to BioNTech hereunder.

(f) Litigation. There is no action, suit, proceeding or investigation pending or, to the knowledge of Acuitas, currently threatened in writing against or affecting Acuitas that questions the validity of this License Agreement or the right of Acuitas to enter into this License Agreement or consummate the transactions contemplated hereby or that relates to the Acuitas LNP Technology.

(g) Infringement. Neither Acuitas nor any of its Affiliates has received any notice of any claim, nor does Acuitas or its Affiliates have any knowledge of any basis for any claim, that any Patent, Know-How or other intellectual property owned or controlled by a Third Party would be infringed or misappropriated by the practice of any Acuitas LNP Technology in connection with the production, use, research, development, manufacture or commercialization of any Licensed Product.

(h) Third Party Infringement. To Acuitas' knowledge, no Third Party is infringing or has infringed any Patent within the Acuitas LNP Technology or is misappropriating or has misappropriated any Know-how within the Acuitas LNP Technology.

9.3 Disclaimers. Without limiting the respective rights and obligations of the Parties expressly set forth herein, each Party specifically disclaims any guarantee that any Licensed Product will be successful, in whole or in part. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS LICENSE AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTY OF ANY KIND UNDER THIS LICENSE AGREEMENT, EITHER EXPRESS OR IMPLIED.

9.4 No Consequential Damages. NOTWITHSTANDING ANYTHING IN THIS LICENSE AGREEMENT OR OTHERWISE, NEITHER PARTY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS LICENSE AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES; PROVIDED THAT THIS SECTION 9.4 WILL NOT APPLY TO BREACHES OF A PARTY'S OBLIGATIONS OR UNDER ARTICLE NINE OR THE PARTIES' INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTION 9.6.

9.5 Performance by Others. The Parties recognize that each Party may perform some or all of its obligations under this License Agreement through Affiliates and permitted subcontractors provided, however, that each Party will remain responsible and liable for the performance by its Affiliates and

permitted subcontractors and will cause its Affiliates and permitted subcontractors to comply with the provisions of this License Agreement in connection therewith.

9.6 Indemnification.

(a) Indemnification by BioNTech. BioNTech will indemnify Acuitas, its Affiliates and their respective directors, officers, employees, Third Party licensors and agents, and their respective successors, heirs and assigns (collectively, "Acuitas Indemnitees"), and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "Third Party Claims") against the Acuitas Indemnitees to the extent arising from or occurring as a result of: (i) the breach by BioNTech of any provision of this License Agreement; (ii) any negligence or willful misconduct on the part of any BioNTech Indemnitee; or (iii) the development or commercialization by or on behalf of BioNTech or any of its Affiliates or Sublicensees of Licensed Product other than if related to an LNP component thereof, except in each case (i)-(iii) to the extent arising from or occurring as a result of the negligence or willful misconduct on the part of an Acuitas Indemnitee or Acuitas' breach of this License Agreement.

(b) Indemnification by Acuitas. Acuitas will indemnify BioNTech, its Affiliates and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, "BioNTech Indemnitees"), and defend and hold each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims against BioNTech Indemnitees to the extent arising from or occurring as a result of: (i) the breach by Acuitas of any provision of this License Agreement; or (ii) any negligence or willful misconduct on the part of any Acuitas Indemnitee, or (iii) **[***].**

(c) Notice of Claim. All indemnification claims provided for in Sections 9.6(a) and 9.6(b) will be made solely by such Party to this License Agreement (the "Indemnified Party"). The Indemnified Party will promptly notify the indemnifying Party (an "Indemnification Claim Notice") of any Losses or the discovery of any fact upon which the Indemnified Party intends to base a request for indemnification under Section 9.6(a) and 9.6(b), but in no event will the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and estimated amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party will furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

(d) Defense, Settlement, Cooperation and Expenses.

(i) Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party will not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor will it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the

Third Party Claim any legal counsel selected by the indemnifying Party (the indemnifying Party will consult with the Indemnified Party with respect to such counsel and a possible conflict of interest of such counsel retained by the indemnifying Party). In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party will reimburse the indemnifying Party for any and all costs and expenses (including reasonable attorneys' fees and costs of suit) and any Third Party Claims incurred by the indemnifying Party in its defense of the Third Party Claim.

(ii) Right to Participate in Defense. Without limiting Section 9.6(d)(i), any Indemnified Party will be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnified Party's own cost and expense unless (i) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.6(d)(i) (in which case the Indemnified Party will control the defense) or (ii) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under applicable Law, ethical rules or equitable principles, in which case the indemnifying Party will assume one hundred percent (100%) of any such costs and expenses of counsel for the Indemnified Party.

(iii) Settlement. With respect to any Third Party Claims that relate solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party will have the sole right to agree to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, will deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.6(d)(i), the indemnifying Party will have authority to agree to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, delayed or conditioned). The indemnifying Party will not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party will admit any liability with respect to or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, delayed or conditioned.

(iv) Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will, and will cause each other indemnified party to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith, at the indemnifying Party's expense. Such cooperation will include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified parties and other employees and agents available on a mutually convenient basis to provide

additional information and explanation of any material provided hereunder, and the indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket costs and expenses in connection therewith.

(v) Costs and Expenses. Except as provided above in this Section 9.6(d), the costs and expenses, including attorneys' fees and expenses, incurred by the Indemnified Party in connection with any claim will be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

9.7 Insurance. Each Party will maintain at its sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of activities to be performed under this License Agreement, and any agreement related hereto and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the respective industry of such Party for the activities to be conducted by such Party under this License Agreement. Subject to the preceding sentence, such liability insurance or self-insurance program will insure against all types of liability, including personal injury, physical injury or property damage arising out of the manufacture, sale, use, distribution or marketing of Licensed Product. The coverage limits set forth herein will not create any limitation on a Party's liability to the other under this License Agreement.

10. Term and Termination.

10.1 Term. This License Agreement will commence as of the License Agreement Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, will continue on a Licensed Product-by-Licensed Product and a country-by-country basis, until there are no more payments owed to Acuitas in such country (the longest such period of time hereunder, the "Term"). Upon there being no more such payments hereunder in such country, the license contained in Section 2.1 will become fully paid up and will remain in effect with respect to such Licensed Product in such country.

10.2 Termination by Acuitas.

(a) Breach. Acuitas will have the right to terminate this License Agreement in full upon delivery of written notice to BioNTech in the event of any material breach by BioNTech of any terms and conditions of this License Agreement, provided that such breach has not been cured within [***] days after written notice thereof is given by Acuitas to BioNTech specifying the nature of the alleged breach.

(b) Disputed Breach. If BioNTech disputes in good faith the existence or materiality of a breach specified in a notice provided in accordance with Section 10.2(a), and BioNTech provides Acuitas notice of such dispute within such [***] -day period, then Acuitas shall not have the right to terminate this License Agreement under Section 10.2(a) unless and until it is finally determined, in accordance with Section 11.1, that BioNTech has materially breached this License Agreement and that BioNTech fails to cure such breach within [***] days following such decision. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this License Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. During the pendency of any such dispute, BioNTech shall pay to Acuitas all Acuitas Milestone payments and royalty payments set forth herein.

10.3 Termination by BioNTech.

(a) Breach. BioNTech will have the right to terminate this License Agreement in full upon delivery of written notice to Acuitas in the event of any material breach by Acuitas of any terms and conditions of this License Agreement, provided that such breach has not been cured within [***] days after written notice thereof is given by BioNTech to Acuitas specifying the nature of the alleged breach.

(b) Discretionary Termination. BioNTech will have the right (i) to terminate this License Agreement in full at its discretion for any reason by delivering written notice to Acuitas, such termination to be effective [***] days following the date of such notice.

(c) Alternative to Termination Under Section 10.3(a). If BioNTech has the right to terminate this License Agreement under Section 10.3(a) as a result of a material breach by Acuitas (including following expiration of all applicable cure periods thereunder) that fundamentally impairs the value of BioNTech's rights hereunder with respect to the Licensed Target, then BioNTech may, in lieu of exercising such termination right, elect by written notice to Acuitas before the end of such applicable cure period to have this License Agreement continue in full force and effect for the Term, provided that the following will apply: **[***].**

10.4 Termination Upon Bankruptcy. All rights and licenses granted under or pursuant to this License Agreement by Acuitas are, and will otherwise be deemed to be, for purposes of Section 65.11(7) of the Bankruptcy and Insolvency Act, R.S.C. 1985, c. B-3 and Section 32(6) of the Companies' Creditors Arrangement Act, R.S.C. 1985, c. C-36 (the "Insolvency Legislation"), a grant of "right to use intellectual property" as used in the Insolvency Legislation. The Parties agree that BioNTech and its Affiliates and Sublicensees, as licensees of such rights under this License Agreement, will retain and may fully exercise all of their rights and elections under the Insolvency Legislation subject to the payment of amounts provided for herein. Without limiting BioNTech's rights under the Insolvency Legislation, if Acuitas becomes insolvent or makes an assignment for the benefit of its creditors or there is filed by or against the Acuitas any bankruptcy, receivership, reorganization or similar proceeding (an "Insolvency Event") pursuant to or under the Insolvency Legislation or otherwise, BioNTech shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of Acuitas, shall be promptly delivered to it (i) before this License Agreement is rejected by or on behalf of Acuitas, within [***] days after BioNTech's written request, unless Acuitas, or its trustee or receiver, elects within [***] days to continue to perform all of its obligations under this License Agreement, or (ii) after any rejection of this License Agreement by or on behalf of Acuitas, if not previously delivered as provided under clause (i) above. All rights of the Parties under this Section 10.4(b) and under Section 65.11(7) of the Bankruptcy and Insolvency Act, R.S.C. 1985, c. B-3 and Section 32(6) of the Companies' Creditors Arrangement Act are in addition to and not in substitution of any and all other rights, powers, and remedies that each party may have under this License Agreement, the Insolvency Legislation, and any other

applicable Laws. BioNTech shall have the right to perform the obligations of Acuitas hereunder with respect to such intellectual property, but neither such provision nor such performance by BioNTech shall release Acuitas from any such obligation or liability for failing to perform it.

10.5 Effects of Termination. Upon termination (but not expiration pursuant to Section 10.1) of this License Agreement for any reason:

(a) Cessation of Rights. Except as otherwise expressly provided herein, including in Sections 8.5, 10.3(c) and 10.5(b), all rights and licenses granted by Acuitas to BioNTech in Section 2.1 will terminate.

(b) Sell Off. Notwithstanding the termination of BioNTech's licenses and other rights under this License Agreement, BioNTech shall retain the right to distribute, sell or otherwise dispose of its existing inventory of the Licensed Products, in each case that is intended for distribution, sale or disposition in the Territory, for a period of not more than [***] months following the date of the effective termination, as though this License Agreement had not been terminated, and such distribution, sale or other disposition shall not constitute infringement of the Patents or other intellectual property or proprietary rights of Acuitas or its Affiliates. BioNTech's right to distribute, sell or otherwise dispose of its existing inventory of the Licensed Products pursuant to this Section 10.5 (b) shall be subject to BioNTech's continuing obligation to pay royalties with respect to the Net Sales.

10.6 Survival. In addition to the termination consequences set forth in Section 10.5, the following provisions will survive termination or expiration of this License Agreement: Articles 1 and 8 and Sections 4.4, 5.1, 9.3, 9.4, 9.6, 9.7, 10.4, 10.5, 10.6, 11.1, 11.2, 11.5, 11.7, 11.8, 11.9, 11.10, 11.11 and 11.12. Termination or expiration of this License Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this License Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon expiration of this License Agreement.

11. General Provisions.

11.1 Dispute Resolution.

(a) Disputes. Disputes arising under or in connection with this License Agreement will be resolved pursuant to this Section 11.1; provided, however, that in the event a dispute cannot be resolved without an adjudication of the rights or obligations of a Third Party (other than any BioNTech Indemnitees or Acuitas Indemnitees identified in Section 9.6), the dispute procedures set forth Sections 11.1(c) and 11.1(c) will be inapplicable as to such dispute.

(b) Dispute Escalation. In the event of a dispute between the Parties, the Parties will first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within [***] days, any Party may, by written notice to the other, have such dispute referred to each Party's [***], who will attempt in good faith to resolve such dispute by negotiation and consultation for a [***] day period following receipt of such written notice

(c) Dispute Resolution. In the event the [***] of the Parties are not able to resolve such dispute as set forth above, the Parties agree to try to solve such dispute amicably by mediation. The Parties shall conduct a mediation procedure according to the Mediation Rules of the World Intellectual Property Organization (WIPO) in effect on the date of the commencement of the mediation

proceedings. The location of the mediation proceedings will be London, England. The number of mediators will be [***]. The language of the mediation proceedings will be English. If the dispute has not been settled pursuant to the said rules within [***] days following the filing of a request for mediation or within such other period as the Parties may agree in writing, either Party may submit the dispute to final and binding arbitration. Any dispute relating to the validity performance, construction or interpretation of this Agreement, which cannot be resolved amicably between the Parties after following the procedure set forth in this Section 11.1, shall be submitted to arbitration in accordance with the Arbitration Rules of WIPO in effect on the date of the commencement of the arbitration proceedings. The location of the arbitration proceedings will be London, England. The number of arbitrators will be [***]. The language of the arbitration proceeding will be English. The decision of the arbitrators shall be final and binding upon the Parties (absent manifest error on the part of the arbitrator(s)) and enforceable in any court of competent jurisdiction.

(d) Injunctive Relief. Notwithstanding the dispute resolution procedures set forth in this Section 11.1, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to any dispute resolution procedures hereunder.

(e) Tolling. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) will be tolled while the dispute resolution procedures set forth in this Section 11.1 are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result.

(f) Prevailing Party. The prevailing Party in any arbitration under Section 11.1(c) or any other suit related to this License Agreement will be entitled to recover from the losing Party all out-of-pocket fees, costs and expenses (including those of attorneys, professionals and accountants and all those arising from appeals and investigations) incurred by the prevailing Party in connection with such arbitration or suit.

11.2 Cumulative Remedies and Irreparable Harm. All rights and remedies of the Parties hereunder will be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at Law or otherwise. Each Party acknowledges and agrees that breach of any of the terms or conditions of this License Agreement may cause irreparable harm and damage to the other and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party may be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages or posting bond. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of Law or equity, including money damages.

11.3 Relationship of Parties. Nothing in this License Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided therein. There are no express or implied third party beneficiaries hereunder (except for BioNTech Indemnitees and Acuitas Indemnitees for purposes of Section 9.6). For clarity, BioNTech does not grant to Acuitas any rights or licenses under this License Agreement to any BioNTech technology or intellectual property rights.

11.4 Compliance with Law. Each Party will perform or cause to be performed any and all of its obligations or the exercise of any and all of its rights hereunder in good scientific manner and in compliance with all applicable Law.

11.5 Governing Law. This License Agreement will be governed by and construed in accordance with the Laws of England and Wales, without respect to its conflict of Laws rules, provided that any dispute relating to the scope, validity, enforceability or infringement of any Patents or Know-How will be governed by, and construed and enforced in accordance with, the substantive Laws of the jurisdiction in which such Patents or Know-How apply.

11.6 Counterparts; Facsimiles. This License Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Facsimile or PDF execution and delivery of this License Agreement by either Party will constitute a legal, valid and binding execution and delivery of this License Agreement by such Party.

11.7 Headings. All headings in this License Agreement are for convenience only and will not affect the meaning of any provision hereof.

11.8 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this License Agreement. Accordingly, the rule of construction that any ambiguity in this License Agreement will be construed against the drafting party will not apply.

11.9 Interpretation. Whenever any provision of this License Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" (or "includes without limitations"). "Herein," "hereby," "hereunder," "hereof" and other equivalent words refer to this License Agreement as an entirety and not solely to the particular portion of this License Agreement in which any such word is used. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Unless otherwise provided, all references to Sections and Appendices in this License Agreement are to Sections and Appendices of this License Agreement. References to any Sections include Sections and subsections that are part of the related Section.

11.10 Binding Effect. This License Agreement will inure to the benefit of and be binding upon the Parties, their Affiliates, and their respective lawful successors and assigns.

11.11 Assignment. This License Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer licenses or other rights created by this License Agreement, except as expressly permitted hereunder or otherwise without the prior written consent of the other Party, which consent will not be unreasonably withheld; provided that either Party may assign this License Agreement without such consent to an Affiliate or to its successor in connection with sale of all or substantially all of its assets or business or that portion of its business pertaining to the subject matter of this License Agreement (whether by merger, consolidation or otherwise).

11.12 Notices. All notices, requests, demands and other communications required or permitted to be given pursuant to this License Agreement will be in writing and will be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, or registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to BioNTech:
BioNTech SE
An der Goldgrube 12
D-5513 Mainz
Germany
Attention: [***]

If to Acuitas:
Acuitas Therapeutics Inc.
6190 Agronomy Road, Suite 405
Vancouver, B.C.
Canada V6T 1Z3

Attention: [***]

With a copy to: McCarthy Tetrault LLP
Suite 2400 745 Thurlow Street
Vancouver, B.C.
Canada V6E 0C5
Attention: [***]

Either Party may change its designated address by notice to the other Party in the manner provided in this Section 11.12.

11.13 Amendment and Waiver. This License Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties; provided that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. Any waiver of any rights or failure to act in a specific instance will relate only to such instance and will not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

11.14 Severability. In the event that any provision of this License Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and the Parties will negotiate in good faith to modify the License Agreement to preserve (to the extent possible) their original intent.

11.15 Entire Agreement. This License Agreement together with the Development and Option Agreement and any other license agreements entered into during the Term pursuant to the Development and Option Agreement are the sole agreement with respect to the subject matter hereof and supersedes all other agreements and understandings between the Parties with respect to same.

11.16 Force Majeure. Neither Acuitas nor BioNTech will be liable for failure of or delay in performing obligations set forth in this License Agreement (other than any obligation to pay monies when due), and neither will be deemed in breach of such obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of Acuitas or BioNTech; provided that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.

[Remainder of this Page Intentionally Left Blank]

WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers as of the License Agreement Effective Date.

ACUITAS THERAPEUTICS INC.

By: _____
(Signature)

Name: Thomas Madden

Title: President & CEO

Date: April 7, 2020

BIONTECH RNA PHARMACEUTICALS GMBH

By: _____
(Signature)

Name: _____

Title: _____

Date: _____

Appendix 1.1

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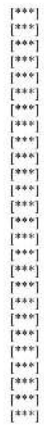

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Appendix 1.17

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Appendix 1.23

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Appendix 1.53

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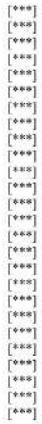

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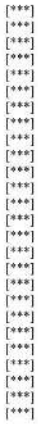

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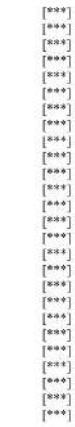

Appendix 2.4

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Appendix 9.2

Exceptions to Acuitas' Representations and Warranties in Section 9.2

Exhibit 4.54

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

PURCHASE AGREEMENT ("PA")[1] for the further development, production, purchasing options and supply of COVID-19 Vaccines for EU Member States

NUMBER — SANTE/2021/03/020

1. **The European Commission**, acting on behalf and in the name of the Member States set out in Annex III (hereinafter referred to as "Participating Member States"),[2]:

being represented for the purposes of the signature of this PA by Ms Stella Kyriakides, Commissioner of Health and Food Safety

on the one part and

2. **Pfizer Inc.**

Incorporated in Delaware (Registration Number 0383418) with its registered address at 235 East 42nd Street

10017 New York City, NY (UNITED STATES)

appointed as the leader of the group by the members of the group that submitted the joint tender

(hereinafter referred to as **"Pfizer"**)

and

BioNTech Manufacturing GmbH

Registered with the commercial register of the lower court (Amtsgericht) of Mainz, Germany under HRB 47548, with its registered address at An der Goldgrube 12

55131 MAINZ, GERMANY
(hereinafter referred to as **"BioNTech"**)

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1 This PA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020) 4192 final on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

2 As provided for in Article 4(5)(b) of Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID - 19 outbreak.

as a member of the group (collectively '**the Contractor**'), represented for the purposes of the signature of this PA which has the form of a framework contract by [***]

on the other part,

HAVE AGREED

to the **special conditions and the general conditions of this PA** and the following Annexes and Attachments:

Annex I – Model for Vaccine Order Form

Annex II – Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, annexed to the Commission Decision C(2020) 4192 final of 18 June 2020

Annex III – Participating Member States

Annex IV – Subcontractors

Annex V – Participating Contractor Affiliates

Attachment 1 – Specifications

Attachment 2 – Delivery Documentation

Attachment 3 – Delivery Specification

Attachment 4 – Labelling and Packaging Specifications

Attachment 5 – Return and Disposal of Product Materials

which form an integral part of this PA.

[***]
[***]
[***]
[***]

For any other proposed amendments, the parties will discuss the impact thereof in good faith and any such shall require the written prior approval of the Commission and the Participating Member States, not to be unreasonably withheld or delayed.

This PA sets out:

1. the procedure and conditions by which the Participating Member States will pay for the services and/or supplies from the Contractor;

2. the provisions that apply to any Vaccine Order Form which the Participating Member States and the Contractor may conclude under this PA; and

3. the obligations of the parties during and after the duration of this PA.

All documents issued by the Contractor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this PA. In all circumstances, in the event of contradiction between this PA and documents issued by the Contractor, this PA prevails, regardless of any provision to the contrary in the Contractor's documents.

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I. SPECIAL CONDITIONS

I.1 ORDER OF PRIORITY OF PROVISIONS

If there is any conflict between different provisions in this PA, the following rules must be applied:

(a) The provisions set out in the special conditions and Article II.6 of the general conditions (Liability) take precedence over those in the other parts of the PA.

(b) The other provisions set out in the general conditions take precedence over those in the Annexes and Attachments.

(c) The provisions set out in the PA take precedence over those in the Vaccine Order Forms.

I.2 DEFINITIONS

The following definitions shall apply to this PA:

'Additional Order': has the meaning set forth in Article I.6.2;

'Additional Product': has the meaning set forth in Article I.6.2;

'Affiliate': means in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;

'Authorisation': means a Conditional Marketing Authorisation and/or Marketing Authorisation that permits the Products to be placed on the market in the European Economic Area;

"Commission Experts" means up to three (3) clinical expert individuals employed by, or advising, the Commission in connection with the COVID-19 pandemic, such individuals to be identified by the Commission and communicated to Contractor promptly following the Effective Date (it being understood that if Contractor expresses a reasonable objection to the identity of one or more Commission Experts, the Commission will suggest (an) alternative expert(s));

'Conditional Marketing Authorisation': means a conditional marketing authorisation granted by the European Commission, as amended or varied from time to time, as referred to in Article 14-a of Regulation (EC) No 726/2004;

'Confidential Information': means any information disclosed to or obtained by one party to the other party, either directly or indirectly, or which the disclosing party indicates in writing at the time of disclosure to, or receipt by, the recipient is to be considered confidential or proprietary, or which such recipient knows or ought reasonably to know is information of a

confidential or proprietary nature, including the terms of this PA and any Vaccine Order Form. Confidential Information shall not include any information (i) the receiving party can prove was known to it prior to the date of disclosure; (ii) the receiving party can prove was lawfully obtained from a third party without any obligation of confidentiality; (iii) is or becomes part of the public domain other than through any act or omission of the receiving party; or (iv) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as evidenced by the receiving party's records;

'Conflict of interest': a situation where the impartial and objective Implementation of the PA by the Contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the PA;

'Contracted Doses': has the meaning set forth in Article I.6.2;

'Control': means the possession by a person or an entity, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person or entity (whether through the ownership of voting shares, by contract or otherwise) and **"Controls"** and **"Controlled"** shall be interpreted accordingly;

"COVAX Facility" means the COVID-19 Vaccines Global Access procurement initiative led by Gavi, UNICEF, the Vaccine Alliance, the World Health Organization (WHO) and the Coalition for Epidemic Preparedness Innovations (CEPI), for the procurement and delivery of doses of approved vaccine for COVID-19;

'Delivery Price': has the meaning set forth in Article I.8.2;

'Delivery Schedule': has the meaning set forth in Article I.6.3, as such may be modified by agreement of the parties pursuant to the provisions in Articles I.6.2 and I.6.3;

'Effective Date': has the meaning set forth in Article I.4.1;

'Force majeure': any unforeseeable, exceptional situation or event beyond the reasonable control of the parties that prevents either of them from fulfilling any of their obligations under the PA,[***].

'Formal notification' (or 'formally notify'): form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

'Fraud': an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii)

the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests, it being understood that the Union's financial interests are impacted within the framework of this PA as the Union is engaging resources into the coordination and preparation of the PA, resulting from Decision C(2020) 4192 final of 18 June 2020 which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States ("the Decision"), this agreement being based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union[3] ("the ESI Regulation") ;

'Good Manufacturing Practice': means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2017/1572, Directive 2003/94/EC and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU entitled "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use";

'Implementation of the PA': the purchase of services or supplies envisaged in the PA through the signature and performance of Vaccine Order Forms;

'Indemnified Persons': has the meaning set forth in Article 0;

'Irregularity': any infringement of a provision of Union law resulting from an act or omission by the Contractor within the meaning of Article 1(2) of the Council (EC, Euratom) Regulation 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (in OJ 23.12.95, L 312/1) , which has, or would have, the effect of prejudicing the Union's budget, it being understood that the Union's financial interests are impacted within the framework of this PA, as the Union is engaging resources into the coordination and preparation of the PA, resulting from the Decision which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States, this agreement being based on Article 4(5)(b) of the ESI Regulation;

[***]

"Key Supply/ies": means those critical components, services and other critical input items required for the development, production and supply of the Vaccine pursuant to this PA, for which a delay in their supply is capable of materially adversely affecting the timely performance of the Contractor's delivery obligations under this PA.

[***]
[***]

'Latent Defect': means a defect causing the Product to not conform to the applicable Specifications which could not have been detected by the Participating Member State, its designee, or their personnel at delivery through visual inspection;

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3 OJ L 70, 16.3.2016, p.1, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID - 19 outbreak, OJ L 117, 15.4.2020, p. 3.

'Law(s)': means, collectively, all applicable supranational, national and local laws, common laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any government, administrative or judicial authority having the effect of law;

'Losses': has the meaning set forth in Article 0;

'Marketing Authorisation': means the marketing authorisation (other than Conditional Marketing Authorisation), in respect of the Product granted by the European Commission, as amended or varied from time to time, that allows the Product to be placed on the market in the European Economic Area according to applicable Law;

"New Countries": has the meaning set forth in Article I.6.3;

'Non-Complying Product': has the meaning set forth in Article I.6.14;

"Non-EU Key Supply/ies": means **Key Supply/ies** for which, at the time of production of the Vaccine pursuant to this PA, no supplier exists in the European Union that could provide the component, service and other input item from the territory of the EU. [***]

'Notification' (or 'notify'): form of communication between the parties made in writing including by electronic means;

'Participating Contractor Affiliate': means an Affiliate of Pfizer or BioNTech as identified in Annex V;

"**PMS Experts**" means, in relation to each Participating Member State, one (1) clinical expert employed by, or advising, such Participating Member State in connection with the COVID-19 pandemic, the identity of such individual to be communicated by the Commission to Contractor promptly following the Effective Date (it being understood that if Contractor expresses a reasonable objection to the identity of a PMS Expert, the relevant Participating Member State will suggest an alternative expert);

[***]**'Product'**: means the Vaccine;

'Product Materials': means all packaging materials and components needed for delivery of the Product;

'Professional conflicting interest': a situation in which the Contractor's previous or ongoing professional activities affect its capacity to implement the PA or to perform a Vaccine Order Form to an appropriate quality standard;

'Record': means books, documents, and other data, of all matters relating to performance of obligations under this PA;

'Related person': any natural or legal person who is a member of the administrative, management or supervisory body of the Contractor, or who has powers of representation, decision or control with regard to the Contractor;

[***][***]**'Specifications'**: means the specifications for the manufacture, testing and testing procedures, and supply of the Product as set out in Attachment 1 (Specifications), and as such specifications may be amended, supplemented or otherwise modified by the Contractor and communicated to the Commission;

'Taxes': has the meaning set forth in Article II.17.1;

'Term': means the term of the PA set out in Article I.4.2 of the PA;

'Thermal Shipper': has the meaning set forth in Article I.6.8;

'Third Party Claim': has the meaning set forth in Article 0.

'Vaccine': the medicinal product, being BNT162b2, a nucleoside-modified messenger RNA (mRNA) vaccine that encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S) for which Authorisation has been granted, [***].

'Vaccine IP Rights': has the meaning set forth in Article I.11;

'Vaccine Order Form": has the meaning set forth in Article I.5.2; and

[***]Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this PA in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Annexes or Attachments shall be construed to refer to Articles, Annexes or Attachments of this PA, and references to this PA include all Annexes and Attachments hereto, (h) the word "notice" means notice in writing or by email (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this PA, (i) provisions that require that a party or parties "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (including e-mail), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof.

I.3 SUBJECT MATTER

The subject of the call for tenders SANTE/2021/03/020 is securing the purchase of certain vaccine doses for the Participating Member States.

Following the Decision, taken in accordance with Article 4(5)(b) of the ESI Regulation, the Commission is running procurement procedures on behalf of Participating Member States, with a view to signing EU-level Advance Purchase Agreements and Purchase Agreements with vaccine manufacturers.

An APA between the Parties was signed on 20 November 2020 ("**APA**"). Subsequently, a PA between the Parties was signed on 17 February 2021 ("**PA.1**").

In compliance with Article 164(I)(d) as well as Annex I, Points 11.1(b)(ii) and 11.1(c) of the Financial Regulation, the Commission launched on 9 April 2021 a negotiated procedure without prior publication of a contract notice for the procurement of additional doses of vaccines. This procedure was justified by the need to urgently secure an exceptionally high amount of additional doses of vaccines to address the pandemic within a reasonable period of time, as well as by the absence of competition for technical reasons. This PA is for such additional doses, and while it is organised following the Decision, it is entirely separate from the APA and from the PA.1 between the Parties.

In view of its importance, this PA will be approved for signature on behalf and in the name of the Participating Member States by a separate individual Commission decision.

The Conditional Marketing Authorisation for the Vaccine was granted on 21 December 2020.

The Commission, on behalf of the Participating Member States, wishes to purchase the Vaccine through this PA to ensure the availability in the European Union of sufficient vaccine doses to address the pandemic [***].

On the basis of this PA, the European Commission commissions the Contractor to commit to produce and deliver 900 million doses of the Vaccine which shall be ordered by the Participating Member States (via specific Vaccine Order Forms) at the price and conditions, including timeframe, agreed under this PA, with the option to obtain a further 900 million doses of the Vaccine subject to the conditions set out in this PA.

The Contractor or a Participating Contractor Affiliate shall supply to the Participating Member States the agreed doses of the Vaccine pursuant to the Vaccine Order Forms.

The Vaccine Order Forms shall be signed by the Contractor and shall incorporate by reference this PA.

I.4 ENTRY INTO FORCE AND DURATION OF THE PA

I.4.1 The PA enters into force on the date on which the last party signs it (**"Effective Date"**).

I.4.2 The PA is concluded for a period of thirty six (36) months with effect from the Effective Date (**"Term"**).

I.4.3 Contractor and the Participating Member States may not sign any Vaccine Order Form after the PA expires.

I.4.4 The PA continues to apply to such Vaccine Order Forms after its expiry. [***].

I.4.5 Renewal of the PA

The PA will expire automatically at the end of the Term, unless it is extended in mutual written agreement between the parties. For the avoidance of doubt, if the exercise of the Additional Order involves delivery of doses beyond the Term, the parties shall agree to a renewal until the end of the last month for which deliveries of the Additional Order are foreseen in the relevant delivery schedule. This renewal process will be repeated until all doses have been delivered. Renewal does not change or postpone any existing obligations.

I.5 IMPLEMENTATION OF THE PA

I.5.1 Period of provision of the supplies

The period for the provision of the supplies starts to run as foreseen in Article I.6.3.

