UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF MAY 2024

COMMISSION FILE NUMBER 001-39081

BioNTech SE
(Translation of registrant's name into English)

An der Goldgrube 12
D-55131 Mainz
Germany
+49 6131-9084-0
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On May 6, 2024, BioNTech SE (the "Company") provided a development update and reported its financial results for the three months ended March 31, 2024. The interim condensed consolidated financial statements as well as the operating and financial review and prospects of the Company for the three months ended March 31, 2024 are attached hereto as Exhibit 99.1 and shall be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and incorporated by reference herein.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Jens Holstein

Name: Jens Holstein

Title: Chief Financial Officer

Date: May 6, 2024

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Quarterly Report for the Three Months Ended March 31, 2024

BioNTech SE

Quarterly Report of BioNTech SE for the Three Months Ended March 31, 2024

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 www.biontech.com. The information contained on, or that can be accessed through, our website is not part of this document. Our agent for service solely for the purpose of notices and communications from the Securities and Exchange Commission in the United States is c/o BioNTech US Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139, +1 (617) 337-4701.

Unaudited Interim Condensed Consolidated Financial Statements

Operating and Financial Review and Prospects

Unaudited Interim Condensed Consolidated Financial Statements

Interim Condensed Consolidated Statements of Profit or Loss

(in millions €, except per share data)	Note	Three months ended March 31, 2024 *(unaudited)*	2023 *(unaudited)*
Revenues	3	187.6	1,277.0
Cost of sales	4.1	(59.1)	(96.0)
Research and development expenses	4.1	(507.5)	(334.0)
Sales and marketing expenses	4.1	(15.6)	(12.2)
General and administrative expenses [(1)]	4.1	(117.0)	(111.8)
Other operating expenses [(1)]	4.2	(23.9)	(125.7)
Other operating income	4.3	28.3	57.1
Operating income / (loss)		**(507.2)**	**654.4**
Finance income	4.4	180.1	82.3
Finance expenses	4.4	(4.7)	(29.0)
Profit / (Loss) before tax		**(331.8)**	**707.7**
Income taxes	5	16.7	(205.5)
Profit / (Loss) for the period		**(315.1)**	**502.2**
Earnings / (Loss) per share			
Basic earnings / (loss) for the period per share		(1.31)	2.07
Diluted earnings / (loss) for the period per share		(1.31)	2.05

[(1)] Adjustments to prior-year figures due to change in functional allocation of general and administrative expenses and other operating expenses (please see Note 4.2 for further details).

The accompanying notes form an integral part of these interim consolidated financial statements.

Interim Condensed Consolidated Statements of Comprehensive Income

(in millions €)	Note	Three months ended March 31, 2024 *(unaudited)*	2023 *(unaudited)*
Profit / (Loss) for the period		**(315.1)**	**502.2**
Other comprehensive income			
Other comprehensive income that may be reclassified to profit or loss in subsequent periods, net of tax			
Exchange differences on translation of foreign operations		15.4	(2.1)
Net gain on cash flow hedges		—	1.7
Net other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods		**15.4**	**(0.4)**
Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods, net of tax			
Net gain on equity instruments designated at fair value through other comprehensive income		6.9	—
Net other comprehensive income that will not be reclassified to profit or loss in subsequent periods		**6.9**	**—**
Other comprehensive income / (loss) for the period, net of tax		**22.3**	**(0.4)**
Comprehensive income / (loss) for the period, net of tax		**(292.8)**	**501.8**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements.