I.5.2 Implementation of the PA

The PA shall be implemented following signature between the Commission and the Contractor as follows:

The Contractor agrees to supply an initial total number of 900 million Vaccine doses to Participating Member States collectively, upon their order, in accordance with this PA and the respective Vaccine Order Forms.

The Participating Member States shall place orders for supplies of 900 million Vaccine doses in total in accordance with the allocation communicated by the Commission to the Contractor pursuant to Article I.6.3, by sending the Contractor a completed copy of Annex I ("**Vaccine Order Form**") in paper format or emailed pdf [***]. This Vaccine Order Form shall be signed by an authorised representative of the Participating Member State and the Contractor.

[***] the Contractor must send back to the Participating Member States the duly signed and dated Vaccine Order Form in paper format or emailed pdf.

I.6 SUPPLY OF THE VACCINE

I.6.1 General

During the term of this PA, the Contractor shall supply or have supplied the Product to the relevant Participating Member States, and the Participating Member States shall purchase the Product, subject to and in accordance with the terms and conditions of this PA.

I.6.2 Product supply

At the Effective Date, the Commission orders 900 million doses (**"Contracted Doses"**) of the Product on behalf of the Participating Member States. The Contracted Doses shall be delivered by the Contractor to the Participating Member States in accordance with the allocation provided by the Commission and according to the schedule and in the quantities [***] as set out in the Delivery Schedule.

The Additional Order

The parties acknowledge that the Commission may wish to place an additional binding order (the **"Additional Order"**) for a maximum of up to 900 million doses of the Vaccine, to be exercised (unless otherwise agreed by the parties) in minimum tranches of [***]). Vaccine to be supplied pursuant to an Additional Order will be "**Additional Product**". [***].

The parties also agree that such Additional Order may be placed by the Commission only after (i) the Contractor confirms whether the doses are available (if the request is for more than the minimum Additional Order volume of [***]) and when they can be delivered (ii) the Commission confirms the required allocation between Participating Member States and (iii) the Contractor confirms the delivery schedule which shall be based on the allocation provided (and which shall not commence earlier than [***]).

All Additional Orders must be placed by the Commission by [***] .

The Participating Member States participating in one or more tranches of the Additional Order shall be obliged to send an additional Vaccine Order Form for each tranche of the Additional Order in which they participate. All terms and conditions included in this PA, in particular those included in Article I.6.3 with regard to Deliveries, [***] , shall apply mutatis mutandis to the Additional Order.

The Commission shall communicate to the Contractor the allocation of the Contracted Doses supplied pursuant to the initial order and any Additional Product among the Participating Member States.

Resale and Donation

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[***]
[***]
[***]

I.6.3 Supply mechanism

The supply under this PA shall in principle come from [***], and shall incorporate RNA produced at [***]manufacturing sites, including, [***] sites operated by the following sub-contractors:

[***]
[***]
[***]
[***]
[***]

The parties acknowledge that Contractor is not obliged to use all these sites provided it has sufficient capacity.

Recognising the urgency of the public health crisis and the necessity to hasten/enable supply, (1) the Commission and Participating Member States shall make best reasonable efforts, where appropriate in collaboration with the European Medicines Agency, to expedite any relevant and outstanding authorisations required for supply to commence from the Contractor's controlled manufacturing sites [***]; [***]

Delivery

The Contracted Doses shall be delivered by the Contractor to the Participating Member States in accordance with the allocation provided by the Commission and according to the schedule and in the quantities [***] as set out in the following table (the "**Delivery Schedule**"):

[***]
[***]

Within [***] following the Effective Date, the Commission shall communicate to the Contractor a table how to allocate the 900 million Vaccine doses amongst the Participating Member States. Each Participating Member State shall have a commitment to purchase the number of Vaccine doses as set out in such allocation table and, to operationalise the ordering of the Vaccine, each Participating Member State will enter into a Vaccine Order Form per Article I.5.2. Each Vaccine Order Form will specify in particular the number of doses that the Participating Member State will purchase from the above-mentioned allocation table, the price of all Vaccine doses pursuant to Article I.7, and the liability and indemnification undertakings by the Participating Member State (which will be incorporated by reference from the PA into the Vaccine Order Form). For the avoidance of doubt, the Contractor shall have no obligation to supply any Vaccine doses to any Participating Member State where there is not a Vaccine Order Form, including provisions related to liability and indemnity (which will be incorporated by reference from the PA into the Vaccine Order Form executed by the Participating Member State and the Contractor). It is agreed that the Contractor may discharge its obligations under the Vaccine Order Form acting with one or more Participating Contractor Affiliates.

The Delivery Schedule and logistics will be further refined into a [***] schedule by the Contractor in accordance with provisions below, after the execution of the Vaccine Order Form for that Participating Member State.

To operationalise the Vaccine Order Forms, [***].

For the avoidance of doubt, the Delivery Schedule is firm and no adjustments can be made without the written agreement of the parties. This is without prejudice to the ability of the Contractor to accelerate supply [***] .

[***]
[***]
[***]
[***]
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I.6.4 Manufacturing

The Contractor warrants that [***].

The Contractor confirms that it is in possession of all necessary manufacturing authorisations to undertake the manufacturing of the Vaccine.

The Contractor also warrants that, [***].

For the purpose of fulfilling its obligation to manufacture the Vaccine , the Contractor shall, in principle, procure all Key Supplies [***] .

For each such Key Supply including, in particular, Non-EU Key Supplies, the Contractor commits that it will have in place, when producing the Vaccine doses covered by this PA, an effective supply management system [***].

I.6.5 Legal and regulatory filings and requests

The Contractor shall ensure that all Product is properly labelled and packaged in accordance with the provisions of Article I.6.8 and Good Manufacturing Practice and in accordance with the applicable EU legislation on information on packaging (Title V of Directive 2001/83/EC).

Notwithstanding the above, [***]the Contractor shall comply with all conditions (in the relevant timescales) set out in the Authorisation (where applicable), subject to any exemption, exception or waiver of requirements for the Product granted or permitted by the Participating Member State (including but not limited to serialization).

I.6.6 [***]

I.6.7 Waiver

[***]
[***]

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I.6.8 Packaging, labelling and shipping

At the date of execution of this PA, the Vaccine is expected to be supplied in a thermal shipping box in accordance with Attachment 4 (Labelling and Packaging Specifications) (**"Thermal Shipper"**). [***]. The costs of packaging, packing materials, addressing, labelling, loading and delivery to the agreed Participating Member States' delivery point of the Vaccine [***].

All deliveries shall be accompanied by the documentation specified in Attachment 2 (Delivery Documentation) (which may be updated from time to time by the Contractor upon notice to the Commission), and shall be in accordance with, and subject to, the delivery specification set forth in Attachment 3 (Delivery Specification). The Product shall be labelled and packaged in

accordance with the packaging specifications set forth in Attachment 4 (Labelling and Packaging Specifications).

Final specifications including package size and labels will be communicated to the Commission and to the Participating Member States prior to delivery. All specifications shall be consistent with any conditions set out in the Authorisation and applicable Law.

I.6.9 Storage, transport and product acceptance

[***].

Final storage specifications, based on the Authorisation received, will be communicated to the Participating Member State prior to delivery.

[***]
[***]

I.6.10 Delivery

The Contractor will deliver the doses ordered by each of the Participating Member States to one or more locations selected by the Participating Member State in accordance with the procedure set out in this Article I.6.10 and the Vaccine Order Form. [***]. For the avoidance of doubt, the Participating Member States shall bear all costs and expenses for operating these distribution hubs and for use of the Vaccine, including, but not limited to, those for storage and distribution of the Vaccine after delivery, local duties and local QA testing.

The Participating Member States must have all appropriate facilities and personnel in place to enable the timely receipt of delivered doses. The duly authorised representative of the Participating Member State shall sign to confirm receipt of delivery (the current proposed format of which is as set out in Attachment 2 (Delivery Documentation)). The person signing for receipt must ensure the contents of the delivery match the accompanying shipping documentation proof of receipt.

The Contractor shall deliver the Product [***] to the location agreed pursuant to this Article I.6.10.

The Contractor and the Participating Member State shall agree the location(s) for delivery of shipments of the Product; provided that (i) each location meets the requirements set forth in Attachment 3 (Delivery Specification), and (ii) all locations which are additional to those approved in advance by the Contractor prior to the Effective Date shall be agreed upon by the Contractor and the Participating Member State [***].

All shipments of Product [***] or such other amount as notified to the Commission from time to time by the Contractor in accordance with the terms of this PA.

I.6.11 Product handling

Upon delivery of the Product, the Participating Member State shall store and handle the Product in the manner set forth in the Specifications set forth in Attachment 1 (Specifications), the

instructions in Attachment 3 (Delivery Specification) and the instructions provided by the Contractor to ensure stability and integrity of the Product.

The Participating Member States shall be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product in their [***] following delivery of the Product to the Participating Member State or its designee. Without prejudice to the generality of the foregoing, the Participating Member States shall ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment 5 (Return and Disposal of Product Materials) when disposing of open and unused Product and its packaging components; and (b) such return and disposal complies with Laws regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate.

Participating Member States shall be responsible for and shall ensure that any equipment used to deliver the Product, for example [***] are stored in an appropriate clean and secure location to protect and maintain the functionality of such equipment (in controlled conditions, with no exposure to weather or pests, etc). Within [***] of receipt of the Product, subject to Article I.6.14, the Participating Member State shall take the necessary measures to enable the collection by the Contractor of all such equipment, including [***] in accordance with the Contractor's instructions, consistent with the provisions of Attachment 5 (Return and Disposal of Product Materials).

The Contractor may provide Safety Data Sheets and other agreed information to Participating Member States [***]. .

I.6.12 Title to Product and risk of loss

[***]

I.6.13 Quality tests and checks

[***]

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I.6.14 Rejection of Product; Disposal of rejected shipments

A Participating Member State must visually inspect the Product [***] following the instructions set out in Attachment 3 (Delivery Specification) and may reject any specific delivery of the Product or doses therein that does not conform [***] (**"Non-Complying Product"**) by providing notice to Pfizer Customer Service following an agreed protocol:[***].

Without prejudice to the right to refer the matter to the dispute resolution procedure set out in Article I.1 and the provision on [***] , replacement of Non-Complying Product [***]. The provisions of this Article I.6.14 shall survive termination or expiration of this PA.

I.6.15 Maintenance and retention of Records

Each party shall maintain [***] with respect to its activities under this PA as required by Laws.

The Participating Member State will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If the Participating Member State

does not have a quality system for the activities defined, the Contractor may share details of a proposed quality system for the Participating Member State's compliance.

I.6.16 Diversion issues

All Product delivered to a Participating Member State shall be: (a) stored securely by the Participating Member State; and (b) without prejudice to Article I.6.2, distributed by the Participating Member State in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) or unauthorised resale or export out of the Participating Member State, and to protect and preserve the integrity and efficacy of the Product. [***]

I.7 PRICES

The price of the Vaccine to the Commission and the Participating Member States for the 900 million Contracted Doses and any Additional Order will be [***]

I.8 PAYMENT ARRANGEMENTS

I.8.1 [***]

I.8.2 [***]Delivery Price

The **Delivery Price** for the Contracted Doses and any Additional Order is to be paid by the Participating Member State to the Participating Contractor Affiliate [***]..
[***]
[***]The Participating Contractor Affiliate may claim the payment of the Delivery Price in accordance with this Article I.8.2. The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf for payment of the balance due under a Vaccine Order Form for each provision of supplies to the Participating Member States.

Invoices shall be established by the Participating Contractor Affiliate for a given order of supplies and for an identified delivery scheduled within the Vaccine Order Form.

The Participating Contractor Affiliate may not send an invoice to a Participating Member State before it receives from the Participating Member State [***]in respect of which such invoice is established, which [***] .

The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf or by electronic systems for payment due under the Vaccine Order Form accompanied by the following:

- [***]

Each invoice must contain the following information:

- Name of the Participating Member State concerned
- PA and Vaccine Order Form number/reference
- Order reference
- Billing address
- Product [***]

- Quantity [***]
- [***] reference and date
- Price
- Any applicable taxes, transportation charges or other charges provided for in the Vaccine Order Form
- The ship-to destination
- [***]
- Participating Contractor Affiliate name and bank account.

The Participating Member States must approve the submitted documents or deliverables as conforming to the above requirements and pay [***]. Any payment which falls due on a date which is not a business day may be made on the next succeeding business day. Any dispute by a Participating Member State of an invoice shall be provided to the Participating Contractor Affiliate in writing (along with substantiating documentation and a reasonably detailed description of the dispute) [***]. A Participating Member State will be deemed to have accepted all invoices for which the Participating Contractor Affiliate does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Article I.8.2. The parties shall seek to resolve all such disputes expeditiously and in good faith.

In addition to all other remedies available under this PA or at Law, if a Participating Member State fails to pay any undisputed amounts when due under this PA, the Contractor [***].

The Commission and the Participating Member States shall not, and acknowledge that they will have no right, under this PA, any Vaccine Order Form, any order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to the Participating Contractor Affiliate, against any other amount owed (or to become due and owing) to it by the Contractor or an Affiliate.

[***]
[***]

I.8.3 Bank account

Payments by the Commission must be made to [***]:[***][***][***][***][***]

I.9 COMMUNICATION DETAILS

For the purpose of this PA, communications must be sent to the following addresses:

If to the Commission:

European Commission

Directorate-General for Health and Food Safety

E-mail: SANTE-PROCUREMENT@ec.europa.eu

If to a Participating Member State – See details in Vaccine Order Form

By derogation from this Article I.9, different contact details for the Commission, the Participating Member States or the Contractor may be provided in Vaccine Order Form.

I.10 PROJECT MANAGEMENT

Pfizer, BioNTech and the Commission will each nominate a project manager that will be the sole contact point for and responsible for managing the overall relationship between the parties. Each Participating Member State shall in addition appoint an expert to work on PA implementation at Participating Member State level. Project meetings with the Commission and Participating Member State experts will be held regularly on a timeframe to be determined following execution of the PA to report, amongst other things, on progress of clinical studies, licensing activities, manufacturing status, forecast and deliveries. Details specific to each Participating Member State such as logistics and payments shall be handled directly by the respective Participating Member State experts.

I.11 EXPLOITATION OF THE RESULTS OF THE PA

The Commission acknowledges and agrees [***] (collectively, the **"Vaccine IP Rights"**). [***] . All rights not expressly granted by the Contractor hereunder are reserved by the Contractor.

I.12 INDEMNIFICATION

The Commission, on behalf of the Participating Member States, declares that the use of Vaccines produced under this PA will happen under epidemic conditions requiring such use, and that the administration of Vaccines will therefore be conducted under the sole responsibility of the Participating Member States. [***] .

I.13 APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.13.1 This PA shall be governed by the laws of Belgium.

[***]

I.14 OTHER SPECIAL CONDITIONS

The Contractor shall keep the Commission and the Participating Member States informed about [***] during the pharmacovigilance or vaccine monitoring programmes in relation to the Vaccines which are the object of this PA [***].

SIGNATURES

For the Contractor,

[***][***][***].

For the Commission, on behalf and in the name of the Participating Member States,

[forename/surname/position]

Signature:

Done at [place], [date]

In duplicate in English.

Signature:

Done at [place], [date]

II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT

II.1 DEFINITIONS

All definitions are contained in Article I.2 or in the relevant provisions of this PA.

II.2 ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

II.3 SEVERABILITY

Each provision of this PA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the PA. This does not affect the legality, validity or enforceability of any other provisions of the PA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in good faith between the parties. The PA must be interpreted as if it had contained the substitute provision as from its entry into force.

II.4 PROVISION OF SERVICES AND SUPPLIES

II.4.1 All periods specified in the PA are calculated in calendar days, unless otherwise specified.

II.4.2 The Contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

II.5 COMMUNICATION BETWEEN THE PARTIES

II.5.1 Form and means of communication

Any formal notification under the PA must:

(a) be made in writing in paper or electronic format in the language of the contract;

(b) bear the PA number and, if applicable, the Vaccine Order Form number;

(c) be made using the relevant communication details set out in Article I.9; and

(d) be sent by mail or email.

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

The parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.

II.5.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving party receives it, unless this PA refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.9. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission or the Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.9 registers it.

Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

II.6 LIABILITY

II.6.1 During the term of this PA, [***].

II.6.2 [***].

II.6.3 The Commission and the Participating Member States shall [***]to mitigate both (1) the damages that would otherwise be recoverable from the other or the Contractor pursuant to this PA and the Vaccine Order Forms, and (2) any costs, fees, expenses or losses that may be incurred by the Commission or the Participating Member State, or for which the Contractor may be responsible, under this PA and/or any Vaccine Order Form, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.

II.6.4 Limits on liability

(i) Taking into account the unprecedented nature of the current COVID-19 situation and the exceptional circumstances under which the Vaccine shall be delivered, the parties explicitly agree that [***].

(ii) [***].

(iii) The Contractor shall not be liable for any breach or non-compliance of this PA solely and exclusively towards the Participating Member State or any third parties acting on its behalf, whenever that Participating Member State or third parties acting on its behalf acted in breach of the Participating Member State's obligations under this PA or any Vaccine Order Form;

(iv) The aggregate liability of the Contractor and its Affiliates towards the Commission arising out of or relating to this PA and/or the Vaccine Order Forms (whether arising contractually or extra-contractually), shall not exceed [***].

(v) The liability of the Contractor and its Affiliates towards the Participating Member States arising out of or relating to this PA and/or any Vaccine Order Form concluded with a Participating Member State (whether arising contractually or extra contractually), shall not exceed [***].

(vi) [***].

II.6.5 No limitation of liability

Nothing in this PA excludes or limits the liability of either party for:

[***]

II.6.6 Waiver of sovereign immunity

Each Participating Member State represents that it has adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations pursuant to Article I.12 of this PA.

II.6.7 Recall

In the event of a recall of the Vaccine, [***].

II.7 CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS

II.7.1 The Contractor must take all the necessary measures to prevent any situation of conflict of interest or professional conflicting interest.

II.7.2 The Contractor must notify the Commission in writing as soon as possible of any situation that could constitute a conflict of interest or a professional conflicting interest during the Implementation of the PA. The Contractor must immediately take action to rectify the situation.

The Commission may do any of the following:

(a) verify that the Contractor's action is appropriate;

(b) require the Contractor to take further action within a specified deadline;

(c) decide not to award a Vaccine Order Form to the Contractor.

II.7.3 The Contractor must pass on all the relevant obligations in writing to:

(a) its personnel which is directly involved in the performance of this PA;

(b) any natural person with the power to represent it or take decisions on its behalf;

(c) third parties involved in the Implementation of the PA, including subcontractors.

The Contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

II.8 Representations and warranties

II.8.1 Mutual representations and warranties

The parties each represent and warrant to each other the following:

(i) Organization and authority. They have full right, power and authority to enter into this PA and to perform their respective obligations under this PA;

(ii) No conflicts or violations. The execution and delivery of this PA by such party and the performance of such party's obligations hereunder (i) do not conflict with or violate any laws existing as of the date of entry into force of the PA and applicable to such party and (ii) do not and will not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any [***] contractual obligations of such party; [***]; and

(iii) Valid execution. Such party is duly authorised to execute and deliver this PA, and the person executing this PA on behalf of such party is duly authorised to execute and bind such party to the terms set forth herein.

The above warranties shall also be given by the Participating Member States in respect of the Vaccine Orders Forms and their obligations contained therein.

II.8.2 Warranties of either party

The Contractor warrants to the Commission and the Participating Member States that:

[***]
[***]

In the event of any breach of the Contractor's warranties or undertakings relating to the Vaccine, the Commission's and the Participating Member States' [***].

The Commission and the Participating Member State warrant that the PA is awarded and each Vaccine Order Form is concluded in accordance with applicable Laws.

[***].

II.8.3 Anti-bribery/anti-corruption

The parties represent and warrant that, beyond the mutual consideration set forth in this PA, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from the other party or its agents to induce either party to enter into this PA or perform any part of this PA.

The Contractor has not made, and will not make, in the performance of this PA directly or indirectly any payment, offer, promise, or authorisation of payment of money or anything of value to a government official, political party, candidate for political office, or any other person, and has not sought and will not seek improperly or corruptly to influence any government official, political party, candidate for political office, or any other person, in order to gain an improper business advantage.

II.8.4 No other warranty

Except to the extent set out expressly in this PA, all conditions, warranties or other terms which might have effect between the parties or be implied or incorporated into this PA (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by applicable Law. [***].

II.9 CONFIDENTIALITY

II.9.1 Neither the Commission, a Participating Member State nor the Contractor shall, at any time, without the disclosing party's prior written consent, disclose to any third party any of the other party's Confidential Information.

II.9.2 The Commission, the Participating Member State and the Contractor shall:

(a) use such Confidential Information solely for the purposes for which it was provided;

(b) take all reasonable precautions to prevent any unauthorised use or disclosure;

(c) not disclose or distribute any Confidential Information to any third party except as and to the extent authorised in writing to do so by the disclosing party.

II.9.3 The receiving party shall be permitted to disclose Confidential Information that is required or requested to be disclosed by a governmental authority pursuant to applicable law in connection with any other legal or administrative proceeding, provided that it (i) notifies the disclosing party of any such disclosure requirement or request as soon as practicable and (ii) furnishes only that portion of the Confidential Information which, in the opinion of the receiving party or their legal counsel, is responsive to such requirement or request and (iii) asks the court or other public body, if applicable, to treat the Confidential Information as confidential.

II.9.4 The receiving party shall disclose Confidential Information only to such of its representatives who have a need to know such Confidential Information to fulfil its obligations under this PA; provided, however, before any disclosure of Confidential Information, the receiving party shall bind its representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as contained in this PA; and prior to any disclosure, the receiving party shall instruct its representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. The receiving party shall be responsible for all actions of its representatives, including any breach of the terms hereof, regardless of whether or not such representatives remain employed or in contractual privity with the receiving party.

II.9.5 Notwithstanding the foregoing, in all cases, [***] the Contractor may disclose Confidential Information to their Affiliates without prior written consent of the Participating Member States.

II.9.6 The confidentiality obligations set out in this Article II.9 are binding on the Commission, the Participating Member State and the Contractor during the Implementation of the PA and for as long as the information or documents remain confidential unless:

(a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;

(b) the Confidential Information or documents become public through other means than a breach of the confidentiality obligation;

(c) the applicable Law requires the disclosure of the Confidential Information or documents.

II.9.7 The Contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the Implementation of the PA a commitment that they will comply with this Article. At the request of the Commission, the Contractor must provide a document providing evidence of this commitment.

II.9.8 Neither this PA nor the performance by either party hereunder shall transfer to the receiving party any proprietary right, title, interest or claim in or to any of the disclosing party's Confidential Information (including, but not limited to, any intellectual property rights subsisting therein) or be construed as granting a license in its Confidential Information.

II.9.9 The provisions of this Article II.9 shall survive the termination or expiration of this PA for [***], except with respect to any information that constitutes a trade secret (as defined by the applicable Law), in which case the recipient of such information will continue to be bound by its obligations under this Article II.9 for so long as such information continues to constitute a trade secret, but in no event for a period of less than [***] specified above.

II.9.10 The Contractor acknowledges that the Commission is subject to requirements laid down under Regulation (EC) 1049/2001.The Commission commits that it will consult with the Contractor on any disclosure request concerning documents containing Confidential Information as provided for in Article 4(4) of said Regulation.

II.10 ANNOUNCEMENTS AND PUBLICITY

The parties shall consult together on the timing, contents and manner of any press release relating to the execution of this PA. Other than the foregoing, no party shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this PA or a Vaccine Order Form, the wider transactions contemplated by them, or the relationship between the parties, without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except (i) as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction; or (ii) on terms that are consistent and do not go further than the matters covered in any agreed press release. For clarity, unless consent is granted pursuant to this Article II.10, no announcement or disclosure will [***].

A party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other party in publicity releases, advertising or any other publication, without the other party's prior written consent in each instance, provided, however, that consent is granted for public announcements pursuant to above sub-clause (ii) in this Article II.10.

II.11 PROCESSING OF PERSONAL DATA

II.11.1 Processing of personal data by the Commission

Any personal data included in or relating to the PA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the PA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Director-General of the European Commission's Directorate-General for Health and Food Safety. The data protection notice is available at https://ec.europa.eu/info/data-protection-public-procurement-procedures_en.

The Contractor or any other person whose personal data is processed by the data controller in relation to this PA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the Contractor or any other person whose personal data is processed in relation to this PA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

II.11.2 Processing of personal data by the Contractor

The processing of personal data by the Contractor shall meet the requirements of Regulation (EU) 2016/679 and be processed solely for the purposes set out by the controller.

II.12 SUBCONTRACTING

II.12.1 The Contractor may not subcontract and have the PA implemented by third parties beyond the third parties already mentioned in its tender [***].

II.12.2 In the case of subcontracting, the Contractor remains bound by its contractual obligations and is solely responsible for the Implementation of the PA.

II.12.3 The Contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this PA.

II.13 [***]AMENDMENTS

II.13.1 Any amendment to the PA or a Vaccine Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccine Order Form does not constitute an amendment to the PA.

II.13.2 No amendment can make changes to the PA or a Vaccine Order Form that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

II.14 ASSIGNMENT

Neither this PA nor any interest hereunder will be assignable by a party without the prior written consent of the other party, except as follows: [***]. Neither this PA nor any interest hereunder will be assignable by a party without the prior written consent of the other party, except as follows: Force majeure

II.14.1 If a party is affected by Force majeure, it must immediately notify the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.14.2 A party is not liable for any delay or failure to perform its obligations under the PA or Vaccine Order Form if that delay or failure is a result of Force majeure. [***].

II.14.3 The parties must take all necessary measures to limit any damage due to Force majeure and shall use commercially reasonable efforts to avoid or minimize the delay in performance of their respective obligations affected by Force majeure.

II.15 SUSPENSION OF THE IMPLEMENTATION OF THE PA

II.15.1 Suspension by the Contractor

If the Contractor or a Participating Contractor Affiliate is affected by Force majeure, it may suspend the provision of the services under a Vaccine Order Form.

The Contractor or the Participating Contractor Affiliate must immediately notify the Commission of the suspension. The notification must include a description of the Force majeure and state when the Contractor or the Participating Contractor Affiliate expects to resume the provision of services.

The Contractor or the Participating Contractor Affiliate must notify the Commission as soon as it is able to resume performance of the Vaccine Order Form, unless the Commission has already terminated the PA or the Vaccine Order Form.

II.15.2 Suspension by the Commission or the Participating Member State

Pursuant to the Financial Regulation, the Commission or the Participating Member State may suspend the Implementation of the PA or performance of a Vaccine Order Form or any part of it:

(a) if the procedure for awarding the PA or a Vaccine Order Form or the Implementation of the PA proves to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;

(b) in order to verify whether the presumed Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations have actually occurred.

The Commission or the Participating Member State in question must formally notify the Contractor of the suspension and the reasons for it. Suspension takes effect on the date of formal notification, or at a later date if the formal notification so provides.

The Commission or the Participating Member State in question must notify the Contractor as soon as the verification is completed whether:

(a) it is lifting the suspension; or

(b) it intends to terminate the PA or a Vaccine Order Form under Article II.16.1, (f) or (i).

The Contractor is not entitled to compensation for suspension of any part of the PA or a Vaccine Order Form. For the avoidance of doubt, the Contractor shall not be under any obligation to deliver any Contracted Doses or the Additional Order during the suspension period, and the Delivery Schedule shall be adjusted to take into account the period of such suspension. Equally for the avoidance of doubt, the Contractor shall complete the delivery of any Contracted Doses or Additional Order that were already in transit on the date of the formal notification or at the later date indicated in the formal notification.

II.16 TERMINATION OF THE PA

II.16.1 Grounds for termination by the Commission

The Commission may terminate the PA or the Participating Member State may terminate any on-going Vaccine Order Form (depending on whether the event affects the PA or the Vaccine Order Form) solely in the following circumstances:

(a) [***].
(b) if the Contractor does not implement the PA or perform the Vaccine Order Form in accordance with material aspects of the PA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation;
(c) [***].
(d) if the Contractor or any person that assumes unlimited liability for the debts of the Contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation[5];
(e) if the Contractor or any Related person is in one of the situations provided for in points (c) to (h) of Article 136(1) or Article 136(2) of the Financial Regulation;
(f) if the procedure for awarding the PA or the Implementation of the PA proves to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;
(g) if the Contractor is in a situation that does constitute a Conflict of interest or a Professional conflicting interest which would have a material adverse impact on the performance of the PA;
(h) in case of a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract;
(i) [***].

II.16.2 Grounds for termination by the Contractor

The Contractor may terminate the PA or any on-going Vaccine Order Form solely in the following circumstances:

(a) if the Commission or the Participating Member State does not implement the PA or does not perform the Vaccine Order Form in accordance with material aspects of the

5 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046

PA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation, [***].

II.16.3 Procedure for termination

A party must formally notify the other party of its intention to terminate the PA or a Vaccine Order Form and the grounds for termination.

The other party has [***]following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed in the event the grounds giving rise to termination have not been cured.

If the other party submits observations, the party intending to terminate must formally notify it.

II.16.4 Effects of termination

[***] of the date of termination, the Contractor must submit any invoice required for services that were provided before the date of termination.

The termination or expiration of this PA shall not affect the survival and continuing validity of Articles I.1, I.2, I.4, I.6.2 (so far as it concerns resale and donation), I.6.7, I.6.9, I.6.11, I.6.12, I.6.14, I.6.16, I.7 to I.9, I.11 to I.14, II.3, II.5, II.6, II.8.2, II.8.4, II.9 to II.11, II.15, II.17.4, II.18 to II.28, Attachment 3 (Delivery Specification) and Attachment 5 (Return and Disposal of Product Materials) or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.

Expiry or termination of this PA for any reason shall be without prejudice to either party's other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination; [***].

II.17 INVOICES, VALUE ADDED TAX AND E-INVOICING

II.17.1 Invoices and value added tax

Invoices must contain the Contractor's or the Participating Contractor Affiliate's (or leader's in the case of a joint tender) identification data, the amount, the currency and the date, as well as the PA reference and reference to the Vaccine Order Form.

Invoices must indicate the place of taxation of the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT.

It is understood and agreed between the parties that any prices stated under this PA and Vaccine Order Form are exclusive of any VAT or similar tax and all other taxes which are incurred as a result of manufacturing and supplying the Product (including custom duties, levies and charges and all local taxes) (**"Taxes"**), which shall be added thereon as applicable. Where Taxes are properly chargeable on any amounts payable under this PA or Vaccine Order Form, the party making the payment will pay the amount of Taxes, as specified on the invoice, in accordance with the laws and regulations of the country in which the Taxes are chargeable.

[***]

II.18 PAYMENTS AND GUARANTEES

II.18.1 Date of payment

The date of payment is deemed to be the date on which [***]

II.18.2 Currency

Payments are made in euros or, for non-Eurozone countries, the local functional currency of the Participating Member State. For non-Eurozone countries, the Vaccine Order Form shall set forth the Delivery Price in the local functional currency converted from euro at the exchange rate existing one (1) day prior to the Effective Date of the PA as of 4:00pm London time published in Bloomberg FX Fixings (BFIX), such rates being found via Bloomberg or the website www.bloomberg.com/markets/currencies/fx-fixings.

II.18.3 Costs of transfer

The costs of the transfer are borne as follows:

(a) the Commission or the Participating Member State in question bears the costs of dispatch charged by its bank;
(b) the Contractor or the Participating Contractor Affiliate bears the costs of receipt charged by its bank;
(c) the party causing repetition of the transfer bears the costs for repeated transfer.

II.18.4 Suspension of the time allowed for payment

The Commission or the Participating Member State in question may suspend the payment periods specified in Article I.8 at any time by notifying the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) that its invoice cannot be processed.

[***]
[***]
[***]

.

Suspension takes effect on the date the Commission or the Participating Member State in question sends the notification. The remaining payment period resumes from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. [***] .

II.18.5 Interest on late payment

On expiry of the payment periods specified in Article I.8, the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) is entitled to interest on late payment at the higher of (a) the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) [***] (or such centralized bank reference rate set forth

in the Vaccine Order Form) and (b) [***] The reference rate is the rate in force, as published in the C series of the Official Journal of the European Union, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.18.4 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.18.1.

II.19 RECOVERY

II.19.1 Recovery procedure

In all cases where the recovery procedure as described in the Financial Regulation applies, the parties shall follow the procedure set out in this Article.

Before recovery, the Commission or the Participating Member State in question must formally notify the Contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the Contractor to make any observations [***] .

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by formally notifying a debit note to the Contractor, specifying the date of payment. The Contractor must pay in accordance with the provisions specified in the debit note.

If the Contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the Contractor in writing, recover the amounts due:

(a) by offsetting them against any amounts owed to the Contractor by the Commission or the Participating Member State in question;
(b) by taking legal action.

II.19.2 Interest on late payment

If the Contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.18.5. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.20 CHECKS AND AUDITS

II.20.1 The Commission and the European Anti-Fraud Office may check or require an audit on the Implementation of the PA. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the Contractor.

Such checks and audits may be initiated at any moment during business hours during the provision of the services and up to [***] starting from the payment of the balance of the last specific contract issued under this PA.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the Commission. Audits are carried out on a confidential basis.

II.20.2 The Contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of [***] starting from the payment of the balance of the last specific contract issued under this PA.

II.20.3 The Contractor must grant the appropriate right of access to sites and premises where the PA is implemented, [***] , needed to conduct such checks and audits. The Contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures notified to Commission by the Contractor subject to this not creating any material obstacles for the performance of the auditor's tasks.

II.20.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the Contractor, who has [***] following the date of receipt to submit observations. The Contractor must receive the final report within [***] following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the Participating Member State in question may recover all or part of the payments made in accordance with Article II.19 and may take any other measures which it considers necessary.

II.20.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti-Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the services and up to [***] starting from the payment of the balance of the last specific contract issued under this PA.

II.20.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/19398 ('the EPPO') have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

II.21 RELATIONSHIP OF THE PARTIES

The relationship hereby established between the Contractor and the Commission is solely that of independent contractors. Neither party has authority to act or make any agreements or representations on behalf of the other party. This PA is not intended to create, and shall not be construed as creating, between the parties, the relationship of principal and agent, employer and employee, joint venturers, co-partners, or any other such relationship, the existence of which is expressly denied.

II.22 WAIVER

A waiver by any party of any term or condition of this PA in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this PA shall be cumulative and in addition to any other remedies provided at Law or in equity, except where expressly otherwise agreed.

II.23 FURTHER DOCUMENTS

Each party hereto agrees to execute such further documents and take such further steps as may be reasonably necessary or desirable to effectuate the purposes of this PA.

II.24 HEADINGS

Headings of Articles or other parts of this PA are included herein for convenience of reference only and shall not constitute a part of this PA or change the meaning of this PA.

II.25 ELECTRONIC DELIVERY AND STORAGE

Delivery of a signed PA by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed PA. This PA may be stored by electronic means and either an original or an electronically stored copy of this PA can be used for all purposes, including in any proceeding to enforce the rights or obligations of the parties to this PA.

II.26 ENTIRE AGREEMENT

This PA, together with any Annexes and Attachments, which are hereby incorporated by reference, constitute the entire agreement of the parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto.

II.27 COSTS

Each party will bear its own legal costs in preparing and concluding this PA.

ANNEX I: VACCINE ORDER FORM

This Vaccine Order Form is submitted by:

[*The Government of [•]*] (the "**Participating Member State**"), represented for the purposes of signing this Vaccine Order Form by [forename, surname, function, department of authorising officer],

to:

Pfizer Inc, incorporated in Delaware (Registration Number 0383418) with its registered address at 235 East 42nd Street, 10017 New York City, NY (UNITED STATES) ("**Pfizer**");

and

BioNTech Manufacturing GmbH, registered with the commercial register of the lower court (Amstgericht) of Mainz, Germany under HRB 47548, with its registered address at An ger Goldgrube 12, 55131 Mainz, Germany ("**BioNTech**"),

(Pfizer and BioNTech together the "**Contractor**", represented for the purposes of signing this Vaccine Order Form by [***]).

The Participating Member State and Contractor are together referred to as the "**Parties**" and each individually as a "**Party**".

WHEREAS

— Contractor and the European Commission, acting on behalf of and in the name of the Participating Member States, entered into a Purchase Agreement for the purchase and supply of Contractor's Vaccine for EU Member States dated [•] 2021 (the "**PA**"), the terms of which are binding on the Participating Member States and must be read in conjunction with this Vaccine Order Form.

  The PA provides that each Participating Member State will submit to Contractor a Vaccine Order Form through which Contractor shall make available and deliver to the relevant Participating Member State a proportion of the Contracted Doses or Additional Order as applicable, in accordance with the allocation provided by the Commission pursuant to Article I.6.3 of the PA and at the price and conditions as set out in the PA.

— In accordance with Article I.5.2 and I.6.2 of the PA, the Participating Member State hereby places its order for its full allocated portion of the Contracted Doses or Additional Order (as applicable).

Article I

Subject matter

1. This Vaccine Order Form is submitted by the Participating Member State to Contractor in accordance with the terms of the PA, and forms an integral part of the PA. The terms and conditions of the PA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the PA, the terms of the PA prevail regardless of any provision to the contrary. Any capitalised terms in this Vaccine Order Form will have the meaning attributed to them in the definitions list included in Article I.2 of the PA.
2. This Vaccine Order Form relates to the order for the Participating Member State's full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as set out in the allocation provided by the Commission to Contractor pursuant to Article I.6.2 of the PA. The submission of this signed Vaccine Order Form by the Participating Member State to Contractor constitutes a binding order by the Participating Member State for the purchase of its full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) in accordance with the details set out in the Appendix to this Vaccine Order Form
3. By signature of this Vaccine Order Form, the undersigned Participating Member State warrants to Contractor that:

   a it is irrevocably and unconditionally bound by the terms of the PA (as concluded by the Commission on behalf and in the name of the Participating Member States), including the indemnification obligations and the liability, limitation of liability and exclusions terms set out therein;

   b the provisions of the PA are enforceable against it in accordance with its terms;

   c it shall indemnify the Indemnified Persons in accordance with Article I.12 (Indemnification) of the PA;

   d it has full right, power and authority to enter into this Vaccine Order Form and to perform its respective obligations under it;

   e the person executing this Vaccine Order Form is duly authorized to execute and bind the undersigned Participating Member State to the terms set forth herein and incorporated by reference.

4. [***] .
5.

The Participating Member State represents and warrants that all necessary permissions and approvals have been or will be obtained prior to the time for performance by the Participating Member State, to authorise performance of all of the obligations contained herein.

6. Any change to the Appendix to this Vaccine Order Form requires to be agreed by the parties in writing or by email.

Article II

Delivery, Supply

1. Delivery Address. The Delivery Address(es) for the Participating Member State is as set out in the Appendix to this Vaccine Order Form.

2. Supply of the Products

   The Contractor shall supply the Products as further described in the PA: **[Note:** Include any additional details concerning the supply here.**]**

Article III
Invoices; Notices

1. Invoice and Payments. Contractor shall invoice the Participating Member State in accordance with the terms of the PA. All payments to Contractor or its designated Affiliate shall be made in accordance with the terms of the PA.

   Payment shall be made in the currency set out in the Appendix to this Vaccine Order Form.

2. Notice. Any notice given under this Vaccine Order Form must a) be made in writing in English in paper or electronic format; b) bear the PA number and the number of this Vaccine Order Form; c) be made using the relevant communication details set out in the Appendix to this Vaccine Order Form with respect to the Participating Member State and Contractor (as applicable); d) be sent by mail and email:

Article IV.

Entry into Force and Duration

1. This Vaccine Order Form shall enter into force on the date of signature by the Parties and will remain into force until termination of the PA, or if the PA expires, until the last delivery of Product [***] .

Article V.
Applicable Law and Settlement of Disputes

1. For the avoidance of doubt, Article I.13 (Applicable Law and Settlement of Disputes) of the PA shall apply to any dispute arising out of the implementation of or in connection with this Vaccine Order Form and the Participating Member State irrevocably agrees to be bound by the provisions set out therein.

Appendix

Order Details

a. Participating Member State will purchase [insert amount] number of doses of [Contracted Doses] [Additional Order] of the Vaccine, on the basis of the following delivery schedule:

[***]

b. The price of [Contracted Doses] [Additional Order] is [***] .

The total amount payable by the Participating Member State for the [Contracted Doses] [Additional Order] is [insert amount], [***] .

c. The Delivery Address(es) are as follows:

[insert]

d. Payment shall be made in the following currency pursuant to the provisions of Article II.19.2 of the PA: [to be completed].

e. Details for notices

Participating Member State:

[Name of Participating Member State]
[Full official address of Participating Member State]
[Full name of addressee physical person (contact person)]
[Function of addressee physical person (contact person)]
E-mail: [complete email of addressee physical person (contact person)]

Contractor:

[Add details]

(Signature page follows)

SIGNATURES

For the **Participating Member State**,

[forename/surname/position]

Signature:_____

Done at [place], [date]

For acceptance of the Vaccine Order Form,

Contractor,

[***] Signature: _____

Done at [place], [date]

The invoice will be paid only once the Contractor has returned the signed Vaccine Order Form.

ANNEX II: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020

Agreement

Preamble

Having regard to Article 4(5)(b) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union1as amended by Council regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter "ESI" or "ESI regulation

***

The European Commission ("the Commission")

and

The following Member States: (XXX), hereinafter referred to as "the Participating Member States"

Together referred to as "the Parties"

Agree on the Following:

Article 1: Objective and mandate of the Commission

On the basis of the present agreement, the Commission is mandated to conclude, on behalf of the Participating Member States, Advance Purchase Agreements ("APA") with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID 19 pandemic at Union level.

The Annex to this agreement sets out the negotiating directives for this purpose.

Article 2: Acquisition of vaccine doses

It is the Participating Member States, and not the Commission, that shall acquire vaccine doses from the manufacturers on the basis of the APAs unless otherwise agreed. All relevant vaccination policies shall therefore remain matters for the Participating Member States.

Article 3: APAs containing a right to acquire vaccine doses

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use of such a right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does

not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may be taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

Annex

Initial considerations

A permanent solution to the COVID-19 crisis is most likely to be brought about by the development and deployment of a safe and effective vaccine against the virus. Every month gained in the deployment of a vaccine will save many lives, many jobs and billions of euros.

Therefore, it is the objective of the present Agreement that the EU takes steps to secure sufficient supplies of a safe and effective vaccine for Member States.

Structure and purpose of the procurement

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity

only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.

Under the present agreement, this challenge will be addressed through concluding EU-level Advance Purchase Agreements ("APA") with vaccine manufacturers when necessary, to secure access to vaccine candidates where they are successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. Funding for the up-front payments will come from the Emergency Support Instrument (ESI).

The Parties understand that developing a safe and effective vaccine is a highly complex process and the risk of failure in any such venture is very high. Therefore, the aim is to put in place APAs with a number of manufacturers of leading vaccine candidates, to maximise the chances of having access to at least one successful vaccine.

The Commission will invite all vaccine manufacturers to manifest interest. In general, the Commission will give priority to negotiating specific APAs with those manufacturers that (a) have entered or have firm plans to enter clinical trials still in 2020, (b) have the capacity to develop a successful vaccine and (c) have a proven capacity to produce at scale already in 2021.

Process and governance

In order to run the procurement centrally and efficiently, the European Commission will set up a steering board for the process subject to Article 6 of the present Agreement. It will be co-chaired by the European Commission and a Participating Member State with experience in the negotiations and production capacities for vaccines. The steering board will include senior officials from all Participating Member States to assist and provide guidance throughout the evaluation process.

The co-chairs of the steering board will propose a team of a limited number of experts with relevant experience for the ongoing negotiations from six Participating Member States with production capacities for vaccines. These experts will join with the European Commission in a negotiation team ("joint negotiation team"), which will work on a continuous basis as one unit. That joint negotiation team will start work immediately building on previous contacts with individual companies by the European Commission and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

For compliance with the applicable rules, all members of the steering board and the joint negotiation team will obtain the status of experts associated to the procurement process as provided in the Financial Regulation. Given their access to highly sensitive business information, all those members will be required to sign strict confidentiality and no-conflict-of-interest agreements.

Assisted by the steering board, the European Commission will then decide which of the resulting APAs should be concluded, in particular if financing under ESI is insufficient to finance all relevant packages. The Commission will only consider those APAs for financing where at least four Participation Member States have expressed agreement. Before making any final decisions, the Commission will seek independent scientific advice on the state of progress and the available data on quality, safety and efficacy for the vaccine candidate in question.

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will

have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

For full transparency, the European Commission will report to the IPCR at least once every two weeks on overall progress more generally.

Advanced Purchase Agreements and conditions

To conclude APAs, the joint negotiating team will negotiate funding packages with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price.

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between upfront payments and purchase price is difficult to draw, the Commission will share the total cost related to the vaccine purchase but will in any case contribute no more than 50% of the total cost.

Funding provided up front will be considered as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine.

The up-front payments under the APAs shall be used by manufacturers to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production value chain in the EU required for a rapid deployment of millions of doses of an eventual vaccine. The relevant payments should be structured according to the need of the manufacturer, but subject to the state of the vaccine development, in particular relying on transparency of the associated clinical data and its assessment, at the time of payment. This is in order to avoid obligations to pay in situations where the development work has shown a vaccine candidate likely to be unsuccessful.

The purchase price of the vaccine, as well as the amount of funding provided up front will take into account a transparent estimation of production costs (supported by independent audits where available), as well as the resources already granted from other public sources. Under the APA, the manufacturer can be asked to provide ex post proof supported by independent audits concerning the activities financed by these payments.

The aim of the negotiation is to conclude APAs with individual companies under the best possible conditions. These APAs should specify details with respect to:

a) Payments to be made, such as payment amounts, payment schedules, type of payments requested and the use of those payments related to de-risk investment, financing clinical trials, providing working capital and scaling-up production capacity;
b) Delivery details of the vaccine if successful, such as price per person immunised (or alternatively, number of doses required per person immunised and price per dose), quantity of doses to be delivered and delivery timeline following approval;

and

c) Any other relevant conditions, such as production capacity built or used in the EU or liability arrangements.

For liability arrangements, the joint negotiation team will make its best effort to limit what is required by individual companies for the purpose of indemnification to be included in the terms and conditions of the APA.

The APAs will contain provisions to clarify the law applicable to both the APA and resulting purchase orders as well as the competent courts. The Participating Member States agree that each APA negotiated by the Commission on their behalf with a vaccine manufacturer will have the same applicable law for all Participating Member States, and that the courts corresponding to that applicable law will be competent to hear disputes arising from that APA.

When taking a decision to finance individual APAs, the European Commission, in consultation with the steering board, will take into account the following elements: any available data on quality, safety and efficacy of the vaccine at time of negotiation of the contract, speed of delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, possible flexible future use of any capacity funded, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

The procedure outlined above complies with the ESI Regulation and the Financial Regulation. The latter is aligned to the European procurement Directives, which also provide the basis for national procurement rules. Participating Member States may rely on the procedure run by the European Commission to directly purchase vaccines from the manufacturers as and when any of the vaccines becomes available based on the conditions laid down in the APA. Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.

In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low and middle income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort.

ANNEX III: PARTICIPATING MEMBER STATES

Federal Republic of Germany
French Republic
Italian Republic
Kingdom of Spain
Republic of Austria
Hellenic Republic
Republic of Cyprus
Republic of Malta
Kingdom of Denmark
Kingdom of Sweden
Republic of Finland
Ireland
Portuguese Republic
Kingdom of Belgium
Grand Duchy of Luxembourg
Kingdom of the Netherlands
Republic of Poland
Romania
Republic of Bulgaria
Republic of Slovenia
Republic of Croatia
Czech Republic
Hungary
Slovak Republic
Republic of Lithuania
Republic of Latvia
Republic of Estonia

ANNEX IV: SUBCONTRACTORS

[***]

[***]

[***]

[***]

ANNEX V – PARTICIPATING CONTRACTOR AFFILIATES

Country	Participating Contractor Affiliate
Germany	BioNTech Europe GmbH
France	Pfizer SAS
Italy	Pfizer S.r.l.
Spain	Pfizer S.L.U.
Austria	Pfizer Corporation Austria GmbH
Greece	Pfizer Hellas SA
Cyprus	Pfizer Export B.V.
Malta	Pfizer Export B.V.
Denmark	Pfizer ApS
Sweden	Pfizer Innovations AB
Finland	Pfizer Finland Oy
Ireland	Pfizer Healthcare Ireland
Portugal	Pfizer Biofarmacêutica Sociedade Unipessoal, Lda
Belgium	Pfizer SA
Luxembourg	Pfizer Luxembourg S.A.R.L.
Netherlands	Pfizer B.V.
Poland	Pfizer Export B.V. and Trading Polska sp. z o.o.
Romania	Pfizer Romania SRL
Bulgaria	Pfizer Export B.V.
Slovenia	Pfizer Export B.V.
Croatia	Pfizer Export B.V.
Czech Republic	Pfizer, spol. s r.o.
Hungary	Pfizer Gyógyszerkereskedelmi Kft.
Slovakia	Pfizer Export B.V.
Lithuania	Pfizer Export B.V.
Latvia	Pfizer Export B.V.
Estonia	Pfizer Export B.V.

In addition, any Contractor Affiliate which is involved in the sale or distribution of Product which is resold or donated by a Participating Member State shall be deemed to be a Participating Contractor Affiliate.

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

TRON gGmbH
FreiligrathstraBe 12
D - 55131 Mainz

TRON gGmbH, Freiligrathstraße 12, D-55131 Mainz

BioNTech SE
An der Goldgrube 12
55131 Mainz

[***]
[***]
[***]
[***]
[***]
[***]
[***]

05.05.2021

Transfer of Source Code for MyMUT® Software Versions [***] on May 5th 2021

TRON gGmbH hereby transfers the full source code of the MyMUT® software versions [***] under the URL [***], encrypted zip archive (the "SOURCE CODE"); the key will be sent separately as a printout). With regard to the use of the data and the software by BioNTech SE, TRON recognizes that the software will be used for the so-called IVAC project.

Since the IVAC Supplementary Agreement dated January 1st 2015 between TRON and BioNTech expired on December 31st 2019 and no other related agreement between BioNTech SE and TRON gGmbH has been concluded so far, TRON hereby transfers these data (including inventions, rights to patent applications / patents and so-called trade secrets) subject to the rights of use to which TRON, TRON AFFILIATED COMPANIES and the respective cooperation partners are entitled in the IVAC Supplementary Agreement with the proviso that Sec. 6.4.1. of the Framework Collaboration Agreement ("WP5") between BioNTech SE and TRON gGmbH is applied as amended in Schedule 1, which amendment shall be effective solely for the purpose of this letter and the exploitation of the SOURCE CODE including any so called trade secret inventions contained in the SOURCE CODE. All other terms of the IVAC Supplementary Agreement shall remain unaffected. The parties further agree, via separate amendment, to extend the term of the IVAC Supplementary Agreement to Dec. 31st 2023.

BioNTech SE accepts this transfer under this letter agreement and recognizes the fulfillment of the obligations by TRON according to the IVAC Supplementary Agreement with regard to the above data.

Mainz, 06.05.2021 .....

/s/ Michael Föhlings .....

Michael Föhlings

Mainz, 05.05.2021 .....

/s/ Dr. Andrée Rothermel .....

Dr. Andrée Rothermel

/s/ Sierk Poetting .....

Sierk Poetting

Schedule 1
Amendment to Sec. 6.4.1. of the Framework Collaboration Agreement ("WP5")

This Amendment is agreed by the PARTIES for the sole purpose of regulating the remuneration payable by the relevant BIONTECH PARTY to TRON for the exploitation of a TRADE SECRET INVENTION to the extent any such TRADE SECRET INVENTION is part of the source code of the MyMUT® software versions L and M under the URL [***] encrypted zip archive (the "**SOURCE CODE**"). For this purpose only, Sec. 6.4.1 of the Framework Collaboration Agreement ("WP5") will read as follows:

"For the WP5 CONTRACTUAL PRODUCTS sold by it or its licensees (or sublicensees) to THIRD PARTIES which fall within the scope of protection of a VALID CLAIM of a WP5 PROJECT PATENT or a TRADE SECRET INVENTION, the BIONTECH PARTY shall pay TRON remuneration to the amount of

(i) [***] percent ([***]) of the WP5 CONTRACTUAL PRODUCT's NET SELLING PRICE up to an annual aggregate worldwide NET SELLING PRICE per WP5 CONTRACTUAL PRODUCT of [***]) euro (€[***]); and

(ii) [***] percent ([***]) of the WP5 CONTRACTUAL PRODUCT's NET SELLING PRICE if the annual aggregate worldwide NET SELLING PRICE per WP5 CONTRACTUAL PRODUCT exceeds [***] euro (€[***]).

The aforementioned remuneration under this clause 6.4.1 shall be paid on a country-by-country basis for so long as the relevant WP5 CONTRACTUAL PRODUCT is covered by a VALID CLAIM of a WP5 PROJECT PATENT in the country of sale.

If a WP5 CONTRACTUAL PRODUCT falls within the scope of a TRADE SECRET INVENTION, it is the mutual expectation of the PARTIES that the exploitation of such TRADE SECRET INVENTION will be coherent and jointly together with the exploitation of one or more WP5 PROJECT PATENTS. Based on that understanding, the royalty pursuant to this clause 6.4.1 for the use of a TRADE SECRET INVENTION shall only be payable (x) if the relevant WP5 CONTRACTUAL PRODUCT also falls within the scope of protection of a VALID CLAIM of a WP5 PROJECT PATENT or, (y) in the event that the BIONTECH PARTY should exploit a TRADE SECRET INVENTION by entering into an agreement with a THIRD PARTY, if the relevant WP5 CONTRACTUAL PRODUCT also falls within the scope of protection of a VALID CLAIM of a patent (co)owned by such THIRD PARTY ("THIRD PARTY PATENT").

The royalty is payable, on a WP5 CONTRACTUAL PRODUCT-by- WP5 CONTRACTUAL PRODUCT basis, only once per WP5 CONTRACTUAL PRODUCT, even if a WP5 CONTRACTUAL PRODUCT falls within the scope of protection of several WP5 PROJECT PATENTS and/or TRADE SECRET INVENTIONS.

TRON – Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz gemeinnützige GmbH

Bankverbindung: Mainzer Volksbank eG, IBAN: [***], BIC: [***]
Amtsgericht Mainz: HRB 43191 - **USt.-Id.Nr.:** DE 269156552
[***]

For the avoidance of doubt, the sentence in Sec. 6.4.1. of the Framework Collaboration Agreement "WP5") starting "*If such exploitation is undertaken…..*" shall be deleted in its entirety."

For all other purposes the original version of Sec. 6.4.1 shall remain unchanged, in full effect and shall not be affected by the aforementioned amendment.

TRON – Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz gemeinnützige GmbH

Bankverbindung: Mainzer Volksbank eG, IBAN: [***], BIC: [***]
Amtsgericht Mainz: HRB 43191 - **USt.-Id.Nr.:** [***].
[***].

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

AMENDMENT No 6

to

the License and Collaboration Agreement of 19th May 2015

by and between

BioNTech SE

and

Genmab A/S

[***]

This Amendment No 6 is made and entered into as of June 01, 2021 ("Amendment No 6 Effective Date") by and between BioNTech SE, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany ("Biontech") and Genmab A/S, CVR no. 21023884, a Danish corporation having its principal office at Kalvebod Brygge 43, DK-1560 Copenhagen V, Denmark, on the other side ("Genmab").

(for the purposes of this Amendment No 6, Biontech and Genmab each a "Party" and together the "Parties").

PREAMBLE

WHEREAS, Biontech and Genmab are parties to a certain License and Collaboration Agreement of 19th May 2015 as amended by:

1) the Amendment No 1 dated May 18, 2017, Amendment No 2 dated August 4, 2017, Amendment No. 3 dated May 18, 2018, Amendment No. 4 dated November 25, 2019, Amendment No 5 dated May 08, 2020,

2) the Side Letter dated January 8, 2016, a Side Letter No 2 dated May 13, 2016 (as amended by the Amendment No 1 to Side Letter No 2 dated May 19, 2017 as well as Amendment No 2 to Side Letter No 2 dated May 18, 2018 as well as Amendment No. 3 to the Side Letter No. 2 dated 18 August 2020), a Side Letter No 3 dated September 25, 2017, a Side Letter No 4 dated October 6, 2020, as well as

3) a Letter Agreement dated January 29, 2020, a Letter Agreement dated February 04, 2020 (as amended by Amendment of Letter Agreement dated June 29, 2020) and a Letter Agreement dated November 11, 2020 with an effective date of September 10, 2020

(jointly referred to as the "Agreement");

WHEREAS, Biontech and Genmab wish to adjust the FTE rate;

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, and for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree to amend the Agreement as follows:

1. DEFINITIONS

1.1. Except as otherwise defined herein, the words and phrases in the Agreement shall have the same meaning in this Amendment No 6.

1.2. "Amendment No 6" shall mean this Amendment No 6 to the Agreement.

1.3. "Amendment No 6 Effective Date" shall have the meaning set forth in the first paragraph on the second page of this Amendment No 6.

1.4. References to "Sections" refer to sections of the Agreement and references to "clauses" refer to clauses of this Amendment No 6.

2. AGREED AMENDMENTS

2.1. The Parties agree to amend the Agreement as follows:

2.1.1. Section 7.2 of the Agreement is deleted in its entirety and replaced by the below new Section 7.2 with retroactive effect from the Effective Date:

*"**7.2 FTE Rate.** The Parties agree that the mutual annual rate per FTE of either Party who performs research, Development, consultation or support work under any Research or Development Plan is as follows:*

a. Up until and including 18th May 2018: [***].

b. From and including 19th May 2018 up until and including 30 March 2019: [***].

c. From and including 1 April 2019 up until and including 30 March 2020: [***].

d. From and including 1 April 2020 up until and including 30 June 2020: [***].

e. From and including 1 July 2020 up until and including 31 December 2020: [***].

f. From and including 1 January 2021 up until and including 31 December 2021: [***].

g. From and including 1 January 2022 and onwards: [***] [***] *which shall be adjusted on an annual basis in accordance with the following sentence.* [***].

3. MISCELLANEOUS

3.1. Save as set forth in this Amendment No 6, all other terms and conditions of the Agreement shall remain in full force and effect.

3.2. This Amendment No 6 shall form an integral part of the Agreement and shall be regarded as incorporated into the Agreement in every respect as from the relevant dates stated above.

3.3. The Agreement and this Amendment No 6 constitute the entire agreement between the Parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter. In the event of any conflict, ambiguity or inconsistency between the provisions of this Amendment No 6 and the Agreement, the provisions of this Amendment No 6 shall prevail. Except as specifically modified by this Amendment No 6, the remainder of the terms of the Agreement shall remain in full force and effect, unamended.

3.4. This Amendment No 6 and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales without reference to its conflict of laws provisions.

3.5. This Amendment No 6 may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of the Amendment No 6.

3.6. The Parties agree that this Agreement can be signed using a DocuSign® electronic signature. Such electronic signature is the legally binding equivalent to a Party's handwritten signature and it has the same validity, enforceability and meaning as a handwritten signature and the Parties hereby waive any objection to the contrary.

Signature

[***]

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Amendment No 6 as of the Amendment No 6 Effective Date.

BioNTech SE:		**Genmab A/S**	
Date:	01.06.2021 03.06.2021	Date:	09-Jun-2021
Signature	[***] [***]	Signature:	[***]
Print name:	Sierk Poetting Sean Marett	Print name:	Anthony Mancini
Title:	Managing Director Managing Director	Title:	EVP & COO

CONFIDENTIAL
Execution version

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

AMENDED & RESTATED DEVELOPMENT AGREEMENT

This amended and restated development agreement (this ***Agreement***) is effective as of July 7, 2021 (the ***Effective Amendment Date***) and entered into by and between Sanofi, having a place of business at 54, rue La Boétie, 75008 Paris, France (***Sanofi***), and BioNTech RNA Pharmaceuticals GmbH, having a place of business at An der Goldgrube 12, 55131 Mainz, Germany (***Biontech***). Sanofi and Biontech shall each individually be referred to herein as a ***Party***, and shall be referred to together as the ***Parties***.

RECITALS

A. On November 2 nd, 2015, as amended by an amendment letter dated December 14th, 2017, the Parties entered into a Collaboration and License Agreement (the ***License Agreement***) with the desire to collaborate in the research, development and commercialization of RNA-based therapeutics for the treatment of cancer.

B. Under the License Agreement, a Mixture named Licensed Product #1 (as further defined below) has been approved by the Joint Steering Committee as a Licensed Product Candidate in accordance with Section 2.8 of the License Agreement.

C. On [***], Sanofi selected Licensed Product #1 as the first Licensed Product for further Development and Commercialization in accordance with Section 2.9 of the License Agreement and on [***] Biontech exercised its option to co-Develop and to co-Commercialize Licensed Product #1 in the Field in the Biontech Territory in accordance with Section 4.1 of the License Agreement.

D. The Parties entered into a Development Agreement (the "Original Agreement") on March 29, 2018 in order to jointly Develop Licensed Product #1 in the Field.

E. The Parties hereby wish to amend and restate the Original Agreement in order to address intellectual property rights relating to [***] formulations as well as the corresponding license grants. This Agreement constitutes the Development agreement with respect to Licensed Product #1 under Section 4.1.1 of the License Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties hereby agree as follows:

1. Definitions.

Capitalized terms used in this Agreement shall have the meanings as defined herein, provided that capitalized terms which are used but not defined herein shall have the meanings ascribed to them in the License Agreement.

1.1 ***Additional Co-Development Costs*** is defined in Section 6.3.4.

1.2 ***Approved Co-Development Third Party*** means a Third Party subcontractor or other Third Party engaged by a Party to perform or assist with any of such Party's obligations under this Agreement, and which (a) is listed in Schedule A; or (b) has been approved by the Joint Project Team under Section 6.2(h).

1.3 ***Binding Budget*** is defined in Section 3.3.1.

1.4 ***Biontech Co-Development Know-how*** is defined in Section 4.1.2.

1.5 ***Biontech Co-Development Patents*** is defined in Section 4.2.2.

1.6 ***Biontech Co-Development Technology*** means the Biontech Co-Development Know-how and the Biontech Collaboration Patents.

1.7 ***Budget*** means a rolling [***] budget set out in the Development Plan with respect to the forecasted Shared Development Costs to be incurred by each Party during each such Calendar Year during the Term, as amended or updated from time to time by the Joint Project Team or the Joint Steering Committee (as the case may be) in accordance with this Agreement.

1.8 ***Calendar Quarter*** means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the last Calendar Quarter shall end on the last day of the Term.

1.9 ***Calendar Year*** means each successive period of twelve (12) calendar months commencing on January 1, except that the last Calendar Year shall end on the last day of the Term.

1.10 ***Clinical Data*** means [***], results and analyses [***] generated by or on behalf of either Party or at either Party's direction, or by or on behalf of the Parties together or at their direction, in the course of the performance of the clinical trials under the Development Plan.

1.11 ***Clinical Supply Agreement*** means the Clinical Development and Supply Agreement between the Parties, effective as of October 4th, 2017.

1.12 ***CMC*** means "Chemistry, Manufacturing, and Controls" as such term of art is used in the pharmaceutical industry.

1.13 ***CMC Activities*** means the activities with respect to Licensed Product #1 set out in the CMC Development Plan (or, for the purposes of Section 2.8.3, 2.8.4 and 2.8.5, the activities with respect to Licensed Product #1 proposed to be included in the CMC Development Plan).

1.14 ***CMC Development Plan*** means the development plan setting out the CMC and manufacturing process development activities with respect to Licensed Product #1 as set out in Schedule D, and amended by the Joint Manufacturing Committee or the Joint Steering Committee (as applicable) from time to time pursuant to Section 2.8.5.