Interim Condensed Consolidated Statements of Financial Position

(in millions €)	Note	March 31, 2024 *(unaudited)*	December 31, 2023
Assets			
Non-current assets			
Goodwill		368.7	362.5
Other intangible assets		821.7	804.1
Property, plant and equipment		802.6	757.2
Right-of-use assets		228.3	214.4
Other financial assets	6	1,587.2	1,176.1
Other non-financial assets		83.2	83.4
Deferred tax assets		91.0	81.3
Total non-current assets		**3,982.7**	**3,479.0**
Current assets			
Inventories		345.4	357.7
Trade and other receivables	6	1,639.8	2,155.7
Contract assets		12.1	4.9
Other financial assets	6	6,689.9	4,885.3
Other non-financial assets		337.0	280.9
Income tax assets		273.3	179.1
Cash and cash equivalents		8,976.6	11,663.7
Total current assets		**18,274.1**	**19,527.3**
Total assets		**22,256.8**	**23,006.3**
Equity and liabilities			
Equity			
Share capital		248.6	248.6
Capital reserve		1,228.9	1,229.4
Treasury shares		(10.8)	(10.8)
Retained earnings		19,448.2	19,763.3
Other reserves		(946.7)	(984.6)
Total equity		**19,968.2**	**20,245.9**
Non-current liabilities			
Lease liabilities, loans and borrowings	6	205.0	191.0
Other financial liabilities	6	40.6	38.8
Provisions		8.8	8.8
Contract liabilities		379.2	398.5
Other non-financial liabilities		9.6	13.1
Deferred tax liabilities		39.4	39.7
Total non-current liabilities		**682.6**	**689.9**
Current liabilities			
Lease liabilities, loans and borrowings	6	31.3	28.1
Trade payables and other payables	6	298.8	354.0
Other financial liabilities	6	152.4	415.2
Income tax liabilities		353.2	525.5
Provisions		247.0	269.3
Contract liabilities		361.3	353.3
Other non-financial liabilities		162.0	125.1
Total current liabilities		**1,606.0**	**2,070.5**
Total liabilities		**2,288.6**	**2,760.4**
Total equity and liabilities		**22,256.8**	**23,006.3**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements.

Interim Condensed Consolidated Statements of Changes in Stockholders' Equity

(in millions €, unaudited)	Note	Share capital	Capital reserve	Treasury shares	Retained earnings	Other reserves	Total equity
As of January 1, 2023		**248.6**	**1,828.2**	**(5.3)**	**18,833.0**	**(848.9)**	**20,055.6**
Profit for the period		—	—	—	502.2	—	**502.2**
Other comprehensive loss		—	—	—	—	(0.4)	**(0.4)**
Total comprehensive profit / (loss)		**—**	**—**	**—**	**502.2**	**(0.4)**	**501.8**
Share repurchase program		—	(279.7)	(2.3)	—	—	**(282.0)**
Share-based payments	8	—	(0.6)	—	—	11.5	**10.9**
Deferred taxes		—	—	—	—	(21.0)	**(21.0)**
As of March 31, 2023		**248.6**	**1,547.9**	**(7.6)**	**19,335.2**	**(858.8)**	**20,265.3**
As of January 1, 2024		**248.6**	**1,229.4**	**(10.8)**	**19,763.3**	**(984.6)**	**20,245.9**
Loss for the period		—	—	—	(315.1)	—	**(315.1)**
Other comprehensive income		—	—	—	—	22.3	**22.3**
Total comprehensive profit / (loss)		**—**	**—**	**—**	**(315.1)**	**22.3**	**(292.8)**
Share-based payments	8	—	(0.5)	—	—	15.6	**15.1**
As of March 31, 2024		**248.6**	**1,228.9**	**(10.8)**	**19,448.2**	**(946.7)**	**19,968.2**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements.

Interim Condensed Consolidated Statements of Cash Flows

	Three months ended March 31,	
	2024	**2023**
(in millions €)	*(unaudited)*	*(unaudited)*
Operating activities		
Profit / (Loss) for the period	(315.1)	502.2
Income taxes	(16.7)	205.5
Profit / (Loss) before tax	**(331.8)**	**707.7**
Adjustments to reconcile profit before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	38.3	31.4
Share-based payment expenses	16.3	8.6
Net foreign exchange differences	(28.7)	53.1
Loss on disposal of property, plant and equipment	—	0.2
Finance income excluding foreign exchange differences	(174.9)	(82.3)
Finance expense excluding foreign exchange differences	4.7	1.2
Government grants	(9.1)	(3.0)
Net gain on derivative instruments at fair value through profit or loss	1.7	76.2
Working capital adjustments:		
Decrease in trade and other receivables, contract assets and other assets	498.2	893.8
Decrease in inventories	12.3	15.5
Decrease in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	(288.0)	(861.6)
Interest received and realized gains from cash and cash equivalents	199.4	53.6
Interest paid and realized losses from cash and cash equivalents	(3.7)	(1.2)
Income tax paid	(258.8)	(844.9)
Share-based payments	(2.4)	(725.7)
Government grants received	9.2	—
Net cash flows used in operating activities	**(317.3)**	**(677.4)**
Investing activities		
Purchase of property, plant and equipment	(58.5)	(45.2)
Purchase of intangible assets and right-of-use assets	(78.4)	(9.6)
Investment in other financial assets	(4,895.1)	(680.6)
Proceeds from maturity of other financial assets	2,727.6	—
Net cash flows used in investing activities	**(2,304.4)**	**(735.4)**
Financing activities		
Payments related to lease liabilities	(7.8)	(9.3)
Share repurchase program	—	(282.0)
Net cash flows used in financing activities	**(7.8)**	**(291.3)**
Net decrease in cash and cash equivalents	(2,629.5)	(1,704.1)
Change in cash and cash equivalents resulting from exchange rate differences	6.8	(27.1)
Change in cash and cash equivalents resulting from other valuation effects	(64.4)	—
Cash and cash equivalents at the beginning of the period	11,663.7	13,875.1
Cash and cash equivalents as of March 31	**8,976.6**	**12,143.9**