1.15 ***CMC Know-how*** means the Know-how made, conceived or first reduced to practice by or on behalf of either Party (or its Affiliates), or jointly by or on behalf of the Parties (or their Affiliates), in the conduct of the activities under the CMC Development Plan.

1.16 ***CMC Patents*** is defined in Section 4.2.2.

1.17 ***CMC Technology*** means the CMC Know-how and CMC Patents.

1.18 ***Co-Development Activities*** means the Development and other activities with respect to the Licensed Product #1 in the Field as specified in or reasonably contemplated

by the Development Plan. For the avoidance of doubt, Co-Development Activities exclude the activities set out in the CMC Development Plan.

1.19 ***Co-Development Background Technology*** means, with respect to a Party, all Intellectual Property Rights over which such Party has gained Control outside of the scope of the collaboration under the License Agreement (including the activities under this Agreement) during the Term, excluding any Background Technology.

1.20 ***Co-Development Personnel*** means the individuals engaged by a Party performing Co-Development Activities, including any of the foregoing who are Project Managers, members of the Joint Steering Committee, Joint Project Team, regulatory personnel, quality assurance personnel, quality control personnel, research personnel, and development personnel.

1.21 ***Co-Development Report*** is defined in Section 2.5.

1.22 ***Co-Development Records*** is defined in Section 2.6.1.

1.23 ***CPI*** means the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) in the United States.

1.24 ***Development Plan*** means the development plan set out in Schedule C and amended or updated from time to time (through the proposal of such amendments or updates to the Joint Steering Committee and the approval of such amendments or updates by the Joint Steering Committee), setting forth in reasonable detail: (i) the clinical Development strategy, (ii) the objectives for Development activities and market access, (iii) Development activities, including clinical trials and regulatory filings, (iv) the definition of countries or regions in which clinical trials shall be conducted, (v) an allocation of each Party's responsibilities and (vi) timelines and the associated Budget, in each case (i) to (vi), with respect to Licensed Product #1 in the Field intended for approval or Commercialization in the Biontech Territory. For the avoidance of doubt, the Development Plan excludes the CMC Development Plan.

1.25 ***Effective Amendment Date*** is defined in the introductory paragraph of this Agreement.

1.26 ***Excluded Clinical Trial Costs*** is defined in Section 1.52.

1.27 ***Formulation Know-how*** means:

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v1.28 ***Formulation Patents*** [***]

1.29 ***Formulation Technology*** means the Formulation Know-how and Formulation Patents.

1.30 ***FTE Costs*** means the cost of the Co-Development Personnel incurred by either Party, calculated at the FTE Rate multiplied by the applicable number of FTEs of Co-Development Personnel of such Party (on the basis of actual hours worked by such Co-Development Personnel on the Co-Development Activities or the activities in support thereof). For the avoidance of doubt, when calculating FTE Costs, any full-time employee who works more than [***] hours over the course of a twelve (12) month period shall count as one (1) FTE.

1.31 ***FTE Rate*** means [***] per FTE. Such rate shall be automatically adjusted on an annual basis in accordance with Section 2.2.3.

1.32 ***including*** means "including without limitation" (and ***include*** means "include without limitation").

1.33 ***Initiation*** means, with respect to a clinical trial, the first dosing of a human subject with Licensed Product #1 in such clinical trial.

1.34 ***Joint Financial Committee*** is defined in Section 6.5.1.

1.35 ***Joint Manufacturing Committee*** means the joint manufacturing committee established under the Clinical Supply Agreement.

1.36 ***Joint Patent Committee*** is defined in Section 6.5

1.37 ***Joint Project Team*** is defined in Section 6.2.

1.38 ***License Agreement*** is defined in the preamble.

1.39 ***Licensed Product #1*** means (a) the Mixture specified in Schedule B; or (b) any modified version of such Mixture as proposed by the Joint Project Team pursuant to Section 6.2(f) and approved by the Joint Steering Committee. For the avoidance of doubt, Licensed Product #1 includes any formulation in the Field of any Mixture described in (a) and (b).

1.40 ***Patent Documentation*** is defined in Section 4.9.

1.41 ***Prosecution and Maintenance*** (including variations such as ***Prosecute and Maintain***) means, with respect to a Patent Right, the preparation, filing, prosecution and maintenance of such Patent Right, including paying all maintenance and/or governmental fees to maintain such Patent Right in force, and requests for patent term extensions, supplementary protection certificates, and the like with respect to such Patent Right, together with the conduct of reissue proceedings, derivation proceedings, the defense of oppositions, *ex parte* reexaminations, *inter partes* reviews, post-grant reviews, and other similar proceedings with respect to such Patent Right.

1.42 ***Overspent Costs*** is defined in Section 3.3.2.

1.43 ***Overspent Costs Notice*** is defined in Section 3.3.2.

1.44 ***Project Manager*** is defined in Section 6.1.

1.45 ***Regulatory Documentation*** means all (a) marketing authorizations or registrations or any other approval, registration or authorization which is granted or accepted by a Regulatory Authority in a country in the Biontech Territory that are required for the Development, Manufacture or Commercialization of a Licensed Product #1 in the Field in such country, and all filings and submissions to a Regulatory Authority with respect to any of the foregoing; (b) correspondence, reports and other filings submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) in order to Develop, Manufacture or Commercialize a Licensed Product #1 in the Field in the Biontech Territory.

1.46 ***Right of Reference*** means the non-exclusive right to cross reference, copy, incorporate by reference or rely upon any Clinical Data solely for the purposes of obtaining or maintaining Marketing Approval for a pharmaceutical product, including (1) a "Right of Reference or Use" as that term is defined in 21 C.F.R. §314.3(b) in the United States, (2) any analogous procedures with respect to biologics or BLAs in the United States and (3) any equivalents thereof outside the United States.

1.47 ***SDEA*** is defined in Section 7.2.

1.48 ***Sanofi CMC Technology*** means: (a) the CMC Know-how which is generated by or on behalf of Sanofi (or its Affiliates) or jointly by or on behalf of the Parties (or their Affiliates) in the conduct of the CMC Activities agreed by the Joint Manufacturing Committee (or, if the Joint Manufacturing Committee cannot agree on such matters, approved by the Joint Steering Committee pursuant to Section 6.3.2(c)) for performance by Sanofi under the CMC Development Plan; and (b) the CMC Patents claiming or covering such CMC Know-how.

1.49 ***Sanofi Co-Development Know-how*** is defined in Section 4.1.1.

1.50 ***Sanofi Co-Development Patents*** is defined in Section 4.2.1.

1.51 ***Sanofi Co-Development Technology*** means the Sanofi Co-Development Patents and the Sanofi Co-Development Know-how.

1.52 ***Shared Development Costs*** means the out-of-pocket costs and expenses and FTE Costs incurred by either Party or its Affiliate, in each case which are: (1) specifically identifiable to, or reasonably allocable to, any Co-Development Activity [***]; and (2) calculated in accordance with IFRS consistently applied, including (to the extent they come within the foregoing):

(a) the costs and expenses associated with the conduct of non-clinical studies [***]

(b) the costs and expenses associated with the conduct of clinical trials [***];

(c) the costs and expenses associated with the preparation, filing, submission, obtaining or maintenance (as applicable) of Regulatory Documentation with respect to any Licensed Product #1 in the Field; and

(d) the costs and expenses with respect to Approved Co-Development Third Parties engaged in the performance of such Co-Development Activity.

Excluded Clinical Trial Costs

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[***]shall be referred to as the ***Excluded Clinical Trial Costs***.

Notwithstanding the foregoing, "Shared Development Costs" shall exclude [***]

1.53 ***Shared Formulation Patent Costs*** is defined in Section 4.10.2.

1.54 ***Tax*** or ***Taxes*** means any federal, provincial, territorial, state, municipal, local, foreign or other taxes and other charges in the nature of a tax.

1.55 ***Term*** is defined in Section 9.1.

1.56 ***VAT*** is defined in Section 3.7.3.

1.57 ***Withholding Tax*** or ***Withholding Taxes*** is defined in Section 3.7.2.

2. Development of Licensed Product #1.

2.1 Development Activities Generally.

2.1.1 Each Party shall:

(a) perform the Co-Development Activities allocated to such Party under the Development Plan in accordance with the terms of this Agreement;

(b) contribute and commit the required resources and use Commercially Reasonable Efforts to meet the objectives set forth in the Development Plan; and

(c) perform its obligations under this Agreement in accordance with the Applicable Law.

2.1.2 The Development Plan in force at the Effective Amendment Date is set out in Schedule C. No later than [***] (or such other period as agreed by the Joint Steering Committee under Section 6.3.2(f)) prior to the end of each Calendar Year, commencing [***], the Joint Project Team shall review the Development Plan and propose any updates to the Development Plan to the Joint Steering Committee pursuant to

Section 6.2(c), such that the Joint Steering Committee can review and approve such proposed updated Development Plan pursuant to Section 6.3.2(b) no later than [***] days prior to the end of such Calendar Year. In addition, from time to time, the Joint Project Team shall review any proposal from either Party to amend the Development Plan, for proposal to the Joint Steering Committee pursuant to Section 6.2(c). Upon approval of the Joint Steering Committee of any such update or amendment, the Development Plan shall be deemed to be amended to incorporate such update or amendment.

2.1.3 For clarity, the Development Plan, and accordingly, the Co-Development Activities, shall exclude any CMC Activities conducted under the CMC Development Plan.

2.2 Allocation of Resources/Subcontracting.

2.2.1 Each Party agrees to primarily use its or its Affiliates' internal resources and capacities to fulfil such Party's respective obligations under the Development Plan. Each Party shall use Commercially Reasonable Efforts to minimize the delegation of its obligations hereunder to a Third Party subcontractor (including contract research organizations).

2.2.2 Each Party may subcontract any of its obligations under this Agreement to any of its Affiliates or one or more Approved Co-Development Third Parties, provided that: (i) none of the rights of the other Party are diminished or are otherwise adversely affected as a result of such subcontracting and (ii) the Approved Co-Development Third Party undertakes in writing all obligations of confidentiality and non-use regarding both Parties' Confidential Information which are substantially the same as those undertaken by the Parties under the License Agreement. In the event that a Party performs one or more of its obligations under this Agreement through any such Affiliate or Approved Co-Development Third Party, then such Party shall at all times be responsible for the performance by such Affiliate or Approved Co-Development Third Party of such Party's obligations hereunder.

2.2.3 All internal Co-Development Personnel of each Party (or its Affiliates) shall be expressed in terms of FTEs. The FTE Rate shall be adjusted on an annual basis, the first adjustment shall be on January 1, 2019 and thereafter each adjustment shall be on January 1 of each succeeding Calendar Year. Each such adjustment shall be calculated by increasing the FTE Rate as of December 31, 2018 by the percentage increase in the CPI as of December 31 of the then most recently ended Calendar Year over the level of the CPI on December 31, 2018.

2.3 Conduct of Clinical Trials. Sanofi shall act as the sponsor of any clinical trial conducted pursuant to the Development Plan, provided that Sanofi shall consider in good faith whether to use Biontech's resources in regions where such internal resources are available [***] and whether in certain circumstances Biontech shall be the co-sponsor or sponsor of selected clinical trials. The Party acting as sponsor (or co-sponsor, as applicable) shall ensure that any such clinical trial (for which it is sponsor (or co-sponsor, as applicable)) is performed in accordance with this Agreement, the applicable protocol and Applicable Law, and the other Party shall provide such Party with any assistance as reasonably requested by such Party, in order for such Party to fulfil its obligations as sponsor (or co-sponsor) of such clinical trial. Each Party shall mention or list the other Party as collaborator (e.g. "in collaboration with BioNTech RNA Pharmaceuticals GmbH" or "in collaboration with Sanofi", as applicable)) (and the other Party hereby agrees to such mention or listing) in the relevant clinical trial databases and registers (e.g. clinicaltrials.gov (or equivalent)), in public materials

published by such Party in relation to all clinical trials conducted pursuant to the Development Plan and, to the extent reasonably practicable, on labels of vials used in such clinical trials, as well as when either Party formally presents the Development program under this Agreement at conferences, provided that, prior to any such mention, listing or publication the Parties have agreed in writing the form of information that can be used in such mentions, listings or publications, and all mentions, listings and publications of a Party as collaborator under this Section 2.3 shall be made in all cases in a manner and to the extent consistent with Applicable Law and such agreed form of information.

2.4 Biomarker Execution. [***]

2.5 Reporting. Each Party shall keep the other Party reasonably informed as to its progress, results (including the development of any technology or invention), status and plans with respect to the Co-Development Activities performed by or on behalf of such Party through the provision of periodic, informal oral reports to the other Party's Project Manager. Without limiting the foregoing, each Party shall provide to the other Party a [***] written report (the ***Co-Development Report***) delivered no later than [***] following the end of each [***], such written report shall set out detailed particulars of the following items: (a) the Co-Development Activities performed by such Party during such [***]; (b) the data, results and other Intellectual Property Rights made, conceived and first reduced to practice in the conduct of such Co-Development Activities by or on behalf of such Party; (c) the status of preparation for the planned Co-Development Activities to be performed in the upcoming [***] and the status of such activities; and (d) any other relevant information determined by the Joint Project Team to be included in such report pursuant to Section 6.2(i).

2.6 Maintenance of Records.

2.6.1 During the Term and for a period of at least [***] after the Term (or, if longer, a period required by Applicable Law), each Party shall maintain records reflecting the work done and the results achieved in its performance of the Development Plan (the ***Co-Development Records***), such records shall be in a reasonable level of detail customary for companies engaged in pharmaceutical research. Without limiting the foregoing, such records shall be in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes in compliance with Applicable Law.

2.6.2 Each Party shall make its Co-Development Records available for inspection by the other Party or its representative, during normal business hours and upon reasonable notice, upon reasonable written request of the other Party. Upon request by each Party, the other Party shall deliver to the requesting Party copies of all its Co-Development Records (which may include copies in an electronic format readily accessible by the requesting Party), provided that the requesting Party shall reimburse the reasonable and documented out-of-pocket costs incurred by the other Party in connection with the preparation and delivery of such copies. Each Party shall not be obliged to: (a) provide the other Party with access to its Co-Development Records or (b) deliver to the other Party copies of its Co-Development Records, in each case (a) and (b), more than [***].

2.7 Ownership of Clinical Data. Sanofi shall exclusively own all Clinical Data, [***]

[***] Each Party acknowledges and agrees that Section 4.1.2 of the License Agreement shall not apply to such Clinical Data.

2.8 Manufacturing and Clinical Supply of Licensed Product #1.

2.8.1 The Parties' respective responsibilities relating to the Manufacturing and supply of Licensed Product #1 to be used for Phase I Clinical Trials and Phase II Clinical Trials are set forth in the Clinical Supply Agreement and the License Agreement. If the Joint Steering Committee approves any modification to the Licensed Product #1 set out in Schedule B pursuant to Section 6.3.2(d), at Sanofi's request, the Parties shall promptly update Appendix 1 of the Clinical Supply Agreement, such that the Licensed Product #1 incorporating such modification shall constitute a Drug Product under the Clinical Supply Agreement.

2.8.2 Biontech shall: (a) subject to Section 2.8.3, be responsible for the performance of all CMC Activities with respect to Licensed Product #1 under the CMC Development Plan; (b) perform the CMC Activities allocated to Biontech under the CMC Development Plan in accordance with the terms of this Agreement, and (c) contribute and commit the required resources and use Commercially Reasonable Efforts to meet the objectives set forth in the CMC Development Plan.

2.8.3 If either Party wishes Sanofi to perform any CMC Activities with respect to Licensed Product #1, such Party shall propose to the Joint Manufacturing Committee an update to the CMC Development Plan reflecting such CMC Activities to be performed by Sanofi, and Sanofi may perform such CMC Activities if agreed by the Joint Manufacturing Committee or, if the Joint Manufacturing Committee cannot reach agreement on such matter, upon the approval by the Joint Steering Committee pursuant to Section 6.3.2(c) of such update to the CMC Development Plan.

2.8.4 The initial version of the CMC Development Plan is set out in Schedule D. Thereafter, the Joint Manufacturing Committee shall discuss and approve any amendments to the CMC Development Plan proposed by either Party under Section 2.8.5(a) (provided, with respect to any proposed amendments to the CMC Development Plan to provide for Sanofi's performance of any CMC Activities, if the Joint Manufacturing Committee cannot agree on such matters, the Joint Steering Committee shall decide whether Sanofi may perform such CMC Activities pursuant to Section 6.3.2(c)). Biontech shall keep the Joint Manufacturing Committee fully informed as to its progress, results (including the development of any technology or inventions), status and plans for performing and implementing the CMC Development Plan, including by periodic, informal oral reports to the Joint Manufacturing Committee, and by providing a quarterly report to the Joint Manufacturing Committee with respect to CMC Activities performed under the CMC Development Plan delivered no later than [***] following the end of every Calendar Quarter, such written report shall set out detailed particulars of the following items: (a) the CMC Activities performed under the CMC Development Plan during such [***]; (b) the data, results and other Intellectual Property Rights made, conceived and first reduced to practice in the performance of such CMC Activities; (c) the status of preparation for the planned CMC Activities to be performed under the CMC Development Plan in the upcoming [***] and the status of such CMC

Activities; and (d) any other relevant information determined by the Joint Manufacturing Committee to be included in such report pursuant to Section 2.8.5(b).

2.8.5 The Joint Manufacturing Committee shall be responsible for discussing and approving: (a) any amendments to the CMC Development Plan as proposed by either Party; and (b) the information to be included in the quarterly written reports described in Section 2.8.4. If the members of the Joint Manufacturing Committee cannot agree on such matters, notwithstanding anything to the contrary in Section 3.3.6 of the License Agreement and Sections 9.4 and 9.5 of the Clinical Supply Agreement: (i) with respect to any proposed amendment or update to the CMC Development Plan to provide for Sanofi's performance of any CMC Activities as described in Section 2.8.4, such matter shall be referred to the Joint Steering Committee for decision under Section 6.3.2(c); and (ii) with respect to any other matter, Sanofi shall have the deciding vote, and the third sentence of Section 9.5 of the Clinical Supply Agreement shall not apply with respect to such matter.

2.8.6 For the avoidance of doubt, the Manufacture and supply of any Licensed Product #1 for use in Phase III Clinical Trials pursuant to the Development Plan are subject to Sections 3.3.3 to 3.3.6 of the License Agreement.

3. Development Costs.

3.1 Development Costs related to the Biontech Territory. All Shared Development Costs shall be shared between the Parties pursuant to the following scheme:

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3.2 Development Costs not related to the Biontech Territory. Sanofi shall remain solely responsible [***]

3.3 Budget.

3.3.1 Annual Development Plan Budget.

(a) The Budget shall include particulars of the Shared Development Costs which each Party is reasonably expected to incur with respect to its Co-Development Activities during [***] period. Each Party acknowledges and agrees that [***], the ***Binding Budget***). The initial Binding Budget is set out in Schedule C to this Agreement. Thereafter, the Budget shall be updated in accordance with Section 3.3.1(b).

(b) No later than [***] (or such other period as agreed by the Joint Project Team under Section 6.2(p)) prior to the end of [***], the Parties' respective Joint Project Team representatives shall in good faith discuss the Budget: (i) if such Calendar Year is [***] or [***], for the following [***] (3) Calendar Year period (excluding the Calendar Year(s) comprising the then-current Binding Budget); or (ii) if such Calendar Year is [***] or any Calendar Year thereafter, [***], in each case (i) and (ii), pursuant to Section 6.2(d), and shall submit a proposed Budget to the Joint Financial Committee for review and comments. The Joint Project Team shall consider any comments from Joint Financial Committee with respect to such proposed Budget and may (but shall not be required to) amend such proposed Budget accordingly. Thereafter, the Joint Project Team shall submit the proposed Budget to the Joint Steering Committee for review and approval under Section 6.3.2(b), such that such proposed Budget shall be approved by the Joint Steering Committee no later than [***] prior to the end of such Calendar Year. In addition, the Joint Project Team may discuss any amendment to the Binding Budget pursuant to Section 6.2(d) and propose such amendment to the Joint Steering Committee for approval under Section 6.3.2(c). Notwithstanding the foregoing, from time to time, the Joint Project Team may approve any amendment to the Binding Budget with respect to the then-current Calendar Year under Section 6.2(e) without having to propose such amendment to the Joint Steering Committee, if the proposed amended Binding Budget will not deviate by [***] or more from the Binding Budget for such Calendar Year as of the first day of such Calendar Year.

3.3.2 Overspent Costs.

(a) Each Party shall promptly inform the other Party if it reasonably determines that it will or is likely to incur, or has incurred, any Shared Development Costs during any Calendar Year above [***] of the aggregate Shared Development Costs allocated to such Party in the Binding Budget with respect to such Calendar Year (the ***Overspent Costs***), such notice shall set out the amount of estimated or actual Overspent Costs in question (the ***Overspent Costs Notice***).

(b) Upon the submission of an Overspent Costs Notice from one Party to the other Party under Section 3.3.2(a), either Party may escalate the matter to the Joint Steering Committee. Upon such escalation, the Joint Steering Committee shall promptly (and in any event, no later than [***] after such escalation) discuss and decide whether the Binding Budget shall be amended.

(c) For the avoidance of doubt, if the Joint Steering Committee has approved an amendment to the Binding Budget for the relevant Calendar Year reflecting the Overspent Costs in question, such Overspent Costs shall continue to constitute Shared Development Costs.

(d) If the Joint Steering Committee has not approved an amendment to the Binding Budget for the relevant Calendar Year reflecting the Overspent Costs in question, then such Overspent Costs shall not be considered Shared Development Costs.

3.3.3 Reporting. Shared Development Costs and the Excluded Clinical Trial Costs shall initially be borne by the Party (or its Affiliate) incurring such cost or expense. Each Party shall report to the other Party, [***], the Shared Development Costs and any Excluded Clinical Trial Costs incurred by such Party (or its Affiliate) during [***]. Such report shall include

the details necessary to enable the receiving Party to compare the reported Shared Development Costs against the applicable Budget, including specifying in reasonable detail all Shared Development Costs and any Excluded Clinical Trial Costs incurred by such Party (or its Affiliate) during such [***], whereby all FTE Costs and out-of-pocket costs or expenses with respect to Shared Development Costs shall be allocated to the extent possible to a specific activity under the Development Plan. The Parties shall seek to resolve any questions related to such reports within [***] following receipt by each Party of the other Party's report hereunder.

3.3.4 Invoicing and Reconciliation of Shared Development Costs. Following the end of each [***]: (1) if Sanofi (or its Affiliates), but not Biontech (or its Affiliates), have incurred Shared Development Costs with respect to such Calendar Quarter, then Sanofi may submit an invoice to Biontech with respect to Biontech's share of the Shared Development Costs for such [***] in accordance with the scheme set out in Section 3.1; and (2) otherwise, the Shared Development Costs borne by each Party or its Affiliate with respect to such [***] shall be reported and reconciled as follows:

(a) no later than [***] days after the end of such [***] (provided that, Sanofi shall not be obliged to observe such timeframe if Biontech fails to provide the report described in, and within the [***] period set out in, Section 3.3.3), Sanofi shall submit to Biontech a proposed reconciliation report, setting out the particulars with respect to the reconciliation of the Shared Development Costs incurred by each Party or its Affiliate with respect to such [***]. For the purposes of such reconciliation, the Shared Development Costs incurred by each Party or its Affiliate shall be shared between the Parties in accordance with the scheme set out in Section 3.1;

(b) if Biontech disagrees with such reconciliation report, Biontech may, no later than [***] after Sanofi's submission of the proposed reconciliation report to Biontech, request the Joint Financial Committee to review such report under Section 6.5.2(a);

(c) (1) upon any confirmation by Biontech to Sanofi of its acceptance of such reconciliation report; (2) if Biontech has not requested the Joint Financial Committee to review and discuss such reconciliation report within the [***] period described in clause (b) above, upon the expiry of such [***] period; or (3) if Biontech has requested the Joint Financial Committee to review such reconciliation report within such [***] period, upon approval of such reconciliation report by the Joint Financial Committee:

(i) if the Shared Development Costs incurred by Biontech or its Affiliate in such [***] is less than its agreed share of Shared Development Costs during such [***], Sanofi or its Affiliate shall deliver an invoice to Biontech for any amounts due to Sanofi as a result of such reconciliation;

(ii) if the Shared Development Costs incurred by Sanofi or its Affiliate in such [***] is less than its agreed share of Shared Development Costs during such [***], Sanofi shall notify Biontech that Biontech should issue an invoice to Sanofi for any amounts due to Biontech as a result of such reconciliation,

(d) each Party shall pay the relevant reconciliation payment to the respective other Party within [***] days following receipt of the respective invoice from the other Party.

3.4 Records and Audit Rights. Each Party shall keep complete and accurate records for all of its Shared Development Costs, including the details of the FTEs allocated to the performance of its Co-Development Activities based on the actual hours of work spent on such performance. Each Party shall make such records available to the other Party upon request. For the avoidance of doubt, such records shall constitute the records reasonably necessary to verify the accuracy of the costs associated to the applicable Party's Development activities under Section 4.5 of the License Agreement, and the provisions of Section 4.5 of the License Agreement shall apply with respect to such records accordingly.

3.5 Payment. All payments to be made by one Party to the other Party under this Agreement shall be made in Euros by bank wire transfer without deduction for wire transfer fees in immediately available funds to such bank account designated in writing by the receiving Party to the paying Party from time to time.

3.6 Accounting and Currency. Shared Development Costs and Excluded Clinical Trial Costs shall be calculated, recorded and reported under this Agreement in accordance with the last updated IFRS and in Euros. In the case of Shared Development Costs and Excluded Clinical Trial Costs which are initially incurred in a currency other than Euros, exchange conversion of such amounts into Euros shall be made on a [***] basis and shall be made consistent with the incurring Party's normal practices used to prepare its audited financial statements for internal and external reporting purposes, which uses a widely accepted source of published exchange rates.

3.7 Taxes.

3.7.1 Each Party shall be solely responsible for the payment of all Taxes imposed on such Party's income arising directly or indirectly from the activities of the Parties under this Agreement. [***]

3.7.2 [***]

3.7.3 All payments between the Parties under this Agreement are exclusive of applicable statutory value added tax (***VAT***), if any, which shall be listed separately on each invoice. [***]

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4. Intellectual Property and Licensed Products.

4.1 Each Party acknowledges and agrees that:

4.1.1 Sanofi shall solely own all Know-how made, conceived or first reduced to practice:

(a) by or on behalf of Biontech (or its Affiliates) or jointly by or on behalf of the Parties (or their Affiliates) in the conduct of the Co-Development Activities, to the extent such Know-how: (i) is necessary or useful for Developing, Commercializing or otherwise using Licensed Product #1; (ii) if patented, would encompass an activity or composition that is necessary or useful for the Development, Commercialization or other use of Licensed Product #1; or (iii) is otherwise related to Licensed Product #1. [***]

(b) by or on behalf of Sanofi (or its Affiliates) in the conduct of the Co-Development Activities; and

(c) by or on behalf of either Party (or its Affiliates) or jointly by or on behalf of the Parties (or their Affiliates) in the conduct of activities in connection with the preparation of the clinical trials with respect to Licensed Product #1 [***] that were conducted before the effective date of the Original Agreement,

together (a), (b) and (c), the ***Sanofi Co-Development Know-how***.

4.1.2 Biontech shall solely own:

(a) all Know-how made, conceived or first reduced to practice by or on behalf of Biontech (or its Affiliates) in the conduct of the Co-Development Activities to the extent such Know-how does not constitute Sanofi Co-Development Know-how (the ***Biontech Co-Development Know-how***); and

(b) all CMC Know-how; and

(c) all Formulation Know-how.

4.2 As between the Parties:

4.2.1 Sanofi shall: (a) have the exclusive right (but not the obligation), at its sole expense and sole discretion, to control the Prosecution and Maintenance and enforcement of all Patent Rights claiming or otherwise covering any Sanofi Co-Development Know-how (the ***Sanofi Co-Development Patents***) and (b) solely own the Sanofi Co-Development Patents; and

4.2.2 Biontech shall: (a) have the exclusive right (but not the obligation), at its sole expense and sole discretion, to control the Prosecution and Maintenance and enforcement of all Patent Rights claiming or otherwise covering any Biontech Co-Development Know-how (the ***Biontech Co-Development Patents***) and all Patent Rights claiming or otherwise covering any CMC Know-how (the ***CMC Patents***) and (b) solely own the Biontech Co-Development Patents, the CMC Patents, and the Formulation Patents.

For the avoidance of doubt, for the purposes of interpretation of Section 1.48(b) and this Section 4.2, Sanofi Co-Development Know-how, Biontech Co-Development Know-how, CMC Know-how, and Formulation Know-how shall not cease to be Know-how to the extent it is disclosed or claimed by a Sanofi Co-Development Patent, Biontech Co-Development Patent, CMC Patent, or Formulation Patent (as applicable).

4.2.3 Sanofi shall have the exclusive right (but not the obligation), at its sole discretion, to control the Prosecution and Maintenance and enforcement of all Formulation Patents to the extent such Formulation Patents contain:

(i) [***]

(ii) [***]

(iii) [***] or

(iv) [***]

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4.3 For the purposes of Section 7.3.2(b)(ii) *(Co-Development and Co-Commercial License (Biontech Option Product) to Biontech*) of the License Agreement only, Sanofi Co-Development Technology shall constitute Sanofi Technology).

4.4 For the purposes of Section 7.3.1(b)(iii) (*Co-Development and Co-Commercial License (Sanofi Option Product) to Sanofi*) of the License Agreement, Biontech Co-Development Technology, CMC Technology, and Formulation Technology shall constitute Biontech Technology.

4.5 For the purposes of Section 1.88 (*Royalty Term*) of the License Agreement only, a Formulation Patent shall constitute a Licensed Product Patent.

4.6 Sanofi hereby grants to Biontech:

4.6.1 an exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.15), under the Sanofi Co-Development Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized Licensed Products outside of the Field and Discarded Mixtures;

4.6.2 an irrevocable, perpetual, royalty-free, fully paid-up, non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.15), under the Sanofi Co-Development Technology to research, have researched, Develop, have Developed, make, have made, Commercialize and have Commercialized any product in and outside the Field (excluding any Licensed Product and any Discarded Mixture); and

4.6.3 a non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide, royalty-free license, with the right to sublicense (subject to Section 4.15), under the Co-Development Background Technology of Sanofi to the extent required by Biontech for the co-Development and/or the co-Commercialization of Licensed Product #1 in accordance with this Agreement and/or Commercialization agreement concluded in relation to Licensed Product #1 under Section 4.1.3 of the License Agreement.

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4.7 Biontech hereby grants to Sanofi:

4.7.1 an exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.15), under the Biontech Co-Development Technology and the CMC Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized Licensed Products in the Field;

4.7.2 an irrevocable, perpetual, royalty-free, fully paid-up, non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.15), under the Biontech Co-Development Technology to research, have researched, Develop, have Developed, make, have made, Commercialize and have Commercialized any product in and outside the Field (excluding any Licensed Product and any Discarded Mixture);

4.7.3 an irrevocable, perpetual, royalty-free, fully paid-up, non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.15), under the Sanofi CMC Technology to research, have researched, Develop, have Developed, make, have made, Commercialize and have Commercialized products (other than Licensed Products and Discarded Mixtures) in the field of Intratumoral Administration of any agent for any indication;

4.7.4 a non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide, royalty-free license, with the right to sublicense (subject to Section 4.15), under the Co-Development Background Technology of Biontech to the extent required: (a) for the Development and Commercialization of Licensed Product #1 in the Field, and (b) by Sanofi for the co-Development and/or co-Commercialization of any Sanofi Option Product which constitutes Licensed Product #1 in accordance with the Development and/or Commercialization agreement concluded in relation to such Sanofi Option Product under Section 4.2.5 of the License Agreement.

4.7.5 an exclusive, non-transferable (except through assignment of the this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4) worldwide license, with the right to sublicense (subject to Section 4.15), under the Formulation Technology to Develop, have Developed, make, have made, Commercialize and have Commercialized Licensed Products in the Field; and

4.7.6 an irrevocable, perpetual, royalty-free, fully paid-up, non-exclusive non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.15) under the Formulation Technology to research, have researched, Develop, have Developed, make, have made, Commercialize and have Commercialized mRNA-based products (other than Licensed Products and Discarded Mixtures) in the field of Intratumoral Administration for any indication.

4.7.7 In the event BioNTech files any Patent Right covering an [***] formulation that:
(i) [***] and
(ii) [***] and
(iii) [***]
(iv) [***]
(v)[***]
before a Patent Right within the Formulation Technology publishes, then BioNTech hereby grants to Sanofi an irrevocable, perpetual, royalty-free, fully paid-up, non-exclusive, non-transferable (except through assignment of this Agreement pursuant to Section 13.4 of the License Agreement as incorporated into this Agreement under Section 11.4), worldwide license, with the right to sublicense (subject to Section 4.15) under such [***] formulation Patent Right to research, have researched, Develop, have Developed, make, have made, Commercialize and have Commercialized DNA-based uses and products.

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4.8 For the avoidance of doubt, Background Technology, Joint Collaboration Technology (other than for the purposes set out in Section 4.3) Biontech Collaboration Technology (other than for the purposes set out in Section 4.4), Licensed Product Patents, Sanofi Foreground Technology, Biontech Foreground Technology and Joint Foreground Technology shall exclude any Co-Development Technology, CMC Technology, and Formulation Technology, and Section 7.2.3 and the last sentence of Section 7.1 of the License Agreement shall not apply with respect to any Co-Development Technology, CMC Technology, or Formulation Technology.

4.9 With respect to the Co-Development Patents and CMC Patents, each Party shall (a) provide the other Party with written notice reasonably in advance of: (i) any filing of such Patent Rights for which it controls the Prosecution and Maintenance pursuant to Section 4.2 above; and (ii) any other substantive submissions and correspondence to patent office(s) with respect to the Prosecution and Maintenance of such Patent Rights; (b) provide the other Party with any final drafts of any application for such Patent Right to be filed or such substantive submission or correspondence (such application, submissions and correspondence, the ***Patent Documentation***) reasonably in advance of its filing or submission and consider in good faith the incorporation of reasonable comments by the other Party thereon; (c) provide the other Party with a copy of all Patent Documentation once it has been filed or otherwise submitted; (d) provide the other Party with copies of any substantive communications received from patent office(s) with respect to such Patent Rights; (e) notify the other Party of any: (i) [***] and (f) provide the other Party with written notice as early as possible (in any event, no later than [***] prior to abandoning any such

Patent Rights. Each Party shall cause its employees, agents or consultants, at its expense, to execute such documents and to take such other actions as reasonably necessary or appropriate to enable the other Party to prepare, file, Prosecute and Maintain such Patent Rights. In the event that either Party provides the other Party with the written notice described in clause (f) prior to abandoning any Patent Rights, then the other Party shall have the option, exercisable by delivery of written notice thereof within [***] thereafter, to assume the right (but not the obligation), at its sole expense and sole discretion, to control the Prosecution and Maintenance of such Patent Right.

4.10 Formulation Patents.

4.10.1 With respect to the Formulation Patents, (i) the Formulation Priority Application, as well as any Patent Rights filed within [***] of the filing date of the Formulation Priority Application; and (ii) any Formulation Patent that does not claim priority to the Formulation Priority Application, [***]. Additionally and also with respect to Formulation Patents, each Party will (i) provide the other Party's representative on the Joint Patent Committee copies of any material communications received from or filed in patent office(s); (ii) provide the other Party's representative on the Joint Patent Committee with drafts of any substantive submissions and correspondence to patent office(s) with respect to the Prosecution and Maintenance of such Patent Rights reasonably in advance of filing and consider in good faith the incorporation of reasonable comments by the other Party thereon; (iii) provide the other Party's representative on the Joint Patent Committee with copies of any filed substantive submissions and correspondence to patent office(s) with respect to the Prosecution and Maintenance of such Patent Rights; (iv) notify the other Party's representative on the Joint Patent Committee of [***] (v) notify the other Party's representative on the Joint Patent Committee of any intended request for patent term extension, supplemental protection certification or the like prior to the filing or submission of such request, which will be reviewed by the Joint Patent Committee before filing; and (vi) provide the other Party with written notice as early as possible (in any event, no later than [***] prior to abandoning any such Patent Rights. Each Party shall cause its employees, agents or consultants, at its expense, to execute such documents and to take such other actions as reasonably necessary or appropriate to enable the other Party to prepare, file, Prosecute and Maintain such Patent Rights. In the event that either Party provides the other Party with the written notice described in clause (vi) prior to abandoning any Patent Rights, then the other Party shall have the option, exercisable by delivery of written notice thereof within [***] thereafter, to assume the right (but not the obligation), at its sole expense and sole discretion, to control the Prosecution and Maintenance of such Patent Right. Neither Party shall file a terminal disclaimer in connection with a Formulation Patent without the written consent of the other Party. For clarity, with respect to Formulation Patents Prosecuted and Maintained by Sanofi pursuant to Section 4.2.3, Sanofi shall have the sole right (but not the obligation) to (i) use such Patent Rights for patent term extension (PTE) and supplementary protection certificate (SPC) and (ii) [***].

4.10.2 The Parties shall [***] share [***] (i) the costs for preparing and filing (a) the Formulation Priority Application and any other priority patent application(s) filed within [***] of the Formulation Priority Application, (b) PCT application(s) claiming priority to the Formulation Priority Application, and (c) national/ regional stage entries of PCT application(s) claiming priority to the Formulation

Priority Application; and (ii) application filing fees for non-divisional application(s) filed in non-PCT contracting states that claim priority to the Formulation Priority Application ((i) and (ii) the ***Shared Formulation Patent Costs***). [***] Sanofi shall have the right (but not the obligation) to file and validate Formulation Patents in additional countries at its costs, in the name of Biontech. Except for the Shared Formulation Patent Costs, Sanofi shall bear the Prosecution and Maintenance costs of Formulation Patents for which it controls Prosecution and Maintenance pursuant to Section 4.2.3 above. Except for the Shared Formulation Patent Costs, Biontech shall bear the Prosecution and Maintenance costs for Formulation Patents for which it controls Prosecution and Maintenance.

4.11 Patent Enforcement

4.11.1 Each Party (***Enforcing Party***) shall have the first right (but not the obligation), at its sole discretion, to control the enforcement or otherwise abate the infringement of any Patent Rights Prosecuted and Maintained by it in accordance with Section 4.2 above. [***].

4.11.2 [***]

4.12 Each Party shall perform such lawful acts and execute such documents as requested by the other Party from time to time in order to reasonably assist the other Party in the Prosecution and Maintenance and enforcement activities described in this Section 4.

4.13 Each Party shall ensure that all employees and other persons acting on its behalf in performing its obligations under this Agreement shall be obligated, either pursuant to Applicable Law or pursuant to a binding written agreement, to assign to it, or as it shall direct, all inventions made or conceived by such employees or other persons.

4.14 No rights or licenses with respect to any Intellectual Property Rights Controlled by either Party are granted or shall be deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement or the License Agreement.

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5. Profit Sharing.

For the avoidance of doubt, the profit sharing within the Biontech Territory pursuant to Section 4.1.6 of the License Agreement as well as the financial terms (e.g. milestone and royalty payments) agreed for countries outside the Biontech Territory pursuant to Section 6 of the License Agreement shall remain unaffected by this Agreement.

6. Governance.

6.1 Project Managers. Each Party shall designate a Development project manager (***Project Manager***) to act as its primary contact for all operational matters related to this Agreement. Each Project Manager shall be responsible for implementing and coordinating activities hereunder and facilitating the exchange of information between the Parties. Either Party may replace its Project Manager at any time by informing the other Party's Project Manager in advance in writing (which may be by email).

6.2 Joint Project Team. The Parties shall establish a joint project team (the ***Joint Project Team***) made up of the Project Manager and at least [***] other representatives from each Party, which shall be responsible for coordinating all activities under this Agreement. Each Party may replace any of its Joint Project Team representatives upon prior notice to the other Party. In particular, the Joint Project Team shall be responsible for:

(a) the review and discussion of the Development Plan and underlying objectives for Licensed Product #1 in the Field, [***]

(b) co-ordinating the implementation of the Development Plan and the associated Budget;

(c) the review and discussion of any proposed amendment or update to the Development Plan, whether during the annual review under Section 2.1.2 or from time to time during the Term, and the proposal of such amendment or update to the Joint Steering Committee for approval;

(d) the review and discussion of: (i) the Budget for the applicable period pursuant to the annual review under Section 3.3.1(b), taking into account of any comments provided by the Joint Financial Committee under Section 6.5.2(b) and the applicable forecast prepared by the Joint Financial Committee under Section 6.5.2(c); and (ii) any other proposed amendment to the Binding Budget, and the proposal of each such amended Budget to the Joint Steering Committee for approval;

(e) the review and approval of any proposed amendment(s) to the Binding Budget with respect to the then-current Calendar Year, provided that such Binding Budget shall not deviate by [***] or more from the Binding Budget for such Calendar Year as of the first day of such Calendar Year;

(f) the review and discussion of the proposal by either Party of any modification to the Licensed Product #1 [***]

(g) discussion and approval of which party should be responsible for the performance of which Co-Development Activities [***]

(h) discussion and approval of any Third Party proposed to be engaged by a Party to perform or assist with its obligations under this Agreement;

(i) review and discussion of any Co-Development Reports, and discuss and agree whether additional information should be included in future Co-Development Reports;

(j) oversight of all clinical and regulatory matters with respect to the Licensed Product #1 in the Field;

(k) the preparation and review of all material Regulatory Documentation with respect to the Licensed Product #1 in the Field;

(l) the coordination with the Joint Manufacturing Committee in relation to the CMC Development Plan and the forecasting of Drug Products for Clinical Trials (as defined in the Clinical Supply Agreement);

(m) discussion and agreement on target product profiles;

(n) periodically update the Joint Steering Committee with respect to Co-Development Activities performed and other relevant matters;

(o) facilitating the sharing of data and information between the Parties in relation to the Development activities under the Development Plan, regulatory filings and regulatory approvals;

(p) discussion and agreement of any alternative timeframe with respect to the discussion of, and submission to the Joint Financial Committee, a proposed Budget by the Joint Project Team as part of the annual review under Section 3.3.1(b); and

(q) any other responsibilities allocated to the Joint Project Team by the Joint Steering Committee.

6.3 Decisions of the Joint Project Team/Escalation/Joint Steering Committee.

6.3.1 The quorum for each Joint Project Team meeting shall be at least one (1) Joint Project Team representative from each Party. Each Party shall have one collective vote in all decisions of the Joint Project Team with respect to matters falling within its responsibility, and shall use good faith efforts to decide such matters unanimously. If consensus cannot be reached by the Joint Project Team, the relevant matter shall be escalated to the Joint Steering Committee for discussion and decision.

6.3.2 Each Party hereby acknowledges and agrees that, notwithstanding the last sentence of Section 11.2.2 of the License Agreement, the Joint Steering Committee shall be responsible for:

(a) the discussion and agreement of any matter escalated by the Joint Project Team or the Joint Financial Committee under Section 6.3.1 or Section 6.5.3 (as applicable) for resolution by the Joint Steering Committee;

(b) the discussion and agreement of updates to the Development Plan as part of the annual review under Section 2.1.2 or updates to the Budget as part of annual review under Section 3.3.1(b) on an annual basis, each such annual update shall be approved no later than [***] days prior to the end of the relevant Calendar Year;

(c) the discussion and agreement of any other amendment or update to the Development Plan or the Budget, and any amendment or update of the CMC Development Plan to allocate any CMC Activities for performance by Sanofi as referred by the Joint Manufacturing Committee under Section 2.8.5;

(d) the discussion and agreement of any modification to the Licensed Product #1 set out in Schedule B;

(e) [***] and

(f) the discussion and agreement of any alternative timeframe with respect to the review of, and submission to the Joint Steering Committee of, any updates to a Development Plan by the Joint Project Team, as part of an annual review under Section 2.1.2, in the case of (b) to (d), as proposed by the Joint Project Team to the Joint Steering Committee pursuant to Sections 6.2(c) or Section 6.2(d) (as applicable), or, in the case of (c) and with respect to the Budget, as proposed by either Party under Section 3.3.2 to reflect the Overspent Costs in question.

6.3.3 If the Joint Steering Committee cannot agree unanimously on any matter set out in Sections 6.3.2(a) to (d) (inclusive) and (f):

(a) if such matter constitutes an amendment or update to the then-current Binding Budget, which causes an increase of Biontech's aggregate share of budgeted Shared Development Costs with respect to [***] covered by then-current Binding Budget by an amount equal to [***] or more, the third and fourth sentences of Section 11.2.4 of the License Agreement and the first two sentences of Section 13.7 of the License Agreement shall apply (but the last two sentences of Section 13.7 of the License Agreement shall not apply). If the Parties' CEOs are unable to settle any dispute

with respect to such matter escalated to them within thirty (30) days from the date that the dispute has been escalated to the CEOs, then Sanofi shall have the deciding vote with respect to such matters; and

(b) otherwise, the third and fourth sentences of Section 11.2.4 of the License Agreement and the last three sentences of Section 13.7 of the License Agreement shall not apply with respect to such matters, and Sanofi shall have a deciding vote with respect to such matters (for the avoidance of doubt, without having to escalate such matter to the Parties' CEOs).

For the avoidance of doubt, any matter set out in Section 6.3.3(a) which is so decided by the Parties' CEOs pursuant to Section 13.7 of the License Agreement and any matter set out in Sections 6.3.3(a) and 6.3.3(b) which is so decided by Sanofi through its exercise of its deciding vote, shall be treated as having been agreed or approved by the Joint Steering Committee for the purposes of this Agreement.

6.3.4 If, during each of Calendar Year [***], Sanofi exercises its final decision-making authority to approve any amendment or update to the Binding Budget (covering any such Calendar Year) which causes an increase in Biontech's share of Shared Development Costs with respect to such Calendar Year (compared with its share of Shared Development Costs had such amendment or update to the Binding Budget not been implemented), then Biontech shall not be required to pay to Sanofi the amount of such increase (the ***Additional Co-Development Costs***) [***] provided that: (i) Biontech shall not be required to pay more than [***].

6.3.5 The Joint Project Team shall not have the authority to amend or modify the terms and conditions of this Agreement or the License Agreement (save for the amendment of the Development Plan and the Budget in accordance with this Section 6.3) or to waive any obligation of either Party under this Agreement or the License Agreement.

6.4 Meetings of the Joint Project Team. The Joint Project Team shall meet no less than once every [***] months, and more often as reasonably considered necessary at the request of either Party, to, among other matters, provide an update on the progress of the Development activities hereunder. The Joint Project Team may meet in person or by means of teleconference, internet conference, videoconference or other similar communications equipment, provided that at least [***] meeting shall be conducted in person in each Calendar Year. Minutes of all meetings of the Joint Project Team shall be prepared by or on behalf of such representative of the Joint Project Team of either Party as the Joint Project Team may

from time to time agree and shall be transmitted by such representative of such Party to all members of the Joint Project Team within [***] days after the date of the meeting. The minutes shall be deemed to be approved by the other Party if the other Party does not object within [***] days of receipt.

6.5 Joint Financial Committee.

6.5.1 Each Party shall designate [***] representatives which together shall constitute the joint financial committee (***Joint Financial Committee***). Each Party may replace any of its Joint Financial Committee representatives upon prior notice to the other Party.

6.5.2 The Joint Financial Committee shall be responsible for:

(a) review and approval of any reconciliation report as requested by Biontech under Section 3.3.4(b);

(b) review of the proposed Budget submitted by the Joint Project Team under Section 3.3.1(b), and submission of any comments to the Joint Project Team with respect to such proposed Budget within [***] of its receipt of the proposed Budget from the Joint Project Team;

(c) during each Calendar Quarter, preparation of a forecast of Shared Development Costs reasonably expected to be incurred by each Party with respect to the immediately subsequent Calendar Quarter; and

(d) preparation of necessary documentation to support strategic financial decisions of the Joint Steering Committee in connection with the Development Plan.

6.5.3 The quorum for each Joint Financial Committee meeting shall be at least one (1) representative from each Party. Each Party shall have one collective vote in all decisions of the Joint Financial Committee with respect to matters falling within its responsibility, and shall use good faith efforts to decide all such matters unanimously. If consensus cannot be reached by the Joint Financial Committee, the relevant matter shall be escalated to the Joint Steering Committee for discussion and decision. If the Joint Steering Committee cannot agree on such matter unanimously, the third sentence of Section 11.2.4 (and accordingly Section 13.7) of the License Agreement shall apply with respect to such matter accordingly, except that, the reference to "Parties' CEOs" in Section 13.7 shall instead be deemed to be a reference to Biontech's CEO and Sanofi's Chief Financial Officer with respect to such matter, and any such matter to the extent approved or agreed by the Joint Steering Committee or Biontech's CEO and Sanofi's Chief Financial Officer under Section 13.7 of the License Agreement (as applicable) shall be treated as having been agreed or approved by the Joint Financial Committee for the purposes of this Agreement. The Joint Financial Committee shall not have the authority to amend or modify the terms and conditions of this Agreement or the License Agreement or to waive any obligation of either Party under this Agreement or the License Agreement.

6.6 Joint Patent Committee

6.6.1 Each Party shall designate [***] shall constitute the joint patent committee (***Joint Patent Committee***). Each Party may replace its Joint Patent Committee [***] upon notice to the other Party.

6.6.2 The Joint Patent Committee shall be responsible for:

(a) review and approval of Prosecution and Maintenance decisions regarding Formulation Patents as per Section 4.10.1;

(b) review and approval of Patent Documentation related to Formulation Patents as per Section 4.10.1;

(c) reconciliation of Shared Formulation Patent Costs.

6.6.3 [***]

7. Pharmacovigilance and Regulatory Matters.

7.1 Regulatory Matters. Sanofi or its Affiliate shall have the exclusive right (but not the obligation) to file, submit and maintain any Regulatory Documentation in its name (and such Regulatory Documentation, to the extent filed by Sanofi or its Affiliate, shall be the sole property of Sanofi (or its Affiliate, as applicable)), unless otherwise agreed between the Parties. Without limiting the foregoing, Sanofi or its Affiliate shall be the holder of the Marketing Approval for any Licensed Product #1 in the Field to the extent the relevant applications have been filed by Sanofi or its Affiliate. Sanofi shall lead all interactions with all Regulatory Authorities in all regions. [***]

Biontech shall have the right (but not the obligation) to participate in and attend with Sanofi (with not less than two representatives from Biontech) all meetings with Regulatory Authorities in the Biontech Territory, to the extent permitted by the relevant Regulatory Authority and Applicable Law.

7.2 Pharmacovigilance. To the extent Sanofi or its Affiliate is the sponsor of a clinical trial with respect to a Licensed Product #1 in the Field, Sanofi or its Affiliate shall be the host of the clinical and pharmacovigilance related databases with respect to such clinical trial and shall be responsible for compliance with all Applicable Laws pertaining to the safety of such Licensed Product #1. Each Party shall comply with its respective obligations under the Safety Data Exchange Agreement entered into between the Parties dated October 4, 2018 (***SDEA***). For the avoidance of doubt, such agreement shall constitute a "SDEA" under Section 3.2.3 of the License Agreement.

8. Confidentiality and Data Privacy

8.1 For the avoidance of doubt: (a) any information disclosed by one Party to the other Party pursuant to this Agreement (including through any audit or inspection conducted pursuant to this Agreement or during any meeting of the Joint Project Team, Joint Steering Committee, Joint Manufacturing Committee or the Joint Financial Committee) shall constitute information related to the subject matter of the License Agreement for the purposes of the definition of "Confidential Information" under the License Agreement, and the provisions in such definition and Section 8 of the License Agreement shall apply to such information accordingly; and (b) the Sanofi Co-Development Technology, Co-Development Background Technology of Sanofi, Regulatory Documentation filed by Sanofi or its Affiliate and Clinical Data shall constitute Sanofi's Confidential Information (in respect of which Sanofi is the Disclosing Party and Biontech the Receiving Party) and the Biontech Co-Development Technology, CMC Technology and Co-Development Background Technology of Biontech shall constitute Biontech's Confidential Information (in respect of which Biontech is the Disclosing Party and Sanofi the Receiving Party).

8.2 Notwithstanding any other term of this Agreement, neither Party shall, or shall be required to, transfer to the other Party, any personal data if either Party, acting reasonably, determines that such transfer or any subsequent processing of such personal data would not comply with any Applicable Laws relating to the transfer and processing of such personal data. Each Party shall ensure that any transfer and subsequent processing of such personal data by it under or in connection with this Agreement is lawful, and if required the Parties shall negotiate in good faith and seek to enter into such agreements as are reasonably required to ensure the same, including, where applicable, entering into the Standard Contractual Clauses published by the European Commission. For the purposes of this Section 8.2, "personal data" and "process" shall be construed in accordance with the EU General Data Protection Regulation 2016/679.

9. Term and Termination.

9.1 Term. This Agreement shall be effective from the Effective Amendment Date and shall continue until the completion of all Co-Development Activities and CMC Activities, unless terminated earlier in accordance with Section 9.2 or otherwise agreed between the Parties (the ***Term***).

9.2 Termination.

9.2.1 This Agreement shall terminate automatically:

(a) in the event of any termination or expiry of the License Agreement in its entirety;

(b) in the event of any termination of the License Agreement on a Licensed Product-by-Licensed Product basis, where such Licensed Product is Licensed Product #1, under Section 12.3.1 or Section 12.3.2 of the License Agreement; or

(c) in the event of any termination of the Co-Development of an Option Product under Section 12.2.2 or Section 12.3.4 of the License Agreement, where such Option Product is Licensed Product #1.

9.2.2 Either Party may terminate this Agreement with immediate effect by written notice to the other Party:

(a) if the other Party materially breaches any of its material obligations hereunder and fails to cure such breach [***] following its receipt of written notice thereof from the first Party. In the event of a dispute between the Parties as to whether a material breach has occurred, either Party may refer such dispute to the dispute resolution process set out in Section 13.7 of the License Agreement. Any right to terminate under this Section 9.2.2(a) or Section 12.3.4 of the License Agreement and the cure period shall be suspended in the event that, during the cure period, the Party alleged to have been in material breach shall have in good faith initiated dispute resolution in accordance with Section 13.7 of the License Agreement with respect to the alleged breach, which suspension shall continue until such dispute has been resolved in accordance with Section 13.7 of the License Agreement; or

(b) if the other Party breaches its payment obligations under this Agreement with respect to an aggregate outstanding amount of at least [***] and such Party fails to cure such breach within [***] following its receipt of written notice thereof from the first Party.

9.3 Consequences of Termination or Expiry.

9.3.1 *General consequences*.

(a) In the event of any termination or expiry of this Agreement:

(i) within [***] days of such termination or expiry, each Party shall return or deliver to the other Party all of the other Party's Confidential Information disclosed to such Party under this Agreement, as well as any of the other Party's materials delivered by the other Party under this Agreement, provided that each Party shall be permitted to retain and use any Confidential Information of the other Party which is necessary or useful for such Party to exercise any remaining rights or perform its remaining obligations under this Agreement or under the License Agreement; and

(ii) within [***] days of such termination or expiry, the Parties shall reconcile the Shared Development Costs incurred prior to the date of such termination or expiry (to the extent not previously reconciled under Section 3.3.4), in accordance with the principles set out in Sections 3.1 and 3.2, and shall promptly make any required payments to the other Party as a result of such reconciliation. Except as set forth in Sections 9.3.2(a)(iii) and 9.3.2(c), any Additional Co-Development Costs, to the extent not already paid by Biontech as of the date of such termination or expiry, shall become immediately payable by Biontech.

9.3.2 *Specific consequences.*

(a) In the event of any termination of this Agreement as a result of Sanofi's termination of the entirety of the License Agreement under Section 12.2.1 (*Termination by Sanofi for convenience*) of the License Agreement, in addition to the termination events set out in Section 12.4.2 of the License Agreement:

(i) at Biontech's written request, Sanofi shall: (1) transfer control to Biontech of any ongoing clinical trial being conducted by or on behalf of Sanofi under the Development Plan as of the effective date of termination and (2) continue to conduct such clinical trial (the costs of which as between the Parties, and the invoicing and reconciliation of such costs, shall continue to be governed by Section 3), for up to [***] months to enable such transfer to be completed without interruption of any such clinical trial, whereupon after such transfer Biontech will assume the costs of such clinical trial, provided that, with respect to any such clinical trial for which such transfer is expressly prohibited by the applicable Regulatory Authority, Sanofi shall continue to conduct such clinical trial to completion, at Sanofi's cost and expense;

(ii) the licenses granted to Biontech under Section 4.6 of this Agreement shall survive; and

(iii) for any Additional Co-Development Costs, to the extent not already paid by Biontech as of the date of such termination, the payment schedule pursuant to Section 6.3.4 shall continue to apply.

(b) In the event of any termination of this Agreement as a result of Biontech's termination of co-Development of Licensed Product #1 under Section 12.2.2 (*Termination of co-development by Biontech for convenience*) of the License Agreement, for the avoidance of doubt, (i) the termination consequences set forth in Section 12.4.4 of the License Agreement shall apply; and (ii) the licenses granted to Sanofi under Sections 7.3.1 and 7.3.3(ii) of the License Agreement and under Section 4.7 of this Agreement shall survive.

(c) In the event of any termination of this Agreement as a result of Biontech's termination of the License Agreement under Section 12.3.1 (*Termination for Sanofi's breach*) or Section 12.3.3 (*Termination for Sanofi's insolvency)* of the License Agreement, whether in its entirety or with respect to Licensed Product #1 only, in addition to the termination events set out in Section 12.4.6 of the License Agreement, (1) Section 9.3.2(a)(i) of this Agreement shall apply with respect to any ongoing clinical trial conducted by or on behalf of Sanofi under the Development Plan as of the effective date of such termination; (2) the Clinical Supply Agreement shall automatically terminate with respect to Licensed Product #1 (and such termination shall be treated as a termination by Sanofi pursuant to Section 12.3(c) of the Clinical Supply Agreement); (3) the licenses granted to Biontech under Section 4.6 of this Agreement shall survive; and (4) for any Additional Co-Development Costs, to the extent not already paid by Biontech as of the date of such termination, the payment schedule pursuant to Section 6.3.4 shall continue to apply.

(d) In the event of any termination of this Agreement as a result of Sanofi's termination of the License Agreement under Section 12.3.2 (*termination for Biontech's breach*) or Section 12.3.3 (*termination for Biontech's insolvency*) of the License Agreement (whether in its entirety or with respect to Licensed Product #1 only), in addition to the termination events set out in Section 12.4.8 of the License Agreement:

(i) within [***] after such date of termination, Biontech shall provide to Sanofi a report containing the details set out in Section 2.5(a) to (d)

with respect to the Co-Development Activities performed by or on behalf of Biontech prior to the date of such termination, to the extent not previously reported to Sanofi under Section 2.5;

(ii) promptly upon Sanofi's request: (1) Biontech shall assign (or, in the case of agreements relating to Licensed Product #1 and other products being Developed or Commercialized by Biontech, partially assign) to Sanofi, to the extent assignable (or partially assignable, as applicable), Biontech's rights in any or all agreements with Biontech's Approved Co-Development Third Parties to the extent related to the Co-Development Activities; and (2) Biontech shall provide copies of such agreements to Sanofi. To the extent that any such agreement is not assignable (or partially assignable, as applicable) by Biontech, then such agreement shall not be assigned (or partially assigned, as applicable), and upon the request of Sanofi, Biontech shall cooperate with Sanofi in good faith and allow Sanofi to obtain and to enjoy the benefit of such agreement (or, in the case of any agreement relating to Licensed Product #1 and other products being Developed or Commercialized by Biontech, such agreement to the extent relating to Licensed Product #1) in the form of a license or such other rights;

(iii) to the extent the Manufacturing process with respect to Licensed Product #1 has not completely transferred to Sanofi pursuant to Section 3.3.4 of the License Agreement, at Sanofi's request: (1) Biontech shall transfer such Manufacturing process to Sanofi or its designee or (2) continue to supply to Sanofi with clinical quantities of Licensed Product #1 in the Field subject to a supply agreement to be negotiated and agreed in good faith between the Parties, until the earlier of: (i) [***] after the effective date of termination; or (ii) such Manufacturing process having been completely transferred to Sanofi, or establishment by Sanofi of an alternative supply for such Licensed Product on commercially reasonable terms; and

(iv) Biontech shall, at Sanofi's written request, (a) transfer control to Sanofi of any ongoing clinical trial being conducted by or on behalf of Biontech under the Development Plan as of the effective date of termination and (b) continue to conduct such clinical trials, at Biontech's cost in the case of termination of the License Agreement under Section 12.3.2 (*termination for Biontech's breach*) of the License Agreement, and at Sanofi's cost in the case of termination under Section 12.3.3 (termination for Biontech's insolvency) of the License Agreement in the case of, for up to [***] to enable such transfer to be completed without interruption of any such clinical trial, whereupon after such transfer Sanofi will assume the costs of such clinical trial, provided that, with respect to any such clinical trial for which such transfer is expressly prohibited by the applicable Regulatory Authority, Biontech shall continue to conduct such clinical trial to completion, at Biontech's cost and expense;

(e) In the event of any termination of this Agreement as a result of Sanofi's termination of the co-Development of Licensed Product #1 under Section 12.3.4 (*termination for Biontech's breach of co-development obligations*) of the License Agreement or any termination by Sanofi of this Agreement under Section 9.2.2, for the avoidance of doubt, Section 12.4.9 of the License Agreement shall apply, and the following provisions shall apply in addition:

(i) Biontech shall grant to Sanofi: (a) an exclusive, transferable, worldwide license, with the right to sublicense (subject to Section 7.3.4 of the License Agreement), under the Biontech Background Technology in Schedule D of the License Agreement, Biontech's interest in the Joint Collaboration Technology (if any), Biontech Co-Development Technology and Biontech Foreground Technology to Develop, have Developed,

make, have made, Commercialize and have Commercialized Licensed Product #1 in the Field; and (b) a non-exclusive, transferable, worldwide license, with the rights to sublicense (subject to Section 7.3.4 of the License Agreement), under the Biontech Background Technology (to the extent not set out in Schedule D of the License Agreement) to Develop, have Developed, make, have made, Commercialize and have Commercialized Licensed Product #1 in the Field. For the avoidance of doubt, the foregoing licenses shall not limit Section 7.3 of the License Agreement, and shall not be affected by any termination of the License Agreement (whether in its entirety or with respect to a product). For the purposes of Section 7.3.4(a) of the License Agreement, the phrase "the rights granted to such Party pursuant to Section 7.3.1 to 7.3.3" shall be deemed to also include the rights granted to Sanofi under this Section 9.3.2(e)(i), and for the purposes of Section 7.3.4(b) of the License Agreement, the phrase "the rights granted to it under Section 7.3.1(b) or 7.3.2(b)" shall be deemed to also include rights granted to Sanofi under this Section 9.3.2(e)(i);

(ii) the licenses granted to Sanofi under Section 4.7 shall survive;

(iii) Biontech shall no longer have the right to co-Develop or co-Commercialize Licensed Product #1;

(iv) any milestones payable by Sanofi pursuant to Section 6 of the License Agreement with respect to Licensed Product #1 shall be reduced by [***] and any royalties payable by Sanofi pursuant to Section 6 of the License Agreement to the extent relating to the Net Sales of Licensed Product #1 shall be reduced by [***] and

(v) the events set out in Section 9.3.2(d)(i) to (iv) shall apply.

9.3.3 Survival. Upon the expiry or termination of this Agreement, the provisions of this Agreement shall no longer be of any force or effect, save for the following provisions which shall survive such expiry or termination: Sections 1, 2.6.1 (for the duration set out therein), 2.7 (first sentence), 4 (in accordance with Sections 4.16 and 9.3.2), 8.1, 9.3, 10 and 11 (including the Sections of the License Agreement as incorporated into this Agreement under Section 11.4).