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements.

Selected Explanatory Notes to the Unaudited Interim Condensed Consolidated Financial Statements

1. Corporate Information

BioNTech SE is a limited company incorporated and domiciled in Germany. The registered office is located in Mainz, Germany (An der Goldgrube 12, 55131 Mainz). The accompanying unaudited interim condensed consolidated financial statements present the financial position and the results of operation of BioNTech SE and its subsidiaries and have been prepared on a going concern basis in accordance with the International Financial Reporting Standards, or IFRS as issued by the International Accounting Standards Board, or IASB. References to the "Company", "BioNTech", "Group", "we", "us" and "our" refer to BioNTech SE and its consolidated subsidiaries.

We are a global next-generation immunotherapy company pioneering novel medicines against cancer, infectious diseases and other serious diseases. 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 global 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 discover, develop and commercialize our marketed product and other candidate vaccines and therapies. We have built a broad toolkit across multiple technology platforms, including a diverse range of potentially first-in-class therapeutic approaches. This includes investigational mRNA vaccines and therapeutics, cell and gene therapies, targeted antibodies and small molecule immunomodulators.

Our unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2024, were authorized for issuance in accordance with a resolution of the audit committee on May 3, 2024.

2. Basis of Preparation, Significant Accounting Policies and further Accounting Topics

Basis of Preparation and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2024, have been prepared in accordance with International Accounting Standard (IAS) 34 Interim Financial Reporting.

The unaudited interim condensed consolidated financial statements do not include all the information and disclosures required in the audited consolidated financial statements, and should be read in conjunction with our audited consolidated financial statements and accompanying notes included in our Annual Report on Form 20-F as of and for the year ended December 31, 2023.

We prepare and present our unaudited interim condensed consolidated financial statements in Euros and round numbers to millions of Euros. 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.

The unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2024, include BioNTech SE and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Significant Accounting Judgments, Estimates and Assumptions and Accounting Policies

The preparation of the unaudited interim condensed consolidated financial statements requires our management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities and the accompanying disclosures. This includes but is not limited to our judgment relating to our collaboration with Pfizer, Inc., or Pfizer, as described under the subheading "Pfizer Agreement Characteristics" in Note 3 to our audited consolidated financial statements as of and for the year ended December 31, 2023. In order to determine our share of the collaboration partner's gross profits, we used certain information from the collaboration partner, including revenues from the sale of products and certain other sharable expense items, some of which is based on preliminary data shared between the partners.

Our management continually evaluates judgments and estimates, including those related to contingencies, fair value measurement of derivatives, revenues and expenses. Management bases its judgments and estimates on parameters available at the time when the unaudited interim condensed 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. Such changes are reflected in the assumptions when they occur.

The accounting policies adopted in the preparation of the unaudited interim condensed consolidated financial statements are consistent with those followed in the preparation of our audited consolidated financial statements as of and for the year ended December 31, 2023, except for income taxes, which are accounted for using the expected annual tax rate in our unaudited interim condensed consolidated financial statements (see Note 5).