10. Disclaimer of Warranties; Limitation of Liability

10.1 For the avoidance of doubt, the Co-Development Activities constitute Development to be conducted under the License Agreement, and accordingly the provisions of Section 9.3 of the License Agreement shall apply accordingly.

10.2 For the avoidance of doubt, Section 10.3 of the License Agreement shall also apply with respect to this Agreement.

11. General Provisions.

11.1 This Agreement shall be governed by the laws of Germany without reference to its conflict of laws provision. Any dispute arising out of this Agreement shall be constitute a dispute arising between the Parties in connection with the License Agreement, and accordingly Section 13.7 and the second, third and fourth sentences of Section 13.8 of the License Agreement shall apply to any such dispute, subject to Sections 2.8.5, 6.3 and 6.5.3.

11.2 This Agreement (including the Schedules to this Agreement), together with the License Agreement and the Clinical Supply Agreement, represent the entire understanding between the Parties with respect to the subject matter hereof and supersedes all previous oral or written communication or agreements, and all contemporaneous oral communication and agreements between the Parties. Each Party acknowledges and agrees that, if there is any conflict between any provision of this Agreement and any provision of the License Agreement or the Clinical Supply Agreement, such provision of this Agreement shall prevail to the extent of such conflict.

11.3 This Agreement many only be amended, modified or supplemented by the Parties in writing. The same applies to this Section 11.3.

11.4 Sections 13.1, 13.4, 13.5, 13.6, 13.9 and 13.10 of the License Agreement shall be incorporated by reference into this Agreement (and any reference to "this Agreement" in each such incorporated provision shall be construed as a reference to this Agreement).

[*Signatures on the Following Page*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

SANOFI

By: /s/ Alban de La Sablière

Alban de La Sablière,

Head of Sanofi Partnering

BIONTECH RNA PHARMACEUTICALS GMBH

By: /s/ Dr. Sierk Poetting

Dr. Sierk Poetting,

Managing Director

Schedule A - Approved Co-Development Third Parties

Approved Co-Development Third Parties of Sanofi:

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Approved Co-Development Third Parties of Biontech:

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Schedule B –Licensed Product #1

SAR441000 - A Mixture containing the following:

- mRNA encoding Interferon alpha
- mRNA encoding IL12
- mRNA encoding IL15sushi
- mRNA encoding GM-CSF

Schedule C – Development Plan

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Schedule E – [***] Formulation for SAR441000

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THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

SIXTH AMENDMENT TO LEASE AGREEMENT

THIS SIXTH AMENDMENT TO LEASE AGREEMENT (this "**Sixth Amendment**") is dated August 2, 2021 and hereby effective as of August 4, 2021 ("**Effective Date**"), between **TECH PARK 270 III, LLC**, a Maryland limited liability company, having an address at 26 North Euclid Avenue, Pasadena, California 91101 ("**Landlord**"), and **BIONTECH US INC**., a Delaware corporation, having an address at Suite 110, 40 Erie Street, Cambridge, Massachusetts 02139 ("**Tenant**").

RECITALS

A. Landlord and Kite Pharma, Inc., a Delaware corporation ("**Kite**"), have entered into that certain Lease Agreement ("**Original Lease**") dated as of December 1, 2017, as amended and/or affected by that certain First Amendment to Lease Agreement dated January 29, 2018 ("**First Amendment**"), that certain Second Amendment to Lease Agreement dated February 26, 2018 ("**Second Amendment**"), that certain Third Amendment to Lease Agreement dated September 24, 2018 ("**Third Amendment**") that certain Fourth Amendment to Lease Agreement dated May 23, 2019 ("**Fourth Amendment**"), that certain Fifth Amendment to Lease Agreement dated July 7, 2020 ("**Fifth Amendment**"), that certain Expansion Premises Work Letter dated July 7, 2020 ("**Work Letter**"), that certain letter agreement dated June 23, 2020 (the "**June Letter Agreement**"), that certain letter agreement dated July 23, 2020 ("**July Letter Agreement**"), and that certain that certain Acknowledgement of Commencement Date dated December 7, 2017 ("**Acknowledgment of Commencement Date**" and, together with the Original Lease, the First Amendment, the Second Amendment, the Third Amendment, the Fourth Amendment, the Fifth Amendment, the Work Letter, the June Letter Agreement and the July Letter Agreement, the "**Lease**"), wherein Landlord leased to Tenant approximately [***] rentable square feet ("**Premises**") located at Suite 200, 930 Clopper Road, Gaithersburg, Maryland 20878-1301, as more particularly described in the Lease.

B. Landlord, Kite, and Tenant entered into that certain Consent to Assignment dated as of August 2, 2021 ("**Consent**") wherein Landlord consented to the assignment of the Lease from Kite to Tenant since such assignment was not a Permitted Assignment.

C. Landlord and Tenant desire to amend the Lease, among other things, to extend the Base Term for a period of 34 months from the current expiration date of September 30, 2030 to July 31, 2033.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing Recitals, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree that the Lease is amended as follows:

1. **Definitions; Recitals**. Terms used in this Sixth Amendment but not otherwise defined shall have the meanings set forth in the Lease. The Recitals form an integral part of this Sixth Amendment and are hereby incorporated by reference.

2. **First Extension Term**. The Base Term expires at midnight on September 30, 2030. The Base Term is hereby extended, such that it shall run for an additional period ("**First Extension Term**") beginning on October 1, 2030 and, unless earlier terminated or extended in accordance with the terms and conditions of the Lease, expiring 34 months thereafter (i.e., July 31, 2033). For purposes of the Lease, "**Term**" shall mean, collectively, the Base Term and the First Extension Term.

3. **Base Rent for First Extension Term**. During the First Extension Term, the Base Rent for the Premises shall be increased on each anniversary of the Adjustment Date (i.e., October 1 of each year)),

by multiplying the monthly Base Rent payable immediately before such Adjustment Date by the Rent Adjustment Percentage (i.e., [***]%) and adding the resulting amount to the monthly Base Rent payable immediately before such Adjustment Date, as set forth in Section 4 of the Lease. The Parties acknowledge that the first Adjustment Date after the Effective Date shall occur on October 1, 2021. Base Rent, as so adjusted, shall thereafter be due as provided in Section 4 of the Lease.

4. **Amendment to Basic Lease Provisions (Tenant's Notice Address)**. Tenant's Notice Address under the Lease is hereby changed to the following:

Tenant's Notice Address:

[***]
[***]
[***]
[***]

With copies via e-mail to:

[***]
[***]
[***]

5. **Identification Signage**. Notwithstanding any contrary provision contained in Section 38(b) of the Lease, Tenant shall have the right to install and affix the Identification Signage on the façade of the Building facing Clopper Road subject to the terms and conditions as more fully set forth in Section 38(b) of the Lease.

6. [***]

7. **Roof Equipment**. Notwithstanding any contrary provision contained in Section 41 of the Lease, Tenant shall have the right (and, where applicable, the obligation) to install, maintain, and remove the Roof Equipment on the top of the roof the Building subject to the terms and conditions as more fully set forth in Section 41 of the Lease.

8. **Landlord Representations**. Landlord represents and warrants to Tenant that (i) the Lease, as amended by this Sixth Amendment, represents the entire agreement between Landlord and Tenant and there are no further or other instruments or agreements, written or verbal, between Landlord and Tenant regarding the lease of the Premises, (ii) Tenant is not in default pursuant to the terms of the Lease, and to Landlord's Knowledge (as defined below), no event has occurred that, with the passage of time, or the giving of notice, or both, would constitute a default by Tenant under the Lease, (iii) both the Commencement Date and the Expansion Premises Commencement Date have occurred; (iv) [***]. For purposes of this paragraph, "**Landlord's Knowledge**" means the current actual knowledge after reasonable inquiry of Lawrence J. Diamond, Co-Chief Operating Officer of Alexandria Real Estate Equities, Inc. In no event whatsoever shall Mr. Diamond have any personal liability under this Sixth Amendment.

9. **Miscellaneous**.

a. This Sixth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Sixth Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Sixth Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

c. This Sixth Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000), or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Sixth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Tenant and Landlord represents and warrants to the other that neither has dealt with any broker, agent, or other person (collectively, "**Broker**") in connection with this Sixth Amendment and that no Broker brought about this transaction by or through the actions of such party. Landlord and Tenant hereby agrees to indemnify and hold each other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with either Landlord or Tenant, respectively, with regard to this Sixth Amendment.

e. Except as amended and/or modified by this Sixth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Sixth Amendment. In the event of any conflict between the provisions of this Sixth Amendment and the provisions of the Lease, the provisions of this Sixth Amendment shall prevail. Regardless of whether specifically amended by this Sixth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Sixth Amendment. All references in the Lease to the "Lease" shall be deemed to be a reference to the Lease as amended by this Sixth Amendment.

[SIGNATURES APPEAR ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Sixth Amendment under seal as of the day and year first above written.

TENANT:

BIONTECH US INC.,
a Delaware corporation

By: /s/ Richard Gaynor (SEAL)
Name: Richard Gaynor
Title: President

LANDLORD:

TECH PARK 270 III, LLC,
a Maryland limited liability company

By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company,
managing member

By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company,
managing member

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By:_____(SEAL)
Name:_____
Title:_____

IN WITNESS WHEREOF, the parties hereto have executed this Sixth Amendment under seal as of the day and year first above written.

TENANT:

BIONTECH US INC.,
a Delaware corporation

By: /s/ Richard Gaynor _____(SEAL)
Name: Richard Gaynor
Title: President

LANDLORD:

TECH PARK 270 III, LLC,
a Maryland limited liability company

By: ARE-MM Tech Park 270 III, LLC,
a Delaware limited liability company,
managing member

By: ARE-930 Clopper Road, LLC,
a Delaware limited liability company,
managing member

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS CORP.,
a Maryland corporation,
general partner

By: /s/ Gregory Kay _____(SEAL)
Name: Gregory Kay
Title: Senior Vice President
Real Estate Legal Affairs

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

Side Letter No 5

to

LICENSE AND COLLABORATION AGREEMENT

by and between

BioNTech SE

and

Genmab A/S

This Side Letter No 5 is made and entered into as of 12th August 2021 (***Side Letter No 5 Effective Date***) by and between **BioNTech SE**, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany **(*Biontech*)** and **Genmab A/S**, CVR no. 21023884, a Danish corporation having its principal office at Kalvebod Brygge 43, DK-1560 Copenhagen V, Denmark, (***Genmab***) (Biontech and Genmab each a ***Party*** and together the ***Parties***).

PREAMBLE

WHEREAS, the Parties entered into a License and Collaboration Agreement as of 19th May 2015, with subsequent amendments and side letters ("Agreement") under which the Parties collaborate with respect to research, development and commercialization of among others the Collaboration Products [***];

WHEREAS, the Parties would like to develop [***] and Genmab has entered into a certain [***] (said agreement is hereinafter referred to as the "[***]") under which [***], ("[***]") would conduct certain work with such objective under specific Project Schedules (as defined below) executed under the [***];

WHEREAS, the Parties would inter alia like i) to clarify how ownership of intellectual property arising under the [***] will be treated under the Agreement and ii) to ensure that Genmab has the necessary rights to grant the licenses under the [***] to [***];

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, and for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree to the following:

1. Except as otherwise defined herein, the words and phrases in the Agreement shall have the same meaning in this Side Letter No 5.

2. DEFINITIONS

[***]

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3. Genmab has provided a copy of the executed version of the [***] to a limited group of representatives of Biontech under the [***] dated 6th January between [***], Biontech and Genmab US, Inc., subject to the letter agreement between Biontech and Genmab US, Inc. dated 4th June 2021. The [***] is hereby incorporated into this Side Letter No 5 by reference. Notwithstanding Section [***] of the [***], the Parties and [***] have agreed that any [***] IP generated under Project Schedule [***] shall be equally and jointly owned by

[***]. Project Schedule [***] is hereby incorporated into this Side Letter No 5 by reference. In case Genmab and [***]negotiate an amendment to the [***] that relates to and/or affects a [***] Project Schedule that has been entered into in accordance with Section 4 below, Genmab shall involve Biontech in the process by (i) [***] and (ii) [***] Genmab and [***] shall not amend the [***] in a way that adversely affects Biontech's rights with respect to a [***] Project Schedule that has been entered into in accordance with Section 4 below, without obtaining Biontech's prior written consent, which can be provided via e-mail and which shall not be unreasonably withheld or delayed. The Parties acknowledge and agree that this Side Letter shall only apply to [***]

collectively, "[***] Project Schedules".

Genmab acknowledges and agrees that the [***] Project Schedules are subject to the approval of Biontech in accordance with Section 4 below. Furthermore, Genmab acknowledges and agrees that it shall use commercially reasonable efforts to negotiate with [***] to secure that [***] IP generated under all future executed [***] Project Schedules shall be jointly and equally owned by [***].

4. Subject to the terms and conditions of this Side Letter No 5, Biontech hereby accepts and agrees

   a) that Genmab may enter into t the [***] Project Schedules under the [***] and that the terms of the [***] will be applicable to such [***] Project Schedules; provided, however, Genmab discloses the initial version of the relevant [***] Project Schedules (including the budget) to Biontech for review. Genmab shall continue to consult in good faith with Biontech throughout the negotiation of the [***] Project Schedules and shall not execute any [***] Project Schedules without Biontech's prior written consent, which can be provided via e-mail and which shall not be unreasonably withheld or delayed; and

   b) that Genmab may enter into any Change Orders to any [***] Project Schedules and that the terms of the [***] will be applicable to such Change Orders; provided, however, Genmab discloses the initial version of the relevant Change Order (including changes to the budget, if any) to Biontech for review. Genmab shall continue to consult in good faith with Biontech throughout the negotiation of the relevant Change Order and shall not execute any Change Order to a [***] Project Schedule without Biontech's prior written consent,

which can be provided via e-mail and which shall not be unreasonably withheld or delayed.

Biontech agrees to adhere to the terms of the [***] with respect to any subject matter covered by any [***] Project Schedule(s) (as amended by any Change Order(s)) that have been entered into in accordance with this Section 4. In case any work performed by Genmab under such [***] Project Schedule(s) or the fulfilment by Genmab of any of its obligations under such [***] Project Schedule(s) or the [***] requires a deviation from the terms of the Agreement, Biontech consents to the performance of such work or fulfilment by Genmab of such obligations, *provided, however*, that (i) Biontech is named third party beneficiary under the relevant [***] Project Schedule(s) pursuant to Section 21 below and (ii) that (A) [***] IP under Sections [***] of the [***] arising out of any work performed under the [***] Project Schedule(s) will, as between Biontech and Genmab, be treated as Program Inventions under the Agreement, always subject to Sections [***] of the [***] and subject to Section 9 below, and (B) [***] IP under Sections [***] of the [***] arising out of any work performed under the [***] Project Schedule(s) will, as between Biontech and Genmab, for all practical purposes be treated as Program Inventions under the Agreement, provided that Genmab shall [***] of such [***] IP with [***], and if set forth in the relevant [***] Project Schedule(s), Biontech, and always subject to Sections [***] of the [***] and subject to Section 10 below.

5. On Genmab's reasonable request, Biontech shall without undue delay provide Genmab with reasonable assistance in connection with the performance of Genmab's obligations under the [***] in relation to any [***] Project Schedule(s) entered into in accordance with Section 4 above (as amended by any Change Order(s)) in the event such assistance is reasonably required to comply with the [***] (including the relevant [***] Project Schedule(s)).

6. All and any costs (including but not limited to any termination costs) incurred by or on behalf of Genmab in relation to any [***] Project Schedules (as amended by any Change Order(s)) that have been entered into in accordance with Section 4 above shall constitute [***] in accordance with the [***] mechanism under the Agreement. Any [***] incurred by Genmab under the [***] shall be borne solely by Genmab and shall not be considered [***] except to the extent that such [***] are a result of any breach by Biontech of any of its obligations pursuant to this Side Letter No 5 (including, for clarity, any in relation to any work performed on behalf of Genmab pursuant to a [***] Project Schedule).

7. Any [***] Intellectual Property is deemed to be comprised by the term "[***]" when such term is used in the Agreement, including but not limited to Section [***] thereof.

8. Any [***] Intellectual Property is deemed to be comprised by the term "[***]" when such term is used in the Agreement, including but not limited to Section [***] thereof.

9. Genmab shall inform Biontech of any [***] IP generated under any [***] Project Schedule. To the extent such [***] IP is generated by [***] or its employees, agents or independent contractors, such information shall be made without undue delay upon Genmab's receipt of [***] notification in accordance with Section [***] of the [***]. To the extent such [***] IP is generated by Genmab or its employees, agents or independent contractors, such information shall be made without undue delay upon Genmab's notification to [***] in accordance with Section [***] of the [***]. All [***] IP, including Intellectual Property thereto, which as between Genmab and [***] would be solely owned by Genmab under the [***] (cf. Section [***] of the [***]) ("[***] IP") shall be deemed Program Inventions under the Agreement. With respect to any such Program Inventions that would constitute [***] IP and be jointly owned by the Parties pursuant to Section [***] of the Agreement, the Parties hereby agree that such [***] IP shall solely be used by the Parties within the scope of the Agreement.

10. Notwithstanding Section [***] of the [***], Genmab shall not be entitled to practice, exploit or license [***] IP, including Intellectual Property thereto, which as between Genmab and [***] would be jointly and equally owned by [***] under the [***] without the prior written consent of Biontech. If Biontech provides such written consent, Genmab hereby grants to Biontech a [***] sublicense [***] under its rights under Section [***] [***] of the [***] within the scope of such consent. In the event a [***] Project Schedule that has been entered into in accordance with Section 4 above states that [***] IP generated under such executed [***] Project Schedule shall be jointly and equally owned by [***], this Section 10 shall also be applicable to Biontech *mutatis mutandis* with respect to such [***] IP.

11. To the extent Biontech performs any part of any [***] on behalf of Genmab, Biontech hereby agrees that such work shall be subject to the terms of the [***], including but not limited to Sections [***] in the [***], and hereby assigns to Genmab any of its rights to any [***] IP to the extent required to enable Genmab to convey such rights to [***] as required in accordance with the terms and conditions of Section [***] in the [***]. For clarity, the costs incurred by or on behalf of Biontech for such work shall be [***] in accordance with the terms of the Agreement.

12. Notwithstanding any provisions to the contrary in the Agreement, Biontech hereby agrees that Genmab is entitled to grant to [***] a sublicense under the license according to Section [***] in the Agreement in order for [***] to perform its obligations or to exercise any of its rights under the relevant [***] Project Schedules (as amended by any Change Order(s)) that have been entered into in accordance with Section 4 above and the [***].

13. Notwithstanding any provisions to the contrary in the Agreement, [***] hereby agrees that [***] is entitled to grant to [***] a license under any [***] IP in order for [***] to perform its obligations or to exercise any of its rights under the relevant [***] Project Schedules (as amended by any Change Order(s)) that have been entered into in accordance with Section 4 above and the [***].

14. Notwithstanding Section 9 above and any provisions to the contrary in the Agreement, [***] hereby agrees that [***] may grant to [***] a) the license set forth in Section [***] of the [***] with respect to any [***] Intellectual Property and [***] IP and b) the license set forth in Section [***] of the [***] with respect to any [***] IP.

15. To the extent that any [***] would fall within the definition of [***] IP or the definition of [***] Intellectual Property and notwithstanding any provisions to the contrary in the Agreement, [***] hereby agrees that [***] is entitled to grant to [***] the licenses set forth in Sections [***] in the [***].

16. Under its license from [***] pursuant to Section [***] of the [***], and subject to the terms and conditions of the Agreement and the [***], Genmab hereby grants to Biontech a [***] license in [***] under [***] Intellectual Property and the [***] IP [***]), in accordance with the [***] and the relevant [***] Project Schedule(s) and shall, upon Biontech's request, make available to Biontech such [***] Intellectual Property and [***] IP (e.g., any [***] included in such IP) to the extent required to enable Biontech to make use of the license granted in this Section 16.

17. The right to [***] IP as set forth in Section 9 above, the license granted in Section 16 above as well as any disclosures by Genmab to Biontech of [***] IP, [***] IP, [***] Confidential Information, Deliverables (as defined in the [***]) shall be subject to the non-use and confidentiality obligations and restrictions that apply to Genmab under the [***], including without limitation the obligations set forth in Section [***] of the [***]. Biontech hereby agrees to comply with all and any such obligations and restrictions that apply to Genmab under the [***] with respect to such right, license and disclosures.

18. Biontech agrees that Genmab may disclose any Confidential Information of Biontech to [***] under the relevant [***] Project Schedules (as amended by any Change Order(s)) to the extent [***] needs to know such Confidential Information in order to perform its obligations or to exercise any of its rights under the relevant [***] Project Schedules (as amended by any Change Order(s)) and the [***]

19. Genmab and Biontech shall agree on any material decisions to be made under any [***] Project Schedules in relation to 1) any Collaboration Product, 2) [***] Matters relating to any Collaboration Product, or 3) [***] Matters relating to any Collaboration Product ("Material Decisions"). For clarity, Material Decisions could include decisions on e.g. determination of [***] (as defined in the [***]), sourcing of [***] and [***] strategy, [***] strategy and [***] strategy for any Collaboration Product.

20. In case a Committee meeting will address one or more matter(s) that is/are relevant to any [***] Project Schedules ("Matter(s)"), Genmab shall ensure to invite a representative of Biontech to attend such Committee meeting solely with respect to such Matter(s). Without limiting the generality of Section 17 above, Biontech hereby agrees and shall ensure that any such representative shall be bound by the non-use and confidentiality obligations that apply to Genmab under the [***]. For clarity, any such representative shall have the right to participate in such Committee meeting but shall not have the right to vote on any Committee matters. Prior to any such Committee meeting, Genmab and Biontech shall agree on any Material Decisions that are to be taken with respect to the relevant Matter(s) during such Committee meeting and Genmab shall submit its vote on such Material Decisions in accordance with what has been agreed between Genmab and Biontech with respect to such Material Decisions.

21. A [***] Project Schedule that has been approved by Biontech in accordance with Section 4 above, may state that [***] and Genmab have agreed that Biontech is an intended third party beneficiary regarding Genmab's ownership interests in, and Genmab's rights to exploit, the [***] IP and [***] IP under Sections [***] of the [***], and the [***] license to Genmab under Section [***] of the [***] with respect to [***] and related Intellectual Property arising pursuant to performance of such [***] Project Schedule (collectively, the "[***] IP Rights"). In such event, such third party beneficiary designation of Biontech in such [***] Project Schedule reflects a desire of Genmab and Biontech to align their interests with respect to intellectual property rights and licenses as described in the [***]. Regarding Biontech's intended third party beneficiary designation the following conditions will apply: (a) Biontech will not exercise its third party beneficiary rights ("3PB Rights") unless Genmab fails to enforce any of the Genmab IP Rights that are within the scope of such 3PB Rights (taking reasonably into account Biontech's interest as third party beneficiary); (b) if Genmab so fails to enforce any such [***] IP Rights, and if Biontech has reasonably determined that it wishes to exercise its 3PB Rights in respect of such Genmab failure, then before exercising such 3PB Rights, Biontech must first notify Genmab in writing of such determination and its intended exercise, with a description of the [***] IP Rights that Genmab has failed to enforce;
(c) before exercising Biontech's right to enforce pursuant to its 3PB Rights, Genmab shall have [***] to enforce such described [***] IP Rights, or to provide to Biontech commercially reasonable reasons (taking reasonably into account Biontech's interest as third party beneficiary) why Genmab has not undertaken such enforcement; and (d) only if Genmab (i) fails to so enforce, or (ii) has not provided commercially reasonable reasons for its decision not to enforce (taking reasonably into account Biontech's interest as third party beneficiary), in each case of (i) and (ii), within such period pursuant to the foregoing clause (c), will Biontech be free to exercise its 3PB Rights, and only with respect to the

Genmab IP Rights described in Biontech's written notification that Genmab failed to enforce or to explain pursuant to the foregoing clause (c). Notwithstanding the above in this Section 21, in no event shall Biontech have any rights to enforce any 3PB Rights with respect to any Genmab Unilateral Product.

22. This Side Letter No 5 shall be governed by the same governing law as the Agreement, and all disputes arising out of or in connection with this Side Letter No 5 shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce as set forth in Section 17.10 of the Agreement.

23. The Parties agree that this Side Letter No 5 may be signed using a DocuSign® electronic signature. Such electronic signature is the legally binding equivalent to a Party's handwritten signature and it has the same validity, enforceability and meaning as a handwritten signature and the Parties hereby waive any objection to the contrary.

IN WITNESS WHEREOF, the Parties hereto have caused this Side Letter No 5 to be executed and delivered as of the Side Letter No 5 Effective Date.

GENMAB A/S		BIONTECH SE	
By:	[***]	By:	[***]
Name:	[***]	Name:	[***]
Title:	[***]	Title:	[***]

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

UNIVERSITY OF PENNSYLVANIA

AMENDMENT NO. 1 TO COLLABORATION & LICENSE AGREEMENT

This Amendment No. 1 to the Collaboration & License Agreement ("**Amendment**") by and between The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation ("**Penn**"), with offices located at Penn Center for Innovation, 3600 Civic Center Blvd, 9th Floor, Philadelphia, PA 19104-4310, and BioNTech SE, a German corporation ("**Sponsor**"), having a place of business at An der Goldgrube 12, 55131 Mainz, Germany is effective September 8, 2021 ("**Amendment Effective Date**"). Penn and Sponsor may be referred to herein as a "**Party**" or, collectively, as "**Parties**".

RECITALS:

WHEREAS, the Parties entered into a Collaboration & License Agreement dated October 9, 2018 ("**Agreement**") under which the Parties are undertaking the development, manufacture and commercialization of mRNA vaccines for infectious diseases, including RNA synthesis, formulation and GMP manufacturing. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement;

WHEREAS, on January 4, 2021, BioNTech RNA Pharmaceuticals GmbH transferred all its assets to BioNTech SE with economic effect as of January 1, 2021, including the Agreement.

WHEREAS, Penn and BioNTech are now entering into this Amendment because Penn has conducted, at the request of BioNTech, translational research and IND enabling activities revolving around HSV-2 vaccine, and BioNTech desires that Penn conduct additional research and IND enabling activities related to the HSV-2 vaccine development program;

WHEREAS, the Parties want to reimburse Penn for translational research and IND enabling activities undertaken and align on research and IND enabling activities to be conducted at Penn revolving around the HSV-2 mRNA vaccine and future mRNA vaccines for infectious diseases under the Research Program; and

WHEREAS, the Parties now desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

1. **Scope of work and Budget**. The Research Program detailed in Exhibit C to the Agreement and Initial Research Program Budget as set forth in Exhibit G to the Agreement are hereby amended to include the additional research plans and additional research budgets in Attachment A-1 hereto.

2. **Funding of the Research Program.** The following language shall be added to the end of Section 2.3.1 of the Agreement,

   "During the Research Term, Licensee shall provide additional funding to Penn to support additional research and IND enabling activities conducted at Penn as mutually agreed to under work plans described in Exhibits C-1 through C-8 (each an "**Additional Research Plan**") and corresponding budgets in Exhibit G-1 through G-8 (each an "**Additional Research Budget").** Future Additional Research Plans and Additional Research Budgets may be mutually agreed to and if executed by a duly authorized representative of each Party, such Additional Research Plans shall be added to the Agreement as Exhibit C-9, C-10, etc. and such associated Additional Research Budgets as Exhibits G-9, G-10, etc. Any Additional Research Budget shall be in addition to and shall not decrease, draw down from, or otherwise impact the Research Funding Commitment."

3. **Payment of Additional Research Budget.** Licensee shall pay Penn [***] US Dollars ($[***]) in accordance with the terms set forth in Exhibit G-1 to G-8, within [***] after invoice receipt.

4. **Entire Agreement of the Parties; Amendments**. The Agreement, including any Exhibits, as amended by this Amendment, constitutes and contains the entire understanding and agreement of the Parties with respect to the subject matter hereof and cancel and supersedes any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of the Agreement as amended and/or this Amendment shall be valid or effective unless made in a writing referencing the Agreement and/or this Amendment and signed by a duly authorized officer of each Party.

5. **Conflict**. Other than as set forth in this Amendment, all the terms and conditions of the Agreement shall continue in full force and effect. In the event of a conflict between the Agreement and the Amendment, the Amendment shall control.

6. **Counterparts**. This Amendment may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A portable document format (PDF) or electronic copy of this Amendment, including the signature pages, will be deemed an original.

[SIGNATURE PAGE FOLLOWS]

UNIVERSITY OF PENNSYLVANIA

IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereby execute this Amendment as of the date first written above.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

By: /s/ John S. Swartley
Name: John S. Swartley

Title: Associate Vice Provost for Research, and Managing Director, Penn Center for Innovation

BIONTECH SE

By: /s/ Sierk Poetting
Name: Sierk Poetting
Title: Managing Director

I have read and understood the responsibilities of the Designated Penn Contact:

By: /s/ Harvey Friedman, MD
Name: Harvey Friedman, MD

Attachment A-1

Additional Research Budget (Exhibits C-1 through C-7)

Exhibit C-1

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THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

TRON gGmbH, Freiligrathstraße 12, D-55131 Mainz

BioNTech SE
An der Goldgrube 12
55131 Mainz

TRON gGmbH
Freiligrathstraße 12
D - 55131 Mainz

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Transfer of Source Code for MyMUT® Software Version [***] 10.09.2021

TRON gGmbH is currently developing MyMut Software Version [***] and intends to successively transfer the full source code of the MyMUT® software version [***] latest by October 15th, 2021 under the URL [***], encrypted zip archive; the key will be sent separately as a printout) to BioNTech. With regard to the use of the data and the software by BioNTech SE, TRON recognizes that the software will be used for the so-called IVAC project.

Since the IVAC Supplementary Agreement dated January 1st 2015 between TRON and BioNTech expired on December 31st 2019 and no other related agreement between BioNTech SE and TRON gGmbH has been concluded so far, TRON hereby transfer these data (including inventions, rights to patent applications / patents and so-called trade secrets) subject to the rights of use to which TRON, TRON AFFILIATED COMPANIES and the respective cooperation partners are entitled in the IVAC Supplementary Agreement with the proviso that Sec. 6.4.1. of the Framework Collaboration Agreement ("WP5") between BioNTech SE and TRON gGmbH is applied as amended in Schedule 1, which amendment shall be effective solely for the purpose of this letter and the exploitation of the SOURCE CODE including any so called trade secret inventions contained in the SOURCE CODE . All other terms of the IVAC Supplementary Agreement shall remain unaffected. The parties further agree, via separate amendment, to extend the term of the IVAC Supplemental Agreement to Dec. 31st 2023.

BioNTech SE accepts transfer under this letter agreement and recognizes the fulfillment of the obligations by TRON according to the IVAC Supplementary Agreement with regard to the above data.

Mainz, Sep 16, 2021

/s/ Michael Föhlings
Michael Föhlings
Managing Director

/s/ Dr. Andrée Rothermel
Dr. Andrée Rothermel
Managing Director

Mainz, 13-09-2021

/s/ Sierk Poetting
Sierk Poetting
COO, Managing Director BioNTech

Schedule 1
Amendment to Sec. 6.4.1. of the Framework Collaboration Agreement ("WP5")

This Amendment is agreed by the PARTIES for the sole purpose of regulating the remuneration payable by the relevant BIONTECH PARTY to TRON for the exploitation of a TRADE SECRET INVENTION to the extent any such TRADE SECRET INVENTION is part of the source code of the MyMUT® software version N under the URL [***], encrypted zip archive; the key will be sent separately as a printout) (the "SOURCE CODE"). For this purpose only, Sec. 6.4.1 of the Framework Collaboration Agreement ("WP5") will read as follows:

"For the WP5 CONTRACTUAL PRODUCTS sold by it or its licensees (or sublicensees) to THIRD PARTIES which fall within the scope of protection of a VALID CLAIM of a WP5 PROJECT PATENT or a TRADE SECRET INVENTION, the BIONTECH PARTY shall pay TRON remuneration to the amount of

(i) [***] percent ([***]) of the WP5 CONTRACTUAL PRODUCT's NET SELLING PRICE up to an annual aggregate worldwide NET SELLING PRICE per WP5 CONTRACTUAL PRODUCT of [***] euro (€[***]); and

(ii) [***] percent ([***]) of the WP5 CONTRACTUAL PRODUCT's NET SELLING PRICE if the annual aggregate worldwide NET SELLING PRICE per WP5 CONTRACTUAL PRODUCT exceeds [***] euro ([***]).

The aforementioned remuneration under this clause 6.4.1 shall be paid on a country-by-country basis for so long as the relevant WP5 CONTRACTUAL PRODUCT is covered by a VALID CLAIM of a WP5 PROJECT PATENT in the country of sale. If a WP5 CONTRACTUAL PRODUCT falls within the scope of a TRADE SECRET INVENTION, it is the mutual expectation of the PARTIES that the exploitation of such TRADE SECRET INVENTION will be coherent and jointly together with the exploitation of one or more WP5 PROJECT PATENTS.

Based on that understanding, the royalty pursuant to this clause 6.4.1 for the use of a TRADE SECRET INVENTION shall only be payable (x) if the relevant WP5 CONTRACTUAL PRODUCT also falls within the scope of protection of a VALID CLAIM of a WP5 PROJECT PATENT or, (y) in the event that the BIONTECH PARTY should exploit a TRADE SECRET INVENTION by entering into an agreement with a THIRD PARTY, if the relevant WP5 CONTRACTUAL PRODUCT also falls within the scope of protection of a VALID CLAIM of a patent (co)owned by such THIRD PARTY ("THIRD PARTY PATENT").

The royalty is payable, on a WP5 CONTRACTUAL PRODUCT-by- WP5 CONTRACTUAL PRODUCT basis, only once per WP5 CONTRACTUAL PRODUCT, even if a WP5 CONTRACTUAL PRODUCT falls within the scope of protection of several WP5 PROJECT PATENTS and/or TRADE SECRET INVENTIONS."

For the avoidance of doubt, the sentence in Sec. 6.4.1. of the Framework Collaboration Agreement "WP5") starting "*If such exploitation is undertaken…..*" shall be deleted in its entirety.

For all other purposes the original version of Sec. 6.4.1 shall remain unchanged, in full effect and shall not be affected by the aforementioned amendment.

TRON – Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz gemeinnützige GmbH

Bankverbindung: Mainzer Volksbank eG, IBAN: [***]41, BIC: [***]
Amtsgericht Mainz: HRB 43191 - **USt.-Id.Nr.:** DE 269156552
[***]

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

Amendment to Letter Agreement of November 11, 2020 in relation to Genmab's proprietary [***]

This Amendment Agreement to the Letter Agreement of November 11, 2020 (the ***Letter Agreement Amendment***) is entered into as of 15 December 2021 by and between

BioNTech SE, a German corporation having its principal office at An der Goldgrube 12, 55131 Mainz, Germany **(*Biontech*)**

and

Genmab A/S, CVR no. 21023884, a Danish corporation having its principal office at Bredgade 34E, P.O. Box 9068, DK-1260 Copenhagen K, Denmark, (***Genmab***).

(Biontech and Genmab each a ***Party*** and together the ***Parties***)

PREAMBLE

WHEREAS, as of 11 November 2020, the Parties have concluded a letter agreement (the ***Letter Agreement***, as amended from time to time) relating to the potential expansion of the License and Collaboration Agreement concluded by the Parties as of 19 May 2015 (the ***Collaboration Agreement***),

WHEREAS the Letter Agreement has been extended by the Parties several times and will currently expire on 15 December 2021.

WHEREAS, under the Letter Agreement, the Parties are negotiating an amendment to the Collaboration Agreement to expand the terms of the Collaboration Agreement to include Genmab's proprietary [***]. The current status of such negotiation is reflected in (i) the draft Amendment version sent by Genmab to Biontech on [***] attached to this Letter Agreement Amendment as Appendix 1 and (ii) the issues list produced by Biontech in response to such version attached to this Letter Agreement Amendment as Appendix 2.

WHEREAS, the Parties have decided to no longer pursue their collaboration in relation to the [***] product under an amendment to the Collaboration Agreement, but to establish a separate agreement for such purpose (the **[***] *Agreement***).

WHEREAS, the Parties intend to negotiate and execute such [***] Agreement as quickly as possible, but in any event no later than [***].

WHEREAS, until the [***] Agreement has been executed, the Parties wish to continue their development of the [***] product pursuant to the terms of the Letter Agreement, as amended by this Letter Agreement Amendment.

NOW, THEREFORE, the Parties hereby agree as follows:

1. NEGOTIATION OF [***] AGREEMENT

1.1 The Parties agree to negotiate in good faith the [***] Agreement to govern their collaboration in relation to the development of Genmab's proprietary [***] antibody with the goal to execute such agreement as early as possible, but in any event no later than [***].

1.2 The [***] Agreement shall be based on:

(i) [***] and

(ii) [***], and

(iii) [***].

1.3 Biontech will prepare a draft amended and restated Collaboration Agreement and on that basis subsequently a first draft of the [***] Agreement and provide such drafts to Genmab for review as soon as reasonably possible.

2. AMENDMENTS TO LETTER AGREEMENT

2.1 The Parties agree to extend the "Expiry Date" under Letter Agreement until [***].

2.2 In the event that, prior to the Expiry Date or to the execution of the [***] Agreement, (i) the Joint Steering Committee mutually decides to discontinue the Development of the [***] product and/or (ii) a Regulatory Authority suspends the Clinical Study referred to by the Parties as [***] for the [***] product due to product safety or quality issues and such Clinical Study is not allowed to resume prior to the Expiry Date or execution of the [***] Agreement, the following shall apply, unless otherwise agreed in writing:

(a) The Parties shall share all costs for the Development of the [***] product as per the then current Development Plan and Budget to the extent such costs have been incurred or committed to by the Parties during the Negotiation Period, and in accordance with the principles set out in Section 7.3 to 7.11 of the Collaboration Agreement. Following an event described in this Section 2.2, romanette (i) and (ii) above, Genmab and Biontech will each invoice the other party for the costs to be shared in accordance with the principles set out in Section 7.6 of the Collaboration Agreement.

(b) The Parties shall work together to ensure that any ongoing activities related to the [***] product are properly wound down, and shall share costs related to such winding down, if any; and

(c) Neither Party shall have the right to continue Development, Manufacturing or Commercialization of the [***] product without prior written agreement between the Parties.

3. OTHER

3.1 Capitalized terms used in this Letter Agreement Amendment that are not defined in it shall have the meanings given to them in the Letter Agreement, or, to the extent such capitalized terms are not defined in the Letter Agreement, the meanings given to them in the Agreement.

3.2 Save as set forth in this Letter Agreement Amendment, all other terms and conditions of the Letter Agreement shall remain in full force and effect.

3.3 The Parties agree that this Letter Agreement Amendment may be signed using DocuSign® electronic signature. Such electronic signature is the legally binding equivalent to a Party's handwritten signature and it has the same validity, enforceability and meaning as a handwritten signature and the Parties hereby waive any objection to the contrary.

For Genmab A/S:

[***]

Anthony Mancini

Executive Vice President & Chief Operating Officer

For Biontech SE:

Dr. Sierk Pötting

[***]

Managing Director

Appendices:

Appendix 1 - Draft Version of Amendment No 7 to the Collaboration Agreement as provided by Genmab on [***] (with redlines by Genmab)

Appendix 2 – Open Issues List as provided by Biontech on [***]

THE SYMBOL "[***]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

UNIVERSITY OF PENNSYLVANIA

AMENDMENT NO. 2 TO COLLABORATION & LICENSE AGREEMENT

This Amendment No.2 to the Collaboration & License Agreement ("**Amendment No. 2** ") by and between The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation ("**Penn**"), with offices located at Penn Center for Innovation, 3600 Civic Center Blvd, 9th Floor, Philadelphia, PA 19104-4310, and BioNTech SE, a German corporation ("**Licensee**"), having a place of business at An der Goldgrube 12, 55131 Mainz, Germany is effective December 22, 2021 ("**Amendment No. 2 Effective Date**"). Penn and Licensee may be referred to herein as a "**Party**" or, collectively, as "**Parties**".

RECITALS:

WHEREAS, the Parties entered into a Collaboration & License Agreement dated October 9, 2018, as previously amended on September 8, 2021, ("**Agreement**") under which the Parties are undertaking the development, manufacture and commercialization of mRNA vaccines for infectious diseases, including RNA synthesis, formulation and GMP manufacturing. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement;

WHEREAS, on January 4, 2021, BioNTech RNA Pharmaceuticals GmbH transferred all its assets to BioNTech SE with economic effect as of January 1, 2021, including the Agreement.

WHEREAS, the Parties are in active negotiation of a separate collaboration and license agreement ("**Expanded Alliance Agreement**") to, amongst other contemplated research and development programs, develop products based on certain additional Penn background patent rights ("**Additional Penn Background Patents**")

WHEREAS, Parties are now entering into this Amendment No. 2 because the Parties want to begin developing products based on the Additional Penn Background Patents commencing on the Amendment No. 2 Effective Date, while the Parties work diligently to complete their negotiation of the Expanded Alliance Agreement between the Parties;

WHEREAS, the Parties now desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

1. **Term of this Amendment No. 2**. This Amendment No. 2 shall become effective on the Amendment No. 2 Effective Date and terminate upon the earlier of 1) six (6) months from the Amendment No. 2 Effective Date or 2) the effective date of the Expanded Alliance Agreement ("**Amendment No. 2 Term**"). Upon mutual agreement by the Parties, the Amendment No. 2 Term may be extended. At the end of the Amendment No. 2 Term, the Parties shall amend the Agreement to remove the Targeting Research Plan.

2. **Scope of work**. The Research Program detailed in Exhibit C to the Agreement ("Original Research Program") is hereby amended to include the additional research plans in Schedule A-1 hereto (**"Targeting Research Plan**") only during the Amendment No. 2 Term. Execution of this Amendment No. 2 does not obligate the Parties to enter into the Expanded Alliance Agreement. If the Amendment No. 2 Term ends upon the effective date of the Expanded Alliance Agreement, the Parties shall determine by mutual agreement if the Targeting Research Plan shall be moved to and included as a portion of the research program under the Expanded Alliance Agreement.

3. **Funding of the Research Program.** During the Amendment No. 2 Term, up to ($[***]) of the existing funding for the Original Research Program under the Agreement can be reallocated to fund the Targeting Research Plan upon mutual agreement of the Parties ("**Targeting Research Plan Funding**"). Penn represents that the Targeting Research Plan Funding shall not detrimentally impact any existing rights of Licensee under the Agreement. Any portion of the Targeting Research Plan Funding not used under this Amendment No. 2 shall be reallocated to the Original Research Program following termination of this Amendment No. 2. No further funding or payment by Licensee shall be required in connection with this Amendment No. 2, and the used portion of the Targeting Research Plan Funding will not be replenished by Licensee for the Original Research Program at the conclusion of the Amendment No. 2 Term.

4. **Additional Penn Background Patents**. The Additional Penn Background Patents means Penn's rights and interest in the patents and patent applications specifically listed in Schedule B-1 hereto, together with any unlisted patents and patent applications claiming priority thereto, and any continuations, continuations-in-part (to the extent related directly to the subject matter of the parent application or containing new information developed pursuant to the Research Program), reissues, reexamination certificates, substitutions, divisionals, supplementary protection certificates, renewals, registrations, extensions including all confirmations, revalidations, patents of addition, PCTs, and pediatric exclusivity periods and all foreign counterparts thereof, and any patents issued or issuing with respect to any of the foregoing.

5. **Option to Additional Penn Background Patents**. Penn hereby grants to Licensee a time-limited option during the Amendment No.2 Term and pursuant to or superseded by the terms of the Expanded Alliance Agreement to negotiate to acquire a commercial license to Additional Penn Background Patents Controlled by Penn to research, develop, make, have made, use, import, offer for sale, commercialize and sell products using or incorporating Additional Penn Background Patents in the APBP Field of Use (the "**APBP Option**"). For clarity, the APBP Option can only be exercised pursuant to the terms of and under the Expanded Alliance Agreement and shall automatically expire at the end of the Amendment No.2 Term. "**APBP Field of Use**" means a) mRNA based diagnostics and therapeutics including mRNA based CAR-T and TCR therapies and b) lipid nanoparticle based mRNA delivery technologies, each for the diagnosis, detection, evaluation, prophylaxis and treatment of diseases in humans and animals, but specifically excluding the treatment and/or prevention of fibrosis in humans, including fibrosis caused by autoimmune disease and/or inflammation. "**Controlled**" means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide to, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

6. **Prosecution and Maintenance of Additional Penn Background Patents**. Additional Penn Background Patents will be held in the name of Penn. During the Amendment No.2 Term, Penn shall have the sole and exclusive right to control the preparation, filing, prosecution and maintenance of the Additional Penn Background Patents. Patent expense reimbursement by Licensee for the APBP Option to the Additional Penn Background Patents shall be addressed in the Expanded Alliance Agreement.

7. **Entire Agreement of the Parties; Amendments**. The Agreement, including any Exhibits, as amended by this Amendment No. 2, constitutes and contains the entire understanding and agreement of the Parties with respect to the subject matter hereof and cancel and supersedes any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of

any provision of the Agreement as amended and/or this Amendment No. 2 shall be valid or effective unless made in a writing referencing the Agreement and/or this Amendment No. 2 and signed by a duly authorized officer of each Party.

8. **Conflict**. Other than as set forth in this Amendment No.2, all the terms and conditions of the Agreement shall continue in full force and effect. In the event of a conflict between the Agreement and the Amendment No.2, the Amendment No.2 shall control.

9. **Counterparts**. This Amendment No. 2 may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A portable document format (PDF) or electronic copy of this Amendment No. 2, including the signature pages, will be deemed an original.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereby execute this Amendment No. 2 as of the date first written above.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

By: /s/ John S. Swartley, Ph.D.

Name: John S. Swartley, Ph.D.
Title: Associate Vice Provost for Research and Managing Director, Penn Center for Innovation

I have read and understood the responsibilities of the Designated Penn Contact:

By: /s/ Dr. Drew Weissman

Name: Dr. Drew Weissman

BIONTECH SE

By: /s/ Sean Marett

Name: Sean Marret
Title: Managing Director

By: /s/ Jens Holstein

Name: Jens Holstein
Title: Managing Director

Schedule A-1

Additional Research Plans

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Schedule B-1

Additional Penn Background Patents

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Lease Agreement

for

Areas and Rooms in Building M536 and Building M537

at the Behringwerke site in Marburg

between

Pharmaserv GmbH
Emil-von-Behring-Straße 76, 35041 Marburg, Germany

- hereinafter referred to as the "**Lessor**" -

and

BioNTech Manufacturing Marburg GmbH
Emil-von-Behring-Straße 76, 35041 Marburg, Germany

- hereinafter referred to as the "**Lessee**" -

Lessor and **Lessee** individually also referred to as the "Party"
or jointly as the "Parties"

Preliminary remarks

The **Lessee** entered into the Lease Agreement for Buildings M537 and M536 (originally concluded between Pharmaserv GmbH & Co. KG and Chiron Behring GmbH & Co. KG) by way of a Takeover Agreement on July 1, 2021, 12:00 a.m. This Lease Agreement shall hereinafter be referred to as the “Old Agreement” and existed between Pharmaserv GmbH as the **Lessor** and GSK Vaccines GmbH as the Lessee before the takeover by the **Lessee**. The **Old Agreement** automatically ends on November 30, 2021, 12:00 a.m. the following day, according to the Takeover Agreement. The Parties have therefore agreed to reorganize the tenancy from December 1, 2021, 12:00 a.m., under this Lease Agreement.

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Taking into account and continuing the aforementioned premises, the Parties agree as follows:

§ 1

Leased Property

(1) The **Lessor**, as owner, rents to the **Lessee** the areas and rooms marked in green in **Appendix 1**) within building **M536** and building **M537** at the location Behringwerke, Emil-von-Behring-Straße 76, 35041 Marburg, including the circulation and ancillary areas, insofar as these circulation and ancillary areas are marked “green” instead of “gray” in **Appendix 1**) (hereinafter referred to as the “**Leased Property**”).

The technical areas marked in blue may be used by the **Lessee** free of charge for the installation of the Lessee’s own technical equipment, depending on the space available.

The outer roof areas and facade areas and the outer parts of the building are not part of the lease. The **Lessee** is entitled to use these roof and

facade areas free of charge in agreement with the **Lessor**, only to the extent that they are required for the realization of the purpose of the lease pursuant to § 2 of this Agreement.

The other parts of the building structure (for example, non-load-bearing walls), fixtures, fittings and equipment (also referred to in this Agreement as “Finishes”) located in building **M536** and building **M537** are leased to the **Lessee** and part of the **Leased Property** only to the extent that they are listed in **Appendix 1)** or listed as parts of the **Leased Property** in **Appendix 2.1)**.

If and to the extent that internal parts of the building structure (for example walls), fixtures, fittings and equipment are present on the leased areas/rooms, the leased ancillary areas or circulation areas but are not listed in **Appendix 1)** or listed in **Appendix 2.1)**, they are not part of the **Leased Property**, are therefore not owed by the Lessor and are only inserted into the buildings **M537** and **M536** for a temporary purpose (§95 of the German Civil Code [BGB]). These parts of the internal building structure, fixtures, fittings and equipment have been taken over by the **Lessee** from the previous tenants. Insofar as no takeover by the **Lessee** has taken place (for example, because it was not taken into account in corresponding transfer agreements among the previous tenants or with the **Lessee** or because it was ineffectively transferred), the right to use these parts of the internal building structure, fixtures, fittings and equipment is nevertheless not the subject of this Lease Agreement and is solely a matter between the **Lessee** and the previous tenants.

In particular, the lease does not include the Finishes that serve pharmaceutical purposes in the **Leased Property** which have been carried out in the **Leased Property** by the **Lessee** and the previous tenants, in particular by GSK Vaccines GmbH.

(2) In addition to **Appendix 2.1)**, the condition of the **Leased Property** owed by the **Lessor** shall also result from **Appendix 2.2)** (building description of the **Leased Property**, equipment description of the **Leased Property**). The condition of the **Leased Property** set forth in **Appendices 1), 2.1) and 2.2)** shall merely constitute a description of the **Leased Property** and not a warranted characteristic.

The **Lessee** has possessed and used the **Leased Property** without interruption since July 1, 2021. The **Lessee** has not reported any defects.

(3) The following special features are agreed upon with regard to the drainage pipe and wastewater system: drainage pipe (this is the wastewater pipe beginning at the inlet of the floor slab up to the first connection manhole in front of the building) including stormwater pipes (these are the pipes carrying the stormwater away from the roof up to the first connection manhole in front of the building) shall be made available for use, repaired and maintained, serviced and, if necessary, renewed by the **Lessor** for the duration of the lease in proper and functional condition in accordance with the following provisions, regardless of whether they are part of the **Leased Property**:

The drainage pipe extending from the floor slab/floor inlet (as shown in the section attached to **Appendix 9)** marked in red) to the connection to the wastewater disposal system of the Behringwerke Industrial Park shall be refurbished immediately and as soon as possible after the commencement of the lease at the expense of the **Lessor** in accordance with the refurbishment concept – **Appendix 9)** – even if this drainage pipe is not part of the **Leased Property**.

In addition, the wastewater pipes located in the building shall be refurbished by the **Lessor** at the **Lessor**'s expense without delay and as soon as possible after the commencement of the lease in accordance with **Appendix 9)** insofar as they are part of the **Leased Property** (see **Appendix 9)**), whereby the wastewater pipes not required by the **Lessee** shall first be jointly identified, documented by addendum to this Lease Agreement and subsequently professionally plugged. After these pipes have been plugged, they are no longer part of the **Leased Property**. Claims for damages on the part of the **Lessor** due to possible damage to the drainage pipe and the stormwater pipes by the **Lessee** after the commencement of the lease shall remain unaffected by the assignment of duties to the **Lessor** made in accordance with § 1(3)(1).

(4) The **Lessor** shall be entitled to have existing technical building equipment in the **Leased Property**, insofar as it is part of the **Leased Property**, in particular fire protection and fault alarm systems, including the infrastructure required for it, to install it, convert and extend it, expand it and operate it and to renew it.

§ 2

Purpose of the lease, orders, requirements, permits

(1) The **Lessor** shall provide the **Leased Property** to the **Lessee** for the purpose of carrying out pharmaceutical production, together with production-specific ancillary activities, within it with the inclusion of preexisting finishes, fixtures and equipment of the previous tenants and finishes to be carried out by the **Lessee** itself. The **Lessor** shall consent to any changes to the **Leased Property** itself that accompany the finishes made to the **Leased Property** unless good cause stands in the way of the **Lessor**'s consent. Good cause in the sense of this provision includes, in particular, effects of the planned changes on statics, fire protection, development, roof or facade of the **Leased Property**, additional costs threatening the **Lessor** as a result of the changes, or if the changes are opposed by provisions under public law.

Other uses, in particular the storage, handling or other transfer to the **Leased Property** of hazardous materials, explosives, foodstuffs, other perishable goods or objects from which a hazard may emanate or the storage, handling or other transfer of which require special structural conditions or equipment of the **Leased Property** or building which are not described in **Appendices 2.1) and 2.2)** or which are opposed by provisions of public law, are not included in the purpose of the lease.

If a special use within the agreed purpose of the lease requires special equipment (e.g. floor coverings or air-conditioning equipment) of the **Leased Property** that goes beyond the building and equipment descriptions pursuant to **Appendices 2.1) and 2.2)**, it shall be the responsibility of the **Lessee** to provide such equipment at its own expense and to obtain the relevant permits. This shall apply accordingly in the event that changes are made to the **Leased Property** in the course of any finishes. In all other respects, § 11 (6) of this Lease Agreement shall apply.

(2) Official orders and requirements as well as necessary permits that are based exclusively on or required due to the general condition and/or location of the **Leased Property** shall be fulfilled or obtained by the **Lessor** at its own expense for the entire duration

of the lease.

Insofar as official requirements and/or the obtaining/maintenance of official permits are caused by the personal or special operational circumstances of the **Lessee** or in the special circumstances of its business operations, the measures and costs associated therewith shall be the sole responsibility of the **Lessee**.

In this respect, the **Lessee** shall also comply with any official orders and requirements relating to the use of the **Leased Property** issued during the term of the lease at its own expense, even if they are directed against the **Lessee**. The **Lessor** shall provide the **Lessee** with the necessary and reasonable support in this regard.

(3) A change of the purpose of use pursuant to subsection (1) above as well as changes of use of any kind requiring an official permit shall require the prior written consent of the **Lessor**. The **Lessee** shall have no claim to such consent. Any declarations of consent by the **Lessor** shall always, even if this is not repeated in the declaration of consent, be subject to any required official permit, the procurement of which shall be the responsibility of the **Lessee** at its own expense. Prior to the implementation of the approved changes the **Lessee** shall demonstrate to the **Lessor** that either the official permit required for this purpose has been granted in a legally valid manner or that such a permit is not required, and shall comprehensively explain any disruptive impacts of the intended changed use.

(4) Insofar as official permits required for the use intended by the **Lessee** are not granted or are not granted to a sufficient extent, this shall not entitle the **Lessee** to terminate this lease, unless the cause thereof is a deviation of the actual condition of the **Leased Property** from the agreed condition of the **Leased Property**.

§ 3

Regulations on value added tax

(1) In accordance with § 9 of the German Value Added Tax Act, the **Lessor** has waived the VAT exemption pursuant to § 4 (12) (a) of the German Value Added Tax Act ("**UStG**") for the rental of the **Leased Property** (VAT option). As a result, the **Lessee** shall pay VAT in the respective statutory amount in addition to the rent, operating costs and advance payments for operating costs.

The **Lessee** is aware that the **Lessor**'s VAT option is only permissible under the conditions set out in § 9 (2) UStG.

> *Wording of § 9 (2) UStG for informational purposes:*
>
> *"The waiver of tax exemption under subsection (1) is permissible in the case of the creation and transfer of heritable building rights (§ 4 (9) (a)), the renting or leasing of real estate (§ 4 (12) (1) (a)) and the transactions referred to in § 4 (12) (1) (b) and (c) only insofar as the recipient of the service uses or intends to use the real estate exclusively for transactions that do not exclude the deduction of input tax. The entrepreneur must provide evidence of these conditions."*

In view of this, the Parties enter into the following agreements:

(2) The **Lessee** agrees to use the **Leased Property** exclusively for transactions which do not exclude the deduction of input tax by the **Lessor**.

(3) Furthermore, the **Lessee** agrees to provide the **Lessor** at any time, upon request and without delay, with the documents required to enable the **Lessor** to comply with its obligations to provide evidence to the tax authorities pursuant to § 9 (2) UStG. In this respect, the **Lessor** may only require the **Lessee** to submit those documents and/or declarations that are required of it by the responsible tax authorities. The **Lessee** shall be entitled to forward the requested documents directly to the tax authorities.

(4) Should circumstances arise on the part of the **Lessee** or a subtenant, or be assumed by the tax authorities in the course of an external tax audit,

which affect the permissibility of the **Lessor**'s VAT option, the **Lessee** shall be obliged to inform the **Lessor** thereof in written form without delay.

(5) In the event of a sublease, the **Lessee** shall be obligated to opt for VAT for the sublease and otherwise to impose the obligations under § 3 (2) to (5) of this Lease Agreement on the subtenant in the sublease agreement in such a way that the **Lessor** may also derive rights directly against the subtenant under the agreement of the **Lessee** with the subtenant (agreement in favor of third parties, § 328 of the German Civil Code [BGB]). The **Lessee** shall be liable to the **Lessor** for ensuring that the subtenant complies with these obligations.

(6) Insofar and as long as the tax authorities apply a de minimis limitation with no detrimental effect – also recognized by the tax courts – with regard to the term "exclusive" use for transactions which do not exclude the deduction of input tax, this de minimis limit shall at the same time limit the exclusivity referred to in the above provisions.

(7) Should the **Lessee** and/or, in the event of a sublease, the subtenant violate the obligations under § 3 (2) to (6) of this Lease Agreement, the **Lessee** shall compensate the **Lessor** for all damages and other disadvantages caused thereby.

(8) If the precondition for the **Lessor**'s VAT option under § 3 (1) of this Lease Agreement no longer applies because the **Lessee** does not use the **Leased Property** in accordance with the agreement made in § 3 (2) of this Lease Agreement, the **Lessor** shall no longer be obliged to list VAT separately. In this case, the net base rent owed under this Lease Agreement – without prejudice to any further rights and/or claims of the **Lessor** – shall be increased as of the date on which the precondition for the VAT option ceased to apply by the amount corresponding to the VAT that would have been payable by the **Lessee** if the precondition for the VAT option had not ceased to apply. If the **Lessor** only becomes aware of the absence of the precondition for the VAT option after the fact, the **Lessor** shall be entitled to correct the invoices issued to date in such a way that the invoiced rent with VAT shown corresponds to the contractually owed rent without VAT shown. Further claims

of the **Lessor** based on a breach of contract by the **Lessee** shall remain unaffected.

(9) Claims of the **Lessor** against the **Lessee** under § 3 shall become time-barred upon expiration of ten years after termination of the lease. Should the **Lessee** or the subtenant fail to comply with its duty to provide information pursuant to § 3 (4), the limitation period shall be extended to 15 years for all claims based on circumstances of which the **Lessor** has not been informed by the **Lessee** or subtenant in breach of its duty.

§ 4

Lease term

[***]

[***]

[***]

[***]

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[***]

[***]

[***]

(3) Tacit extension of the lease pursuant to § 545 BGB is excluded.

§ 5

Uninterrupted possession of the Leased Property, keys

(1) The **Lessee** is already in possession of the **Leased Property**. The Parties confirm that the **Lessee**'s possession will be maintained uninterrupted.

(2) The **Lessee** is also in possession of the necessary keys. With the consent of the **Lessor**, it is entitled to produce additional keys at its own expense.

All keys shall be handed over by the **Lessee** to the **Lessor** after the end of the lease.

The **Lessee** is entitled, in consultation with the **Lessor**, to install and operate its own locking system for its leased areas at its own expense or to change and expand an existing locking system. The **Lessee** shall provide the **Lessor** with access to the leased areas and rooms for the cases agreed in this Lease Agreement. When moving out, the **Lessee** must restore the **Lessor**'s locking system to its original condition where possible or provide the changed or extended locking system to the **Lessor**, whereby the **Lessee** shall not be entitled to compensation in this case.

§ 6

Rent

(1) The monthly net base rent (graduated rent) also for the option periods is fixed in Appendix 4) by the Parties and is the result of extensive negotiations between the **Lessor** and **Lessee**. A significant reduction in rent was included in these negotiations, as well as the now agreed definition of the **Leased Property** and the corresponding allocation of maintenance and repair obligations.

(2) With regard to the net base rent and with regard to all operating costs pursuant to § 8, the **Lessee** shall also pay VAT at the respective statutory rate, i.e. currently 19%.

(3) The monthly rent, including the advance payment of operating costs pursuant to § 8, shall be paid to the **Lessor** in advance, free of charge, no later than on the [***] working day of each month to the account at Volksbank Mittelhessen eG. [***] with the reference [***].

(4) The **Lessee** shall only be entitled to set off against payment claims of the **Lessor** and to exercise a right of retention if its counterclaims are acknowledged or have become established by a final judgment.

§ 7

Rent adjustment

The monthly net base rent shall increase on January 1 of each year by [***] compared to the previous year. This annual increase is already taken into account in the statement of rent in **Appendix 4** of the Lease Agreement.

§ 8

Operating costs

(1) The **Lessee** shall bear all operating costs in addition to the net base rent. Operating costs are the costs incurred by the **Lessor** on an ongoing basis as a result of ownership of the property or as a result of the intended use of the **Leased Property**, the building or the management unit, its facilities and equipment and the land. The operating costs to be borne by the **Lessee** currently include those pursuant to **Appendix 5.1)** to this Lease Agreement. The operating costs to be borne by the **Lessee** also include the operating costs incurred by the **Lessor** on an ongoing basis as a result of the operation of the Behringwerke site and referred to as “Basic Infrastructure Costs” in **Appendix 5.1)**.

(2) If public assessments are newly introduced or if new operating costs within the meaning of this Lease Agreement are incurred by the **Lessor** as a result of the fulfillment of statutory obligations with respect to the **Leased Property** that have arisen after the conclusion of this Lease Agreement, such costs may be apportioned in accordance with this Lease Agreement, and the advance payment of operating costs may be adjusted accordingly. The adjustment of operating costs specified in **Appendix 5.1)** as well as the establishment of new operating costs

which do not relate to public assessments or the fulfillment of statutory obligations arising after the conclusion of the Lease Agreement with respect to the **Leased Property** may only

be made taking into account the principle of sound financial management. The **Lessor** shall inform the **Lessee** of the operating costs without delay.

(3) Insofar as the **Lessor** provides services in its own business operations which, in the case of their provision by third parties would have to be borne as part of the operating costs in accordance with this Lease Agreement, the **Lessor** may charge for such services at an amount which corresponds to appropriate remuneration plus, if applicable, the VAT in force at the time of performance for these services (e.g., if agreed, supply of energy and media to the location at the respective prices, elevator maintenance).

(4) Unless mandatory provisions to the contrary apply, the operating costs shall be apportioned in accordance with the share of the total area of the building attributable to the **Lessee**. The settlement period shall be the calendar year. The ratio between the **Lessee**'s share of the area and the total area of Building **M536** and Building **M537** agreed only for the purpose of allocating the operating costs is bindingly agreed by the **Parties** in **Appendix 3)** to this Lease Agreement.

(5) The **Lessor** may change the apportionment scale with future effect in agreement with the **Lessee** at its reasonable discretion.

(6) The operating costs referred to as "Basic Infrastructure Costs" in **Appendix 5.1)** shall be determined in accordance with the agreement made in **Appendix 5.1)** for the settlement year and shall be apportioned to the **Lessee** in accordance with the procedures agreed in **Appendix 5.1)**. The Basic Infrastructure Costs shall not be subject to the monthly advance payment of operating costs (**Appendix 5.2)**), but shall be invoiced separately by the **Lessor** and reimbursed by the **Lessee**.

(7) Insofar as fire protection and fault alarm systems and other technical building equipment required for the operation of the building – with the exception of access control equipment – is located in areas shared with other tenants of Building **M536**

and/or Building **M537** and/or other buildings, these buildings shall form the settlement unit for these types of costs. The tenants shall bear the costs of these facilities in proportion to the areas used exclusively by each of them to the total area of the settlement units **M536** and **M537** (**Appendix 3**). The same applies to lightning protection.

(8) The **Lessee** shall make monthly advance payments for the operating costs which, insofar as these are not the operating costs designated as "Basic Infrastructure Costs," shall be determined as follows:

For each calendar year, the **Lessor** shall estimate in advance a budgeted amount of the operating costs and shall invoice the **Lessee** 1/12 plus VAT of this amount as an advance operating cost payment in advance on a monthly basis.

(9) After the end of the settlement period (calendar year), the **Lessor** shall determine all operating costs incurred during the settlement period as part of the statement of operating costs. The **Lessor** shall compare the operating costs actually incurred with the advance operating cost payments made by the **Lessee** and shall notify the **Lessee** of the result by way of the statement of operating costs.

(10) Any difference between the advance payment amount and the settlement amount in favor of the **Lessor**/**Lessee** shall be settled by the **Lessor**/**Lessee** within [***] months after receipt of the statement of account by the **Lessee** plus the VAT applicable at the time of performance.

(11) Objections to the statement of account must be asserted by the **Lessee** in writing with the **Lessor** within [***] months of receipt thereof. Otherwise, any objections to the correctness of the statement of account shall be excluded, unless the **Lessee** is not responsible for the delayed assertion, or the **Lessor** has not expressly pointed out this exclusion period and the consequences of its expiration in the statement of account.

The **Lessor** shall allow the **Lessee** to inspect the accounting documents at the **Lessor**'s business premises during normal business hours at the **Lessee**'s request and after prior agreement on a date within [***] months after receipt of the statement of account.

(12) In the event that the **Lessee** moves out during the settlement period, the apportionment at the next invoice due shall, in case of doubt, be in the ratio of the lease period to the settlement period.

(13) The advance payment amounts current at the commencement of the Agreement are attached to this Agreement as **Appendix 5.2)**. The **Parties** agree that **Appendix 5.2)** shall not be amended and a new Appendix shall not be added to the Agreement in case of a change of the advance payment amounts, but that a mere notification of the change (e.g. in the form of an invoice) by the **Lessor** shall be sufficient.

(14) The **Lessor** shall provide the **Lessee** with the statement of account no later than the end of the [***] month after the end of the settlement period, after it has received all the documents and information required for the preparation of the statement of operating costs. After expiration of this period (these periods), the assertion of any subsequent claims by the **Lessor** shall be excluded, unless the **Lessor** is not responsible for the late assertion.

§ 9

Operator responsibility, liability of the Lessee

(1) The **Lessee** shall, at its own expense, create all the conditions for the legally compliant operation of its business in conformity with the law (operator responsibility).

The **Lessee** shall comply with any requirements imposed by the trade supervisory authority or other bodies at its own expense, insofar as such requirements are specifically related to the **Lessee**'s business or its activities in the **Leased Property**, even if they are directed against the **Lessor**. § 2 (2) of this Lease Agreement shall remain unaffected.

The **Lessee** shall conduct its business in the **Leased Property** in accordance with the applicable statutory regulations and in accordance with the requirements of national and international authorities.

(2) The **Lessee** shall indemnify the **Lessor** against all claims asserted by third parties on account of the **Lessee**'s operator responsibility vis-à-vis the **Lessor**. § 15 (1) of this Agreement shall remain unaffected.

(3) The **Lessee** shall be responsible for any culpable damage to the **Leased Property** and the building as well as to all facilities and equipment belonging to the building or the premises if and to the extent that the damage was caused by the **Lessee** or its bodies, employees, subtenants, visitors, suppliers or service providers commissioned by the **Lessee**, if such persons gained access to the building at the **Lessee**'s instigation or with its approval. The **Lessee** shall be responsible for proving that there was no fault or negligence on its part insofar as damage to the **Leased Property** is concerned.

(4) If, due to blockage, the leaving open of water taps or similar events, a flood or other damage to the building, objects or third parties, the **Lessee** shall, insofar as the event was caused in the **Leased Property**, be responsible for the repair of the damage and the elimination of all consequential damage resulting therefrom. This shall not apply if the damage is attributable to the **Lessor** or third parties who have entered the **Leased Property** at the **Lessor**'s instigation or with its approval.

(5) Claims for compensation by the **Lessor** pursuant to § 548 (1) BGB due to contamination of the **Leased Property** or the building caused by the **Lessee** or its subtenants or other persons entering or driving onto the **Leased Property** with the knowledge of the **Lessee** shall become statute-barred 18 months after the return of the **Leased Property**. Contamination in the sense of this clause refers to harmful environmental effects and pollution of the soil, buildings, parts of buildings, paved outdoor facilities or groundwater. Contamination in this sense refers, in particular, also to harmful changes to the soil and contaminated sites within the meaning of § 2 (3) and (5) of the German Federal Soil Protection Act (BBodSchG).

§ 10

Warranty, liability of the Lessor

(1) The **Lessee** is aware that the **Leased Property** is located on the premises of an industrial park and that the use of the **Leased Property** may be impaired in a manner customary for an industrial park, for example by emissions from neighboring users or by work on supply lines, roads and neighboring buildings and properties.

(2) The **Lessor**'s strict liability for damages for initial defects is excluded.

(3) If the **Lessor** defaults in remedying the defect, the **Lessee** may remedy the defect itself and demand reimbursement of the expenses required for this purpose.

(4) The **Lessee** shall only be entitled to a rent reduction under the condition that a reasonable period of time set by the **Lessee** for the **Lessor** to remedy the defect has elapsed unused.

(5) Claims for damages by the **Lessee**, unless excluded under this Agreement, including those arising from pre-contractual obligations and tort, may only be asserted if the **Lessor** has acted culpably. In the event of a breach of non-essential contractual obligations, however, such claims may only be asserted if they are based on intent or gross negligence on the part of the **Lessor** or its vicarious agents. Material contractual obligations (cardinal obligations) are obligations the fulfillment of which makes the proper execution of the Agreement possible in the first place and the observance of which the Party to the Agreement regularly relies on and may rely on. The **Lessor**'s liability for damages shall be limited to foreseeable, typical damage. If the **Lessor** has covered the above typical risk of damage with insurance, liability for damages shall be limited to the sum insured, unless the insurer can invoke its exemption from performance in whole or in part. The sum insured shall at least correspond to the requirements pursuant to § 14 (1).

(6) All exclusions and limitations of the **Lessor**'s liability contained in this Agreement shall also apply in favor of the **Lessor**'s bodies, representatives and vicarious agents.

(7) All exclusions and limitations of liability of the **Lessor**, its organs, representatives and vicarious agents contained in this Agreement shall apply neither in the case of intent or in the case of injury to life, body or health.

§ 11
Maintenance, repair and cosmetic repairs, structural and technical modifications

(1) In accordance with the negotiations held on November 23, 2021, the **Lessor** shall only be responsible for the maintenance (including servicing and inspection) and repair of the **Leased Property** within the limits of its definition pursuant to § 1 of the Lease Agreement, i.e. of the roof and framework (only to the extent described in Appendix 1 and Appendix 2.1), the building shell and the load-bearing components (including windows and exterior doors) and the fixtures, fittings and equipment of the **Leased Property** described in **Appendices 2.1) and 2.2)**, as well as the drainpipes and stormwater pipes pursuant to § 1 (3) of this Agreement, as well as to maintain and repair the circulation and ancillary areas (marked "gray" in **Appendix 1)**) and other common technical facilities, installations and areas, including the common area. Major maintenance and repair work to be carried out by the **Lessor**, i.e. such work as may have a significant effect on the **Lessee**'s operations, shall be coordinated between the **Lessor** and the **Lessee** well in advance. Prior coordination is not required if there is an imminent danger.

(2) In accordance with the statements in the preliminary remarks of this Lease Agreement, the **Lessee** shall be entitled at its own expense for the maintenance (including servicing and inspection) and repair of the technical facilities and equipment existing in or on Buildings 536 and 537, insofar as these are not listed in **Appendices 2.1) and 2.2)** as part of the **Leased Property**, and shall only be obligated to maintain and repair the same insofar as

such obligation arises from the operator responsibility pursuant to § 9 of this Lease Agreement or a risk to the **Leased Property** or personal injury cannot be ruled out. In particular, all work required by law and/or necessary according to the manufacturer's specifications to maintain the operational readiness and operational safety of these fittings, facilities and equipment shall be carried out by the **Lessee** at its expense. The same shall apply in particular to the maintenance (including servicing and inspection) and repair of the installations and conversions, fixtures and equipment carried out by the previous tenants and by the **Lessee** itself.

(3) Cosmetic repairs are to be carried out neither by the **Lessor** nor by the **Lessee**.

(4) The **Lessor** shall give the **Lessee** written notice of any modernization measures (§ 555 c BGB) to be carried out in the **Leased Property** with a reasonable period of notice prior to commencement of such measures in the **Leased Property**. As a rule, the **Parties** consider a period of three months to be reasonable. The **Lessee**'s special right of termination in the event of modernization measures (§ 555e (1) BGB) is excluded by mutual agreement.

(5) The **Lessee** shall treat with care the sanitary facilities, locks, lighting fixtures, built-in furniture, kitchens, external blinds and thermostats provided by the **Lessor**, insofar as these exist. Defective light bulbs shall be replaced by the **Lessee**. The **Lessee** shall keep the **Leased Property** free of vermin at its own expense and maintain sanitary facilities and social spaces, insofar as they exist in the **Leased Property**, in a proper, in particular hygienic, condition at all times and shall clean the leased areas used only by itself (excluding common areas) regularly and shall properly clean the windows at least twice a year.

(6) With the exception of the extension of the **Leased Property** permitted within the scope of the purpose of the lease pursuant to § 2 (1) of this Lease Agreement, the **Lessee** shall be entitled to make structural and/or technical changes to the **Leased Property** as defined in § 1 of this Lease Agreement itself only with the prior consent of the **Lessor**, to which the **Lessee** shall have no claim. To obtain consent on the part of the

Lessor, the **Lessee** must submit a detailed description of the planned structural change, including all relevant descriptions, a planning diagram and a presentation of the effects of the structural change in terms of permit requirements, insurance requirements, any disruptive environmental impacts such as noise or other emissions and the functioning of the building as a whole. Any declarations of consent by the **Lessor** shall always be issued, even if this is not repeated in the declaration of consent, subject to any necessary official approval, the procurement of which shall be the responsibility of the **Lessee** at its own expense. The **Lessee** shall be liable to the **Lessor** regardless of fault for any damage occurring during or as a result of the structural change, including effects on other leased areas, and for compliance with building regulations, and shall indemnify the **Lessor** in full in this respect. This shall also apply if defects or other impairments of the **Leased Property** or other leased units occur as a result of the structural change. The costs of any structural change, including all planning and permit costs, shall be borne by the **Lessee**.

All construction and/or technical changes to be made by the **Lessee**, insofar as they affect the **Leased Property** itself, must be sufficiently documented in writing, including the type and scope of the changes, prior to implementation of the measure by way of supplementary management.

§ 12

Company signs

(1) The **Lessee** may, taking into account the circumstances at the site and after consultation with the **Lessor**, affix its company name itself at its own expense only on those buildings of which it is the sole user. It shall bear the costs for affixing these signs. If official permits are required for the affixing of these signs, the **Lessee** shall obtain them and bear the costs incurred thereby. The **Lessee** shall be responsible for ensuring the safety of the fixtures which it attaches.

(2) The type, size and location of (display) boxes or boards for internal communication and information that are installed outside the areas used exclusively by the **Lessee** shall also be coordinated between the **Lessee** and the **Lessor**.

(3) If the removal of the company signs pursuant to subsections (1) or (2) is necessary for work on the site or on the **Leased Property**, the **Lessee** shall bear the costs of the removal, storage and reattachment, including any repairs to the fixture necessitated thereby. Upon termination of the lease, the **Lessee** shall remove the company signs at its own expense and remove at its own expense any damage caused by attaching, operating and removing them.

(4) If the **Lessor** erects uniform company signs, the **Lessee** shall share appropriately in the costs of erecting and maintaining such signs.

§ 13
Technical building equipment, supply and disposal

(1) The **Leased Property** shall have a technical connection for the supply of electrical power, drinking water and data communication to the currently existing supply and disposal facilities of the site. The **Lessee** shall itself and at its own expense ensure the supply of the **Leased Property** with the energy and media required for its use by concluding separate energy supply contracts with the **Lessor** or with third parties. The **Lessee** shall itself provide for the adequate heating of the **Leased Property**. If increased connection capacities or connections for other energy or media are required in addition to the connection available at the commencement of the lease, the Parties shall enter into discussions on this matter; the **Lessee** shall have no claim to the establishment of increased connection capacities or further connections.

Wastewater disposal is not the subject of this Lease Agreement and is therefore not owed by the **Lessor** under this Lease Agreement, but is governed by the Wastewater Agreement between the **Lessor** and the **Lessee** dated March 25/April 12, 2021 (**Appendix 8**), as amended.

(2) The **Lessee** shall use the supply and disposal lines installed in the **Leased Property**, e.g. for electricity, gas, nitrogen, compressed air and water/wastewater, only to the extent that no overloads occur.

The **Lessee** may cover any additional demand by extending the lines and necessary technical equipment at its own expense after prior written consent of the **Lessor**, which may only be refused for good cause.

(3) If, as a result of a legally mandatory conversion of a type of energy supply, it is necessary to convert equipment or installations, parts of installations and ancillary equipment belonging to the **Lessee**, the costs of converting these equipment and installations, parts of installations and ancillary equipment shall be borne by the **Lessee**. Any claims for compensation on the part of the **Lessee** as well as claims for a reduction of the rent shall be excluded in this case.

(4) Prior to setting up shelves, heavy machinery, apparatuses and safes in the **Leased Property**, the **Lessee** shall inquire with the **Lessor** about the permissible load limits of the floor and the floor ceilings and obtain the **Lessor**'s prior written consent. The **Lessee** shall be liable for any damage caused by non-compliance with these provisions; any liability on the part of the **Lessor** shall be excluded. If machinery causes disturbances or other detrimental effects on the building, vibrations, cracks, etc., the **Lessor** may revoke the permission granted or impose subsequent conditions. The **Lessor** shall also not be liable for the suitability of the **Leased Property** for the installation or connection of equipment.

§ 14
Insurance

(1) From the time of handover, the **Lessor** shall maintain all-risk property insurance, including fire insurance for the building, as well as liability insurance with a minimum coverage of €10 million. The costs of these insurance policies form – if applicable, on a pro rata basis – part of the operating costs pursuant to § 8 of this Agreement.

(2) The **Lessee** shall be obliged to take out, at its own expense, liability insurance providing coverage for damage to rented property with a minimum sum insured of €10 million from the commencement of the lease, as well as all insurance policies required for operation pursuant to § 2 of this Agreement. Global insurance policies or policies that provide for a deductible on the part of the **Lessee** fulfill this requirement.

In the event of an increase in the insured risk, the **Lessee** shall extend its insurance coverage without being requested to do so.

(3) All insurance policies shall be maintained during the term of the lease, either through a continuation of the respective insurance policy or by taking out new comparable insurance policies. The sole decisive factor is that insurance coverage must exist for the entire term.

(4) Upon request of the other Party, each **Party** shall submit certificates of the insurance policies it is required to take out, showing the amount of the deductible, and shall provide proof of premium payment on request at any time.

(5) Each **Party** agrees to draw the other **Party**'s attention without delay to any lacking or insufficient general or special insurance coverage which it has identified. This shall apply in particular to circumstances which have or may have the effect of changing or increasing the risk, in particular in the case of installations, structural measures or changes of use.

(6) The **Lessee** shall notify the insurer and the **Lessor** immediately of any case of damage and shall ensure that the site of the damage – wherever possible and reasonable – remains unchanged prior to inspection by the insurer. Notwithstanding the foregoing, the Parties shall be obligated to take such measures as are necessary to mitigate the damage or to reduce consequential damages. The **Parties** shall carry out these measures in coordination with each other and with the respective insurer.

§ 15
Termination of the lease, obligation to surrender, restoration of the original condition

(1) Upon termination of the lease, the **Lessee** shall return the **Leased Property** in accordance with the provisions of this Agreement and otherwise in a broom-clean condition and free of substances that are likely to cause hazards, significant disadvantages or significant nuisances

within the meaning of § 3 of the German Federal Emissions Control Act for individuals or the general public (hereinafter collectively referred to as “Contamination”), insofar as they were caused by the **Lessee**.

If there is Contamination of the **Leased Property** or of fixtures, fittings and equipment that are not part of the lease, the **Lessee** shall indemnify the **Lessor** in full, even during the term of the lease, if a claim is made against the **Lessor** for investigation, remediation or other measures relating to the Contamination, as well as against any claims by third parties in connection with such Contamination. However, this shall only apply insofar as the **Lessor** proves that the contamination of the **Leased Property** was caused by the **Lessee** after the commencement of this contractual relationship. This proof of causation by the **Lessor** shall not be required with respect to the fixtures, fittings and equipment that are not part of the lease, in particular those taken over by the **Lessee** from the previous tenants.

(2) In accordance with the statements in the preliminary remarks of this Lease Agreement, the **Lessee** shall be obligated upon termination of the lease to

- to remove all fittings, installations and equipment located in the **Leased Property**, unless these are identified as part of the **Leased Property** in **Appendices 2.1) and 2.2)** to the Lease Agreement, including their connections to the **Leased Property**, in a professional manner at its own expense, even if these fittings, installations and equipment were not introduced to the **Leased Property** by the **Lessee** and regardless of whether this was done before or during the lease established by this Lease Agreement. The Parties clarify that the underground pipes as defined in § 1 (3) of this Lease Agreement and stormwater pipes may remain in the **Leased Property**.

- to restore the **Leased Property** to the structural condition as set forth in **Appendix 1) and Appendices 2.1) and 2.2)**, even if the structural or technical changes have not been made by the **Lessee** and regardless of whether this was done before or during the lease established by this Lease Agreement; and

- to remove its movable inventory at its own expense

unless the **Lessor** has waived this in writing in an addendum to this Lease Agreement.

(4) If the **Lessee** fails to comply with its obligation to return the **Leased Property** in due time pursuant to subsection (1), it shall pay to the **Lessor**, on the basis of a daily settlement per day of the delayed return, 1/30 of the last monthly net base rent paid, plus 1/30 of the last monthly advance payment of operating costs paid, plus the statutory VAT applicable at the time of performance. The assertion of further damages by the **Lessor** remains reserved.

(5) The Parties shall prepare a written handover report on the return of the **Leased Property**.

(6) The **Lessor** agrees to reimburse the **Lessee** in the event that the Lease Agreement is terminated at the end of December 31, 2031 for the documented costs for measures pursuant to § 15 (2) of this Lease Agreement up to an amount of € [***] (in words [***] euros) (“Reimbursement Amount”). In the event that the Lease Agreement is terminated at the end of December 31, 2036 or at the end of December 31, 2041, the maximum Reimbursement Amount in both cases shall be € [***] (in words: [***] euros).

§ 16
Force majeure

Insofar and as long as a **Party** is prevented from fulfilling its contractual obligations for reasons of force majeure, it shall be released from such fulfillment. It shall immediately notify the other **Party** of the circumstances of force majeure and endeavor to remedy such circumstances. To the extent necessary and possible, the **Parties** shall agree on necessary adjustment measures. The **Parties** clarify that force majeure shall be understood to mean an extraordinary event of external origin, unforeseeable and uncontrollable, which cannot be prevented or averted even by the utmost care, e.g. lightning, earthquake, war, warlike conditions, floods etc.

§ 17
Confidentiality

(1) The **Parties** mutually agree to keep confidential any information they receive in connection with the conclusion of this Lease Agreement and its performance, including the economic framework conditions and the provisions of this Lease Agreement as well as any business and trade secrets that may become known. This means that corresponding information may not be disclosed to third parties without the prior written consent of the other Party.

Excluded from this is the disclosure of information to third parties engaged by one **Party** for the performance of the Agreement, but only to the extent that it is absolutely necessary for such performance.

However, it is a prerequisite that such third parties (e.g. lawyers, tax consultants, brokers, experts, tradespeople etc.) are in turn obliged to maintain confidentiality.

The above duty of confidentiality shall apply for a period of up to [***] years after termination of the lease.

(2) Excluded from the duty of confidentiality pursuant to subsection (1) shall be such information which the **Parties** have already received prior to the conclusion of the lease, regardless of its performance, or such information which may be obtained by one of the **Parties** from generally accessible sources without either of the **Parties** having brought this about by violating the duty of confidentiality.

The duty of confidentiality shall not apply if one of the **Parties** discloses the information necessary for this purpose on the basis of a statutory or official order or in legal proceedings in order to safeguard its legitimate interests.

§ 18
Collateral

(1) In order to secure all claims of the **Lessor** against the **Lessee** arising from this Lease Agreement, the **Lessee** shall, within 2 months of signing this Agreement, provide on first demand a directly enforceable guarantee of a bank licensed to do business in accordance with the attached sample (**Appendix 7**) for an amount corresponding to 3 times the monthly base rent at the beginning of the lease, plus advance payment of operating costs at the beginning of the lease, plus VAT.

(2) If the **Lessee** fails to provide a proper lease guarantee within the agreed period, after setting a reasonable grace period, the **Lessor** shall be entitled to terminate the lease without notice for good cause.

(3) The guarantee shall be returned by the **Lessor** to the **Lessee** at the end of 6 months after the termination of the lease, unless the **Lessor** asserts claims from the lease secured by the guarantee against the **Lessee** or the guarantor.

§ 19
Subletting, transfer of use and partial transfer

(1) The **Lessee** shall only be entitled to transfer the use of the **Leased Property** to a third party, and in particular to sublet it, with the **Lessor**'s prior written consent. The **Lessor** shall refuse its consent only for good cause. Good cause within the meaning of this provision shall be deemed to exist, in particular, if the provisions of § 3 of this Agreement are violated or if the third party is in a competitive relationship with the **Lessor** with its services. The **Lessor** now agrees to subletting to affiliated companies pursuant to § 15 of the German Stock Corporation Act (AktG).

(2) In the event of the transfer of use to a third party, the **Lessee** shall be liable for the latter as its vicarious agent.

§ 20
Consideration/prevention of hazards

(1) The **Parties** agree that the above provisions are only practicable if they take consideration of the respective interests of the other **Party**, with the involvement of the other companies on site, and agree in particular to find mutually agreeable solutions to problems which cannot be foreseen and regulated in detail by a contract.

(2) This shall apply, in particular, to measures which the Parties carry out on their own responsibility and at their own expense in accordance with the provisions of this Agreement and to official and other requirements which can only be met by way of mutual agreement.

(3) In case of imminent danger, the **Lessee** shall comply with the instructions of the plant security provider and the plant fire department. It shall also impose this obligation on the personnel employed by it and on third parties commissioned by it.

(4) The placement and storage of objects of any kind (boxes, goods, etc.) outside the **Leased Property**, in particular in shared circulation routes, is not permitted. If, in exceptional cases, the **Lessor** grants its consent to such storage, the **Lessee** shall nevertheless be liable for any damage resulting therefrom.

(5) Packaging material or similar waste resulting from commercial activities may not be disposed of in the general household waste containers, but must be disposed of in the supply facilities designated for this purpose by the **Lessor**.

(6) The **Lessee** shall comply with the parking regulations (**Appendix 6**), ensure that its employees and visitors comply with the parking regulations and support the **Lessor** in enforcing the parking regulations to the best of its ability.

§ 21
Completeness, written form

(1) This Agreement contains all agreements of the **Parties**. No additional agreements, ancillary agreements and assurances exist. If, contrary to the preceding sentence, additional agreements, ancillary agreements or assurances do exist, they are hereby revoked.

(2) Amendments and supplements to this Agreement and its Appendices as well as all declarations of intent under this Agreement must be made in writing to be effective. This shall also apply in the event of an amendment to this written form clause.

(3) The Parties are aware of the statutory written form requirement for lease agreements with a term longer than one year (§§ 550 (1), 126 (1) and (2) in conjunction with § 578 (2) (1) (1) BGB). They therefore mutually agree, upon mutual request of the other Party, to perform all acts and make all declarations necessary to comply with the statutory written form requirement. This provision shall apply not only to the execution of the main Lease Agreement and its Appendices, but also to all ancillary agreements, addenda, amendments or supplements. It shall not bind a subsequent purchaser of the property on which the **Leased Property** is located; § 566 (1) BGB shall be excluded to this extent.

(4) The Agreement shall be executed in duplicate; each Party shall receive one copy.

§ 22
Other provisions

(1) The **Lessor**, its agents, experts and interested parties may enter the **Leased Property** during business hours, after due notice and taking into account the legitimate interests of the **Lessee**, for the purpose of inspecting its condition, leasing it to a subsequent tenant, sale or otherwise for good cause.

Insofar as regulatory requirements (such as GMP regulations) apply to parts of the **Leased Property**, entry shall only be permitted in compliance with such requirements, insofar as

the **Lessee** has provided timely and comprehensive information about the specific requirements and the necessary measures.

In case of imminent danger, they shall be permitted access at any time of the day or night. In this case, the **Lessee** shall provide the appropriate means of access and, if the **Lessee** is not present, shall deposit keys in a quickly accessible location known to the **Lessor**.

In addition, the **Lessor** and its agents shall be entitled to enter the **Leased Property** at any time of day or night in coordination with the **Lessee** (coordination documented, for example, by issuing an access authorization card) in order to access energy rooms, communication nodes, main and floor telephone exchanges, main and floor fire alarm exchanges, battery system rooms and electro-acoustic systems (ELA) including the infrastructure required for this purpose as well as other rooms serving the supply of the **Leased Property**.

(2) The **Lessee** shall be responsible for ensuring traffic safety within the **Leased Property**. The **Lessee** shall be responsible for ensuring safety within the leased areas used exclusively by it as well as the technical areas, insofar as these are also used exclusively by the **Lessee**. Insofar as technical areas are used by both the **Lessee** and the **Lessor** (§ 1 (1) of the Lease Agreement), both Parties shall be equally liable for traffic safety and shall be jointly and severally liable to third parties in the event of a breach of the traffic safety obligation.

(3) All Appendices form an integral part of this Lease Agreement.

(4) As of the date of its entry into force, this Lease Agreement shall replace all existing oral and/or written agreements between the Parties concerning the transfer of the **Leased Property** described in more detail in § 1 of this Lease Agreement. The Old Lease existing between the Parties dated July 1, 2021 shall have ended as agreed with effect from the end of November 30, 2021, 12:00 a.m. the following day. No return of the **Leased Property** to the **Lessor**, even for a limited period of time, has taken place, as the **Lessee** continues to use the **Leased Property** without interruption.

(5) This Agreement is independent of any other lease agreements existing between the Parties.

(6) The Wastewater Agreement between the **Lessor** and the **Lessee** dated March 25/April 12, 2021 is an integral part of this Lease Agreement and is attached to this Agreement as **Appendix 8)**.

(7) The law of the Federal Republic of Germany shall apply to this Agreement and the lease governed by it. Insofar as translations are made of this Agreement, the German version shall be controlling.

(8) Marburg/Lahn is agreed as the place of jurisdiction for all disputes arising from this Agreement.

(9) Should any provision of this Agreement or any future newly included provision be invalid or unenforceable in whole or in part or lose its validity or enforceability at a later date, or should a gap be found in this Agreement, this shall not affect the validity of the remaining provisions. In place of the invalid or unenforceable provisions or to fill the gap, an appropriate provision shall be agreed in due form which, to the extent legally permissible, shall come as close as possible to what the Parties intended or would have intended according to the meaning and purpose of the Agreement if they had considered the point in question.

(10) The **Lessor** assumes no liability for any complete or partial competitive overlaps between the business operations of the **Lessee** and those of other tenants which exist or which will arise in the future. No protection against competition is granted.

(11) The Appendices to this Agreement are:

Appendix 1)	**List of leased areas**
Appendix 2.1)	**List of fixtures, installations and equipment, facilities**
Appendix 2.2)	**Building description of the Leased Property, equipment description of the Leased Property**

Appendix 3)	**Lessee's share of total area of Building M536 and Building M537 in m²**
Appendix 4)	**Monthly net base rent**
Appendix 5.1)	**Operating costs**
Appendix 5.2)	**Advance payment of operating costs**
Appendix 6)	**General Entry and Parking Regulations**
Appendix 7)	**Sample lease guarantee**
Appendix 8)	**Wastewater Agreement dated March 25/April 12, 2021 including Addendum No.1 dated December 14, 2021**
Appendix 9)	**Refurbishment of wastewater pipes**

Marburg, _____*19/01/2022*_____

Pharmaserv GmbH

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Marburg, _____*19/01/2022*_____

BioNTech Manufacturing Marburg GmbH

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Appendix 1)

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Appendix 4)

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APPENDIX 8

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Appendix 1 to the Wastewater Agreement (BioNTech)

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Appendix 1 to the Wastewater Agreement (BioNTech)

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Appendix 3 to the Wastewater Agreement with BioNTech

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Appendix 1 to the Wastewater Agreement (BioNTech) – Addendum 1

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Exhibit 8

Subsidiary	Jurisdiction of Incorporation
BioNTech Cell & Gene Therapies GmbH	Germany
BioNTech Delivery Technologies GmbH	Germany
BioNTech Diagnostics GmbH	Germany
BioNTech Europe GmbH	Germany
BioNTech Innovation GmbH	Germany
BioNTech Innovation and Services Marburg GmbH	Germany
BioNTech Innovative Manufacturing Services GmbH	Germany
BioNTech Manufacturing GmbH	Germany
BioNTech Manufacturing Marburg GmbH	Germany
JPT Peptide Technologies GmbH	Germany
reSano GmbH	Germany
BioNTech Real Estate Holding GmbH	Germany
BioNTech Real Estate Verwaltungs GmbH	Germany
BioNTech Real Estate GmbH & Co. KG	Germany
BioNTech Real Estate An der Goldgrube GmbH & Co. KG	Germany
BioNTech Real Estate An der Goldgrube 12 GmbH & Co. KG	Germany
BioNTech Real Estate Adam Opel Straße GmbH & Co. KG	Germany
BioNTech Real Estate Haus Vier GmbH & Co. KG	Germany
BioNTech R&D (Austria) GmbH	Austria
BioNTech Pharmaceuticals Asia Pacific Pte. Ltd.	Singapore
BioNTech (Shanghai) Pharmaceuticals Co., Ltd	China
BioNTech Turkey Tıbbi Ürünler Ve Klinik Araştırma Ticaret Anonim Şirketi	Turkey
BioNTech UK Limited	UK
BioNTech USA Holding, LLC	Delaware
BioNTech Research and Development Inc.	Delaware
BioNTech US, Inc	Delaware
JPT Peptide Technologies, Inc.	Delaware

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form F-3 No. 333-249991) of BioNTech SE,

(2) Registration Statement (Form S-8 No. 333-253263) pertaining to the 2020 Employee Equity Plan, the 2020 Restricted Stock Unit Plan for North America Employees and the 2017 Employee Stock Ownership Plan of BioNTech SE;

of our reports dated March 30, 2022, with respect to the consolidated financial statements of BioNTech SE and the effectiveness of internal control over financial reporting of BioNTech SE included in this Annual Report (Form 20-F) of BioNTech SE for the year ended December 31, 2021.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Cologne, Germany

March 30, 2022