Furthermore, we recognize acquired contractual rights to cash flows from the sale of patent-protected biopharmaceutical products by unrelated biopharmaceutical companies as royalty assets. Since we do not own the intellectual property or have the right to commercialize the underlying products, royalty assets are recognized as financial assets measured at fair value through profit and loss. We recognize day one gains and losses only when the fair value is evidenced by a quoted price in an active market for the same instrument or is based on a valuation technique that only uses data from observable markets. In all other cases, we defer the difference between the fair value at initial recognition and the transaction price. After initial recognition, we recognize that deferred difference as a gain or loss only to the extent that it arises from a change in a factor that market participants would take into account when pricing the asset or liability.

Standards Applied for the First Time

The IFRS standards applied for the first time as of January 1, 2024, as disclosed in the notes to the audited consolidated financial statements as of and for the year ended December 31, 2023, had no impact on our unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2024.

3. Revenues from Contracts with Customers

Disaggregated information on revenues

Set out below is the disaggregation of our revenues from contracts with customers:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
COVID-19 vaccine revenues	124.2	1,263.5
Other revenues	63.4	13.5
Total	**187.6**	**1,277.0**

COVID-19 Vaccine Revenues

During the three months ended March 31, 2024 and 2023, commercial revenues were recognized from the supply and sales of our COVID-19 vaccine worldwide, mainly comprising our share of the collaboration partner's gross profit derived from sales in the collaboration partner's territory. Overall, our commercial COVID-19 vaccine revenues amounted to €124.2 million during the three months ended March 31, 2024, compared to €1,263.5 million for the comparative prior year period. The year-over-year change was mainly due to lower revenues from the sales of our COVID-19 vaccines worldwide resulting from lower sales demand during the three months ended March 31, 2024.

During the three months ended March 31, 2024, our other revenues were mainly derived from a pandemic preparedness contract effectively supplemented in the first quarter of 2024 with the German government.

Revenues from contracts with customers were recognized as follows:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
Timing of revenue recognition		
Goods and services transferred at a point in time	*33.5*	*143.0*
Goods and services transferred over time	*57.3*	*7.1*
Revenue recognition applying the sales-based or usage-based royalty recognition constraint model[(1)]	*96.8*	*1,126.9*
Total	**187.6**	**1,277.0**

(1) Represents sales based on the share of the collaboration partners' gross profit.

4. Income and Expenses

4.1 General Expenses

Cost of Sales

From the three months ended March 31, 2023, to the three months ended March 31, 2024, cost of sales decreased by €36.9 million or 38% from €96.0 million to €59.1 million, mainly due to recognizing lower cost of sales from our decreased COVID-19 vaccine sales, which included the share of gross profit that we owe our collaboration partner, Pfizer, and royalty expenses based on our sales. In addition, cost of sales was impacted by expenses arising from inventory write-downs to net realizable value due to inventories expected to be unsellable, not fulfilling the specification defined by our quality standards, shelf-life expiry or destruction of inventory amounting to €36.0 million, compared to €73.7 million in the previous period. The inventories valued at net realizable value in our consolidated statement of financial position as of March 31, 2024, take contractual compensation payments into consideration.

Research and Development Expenses

From the three months ended March 31, 2023, to the three months ended March 31, 2024, our research and development expenses increased by €173.5 million or 52%, from €334.0 million to €507.5 million, mainly influenced by progressing clinical studies for pipeline candidates and our newly acquired clinical stage antibody drug conjugate (ADC) and antibody product candidates which further expand our oncology pipeline. Further contributions to the increase coming from wages, benefits and social security expenses resulting from a significant increase in headcount.

General and Administrative Expenses

From the three months ended March 31, 2023, to the three months ended March 31, 2024, our general and administrative expenses increased by €5.2 million or 5%, from €111.8 million to €117.0 million, primarily driven by increased expenses for IT environment and wages, benefits, and social security expenses resulting from a significant increase in headcount.

4.2 Other Operating Expenses

Other operating expenses recognized during the three months ended March 31, 2024 and 2023 are shown in the following table:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
Litigation costs[(1)]	21.2	7.6
Loss on derivative instruments at fair value through profit or loss	2.7	—
Foreign exchange differences, net	—	116.5
Other	—	1.6
Total	**23.9**	**125.7**

(1) Adjustments to prior-year figures relate to reclassifying legal costs in connection with certain litigation as other operating expenses, rather than general and administrative expenses, to reflect changes in reporting.

During the three months ended March 31, 2024, other operating expenses decreased compared to the three months ended March 31, 2023, primarily because the foreign exchange differences arising on operating items changed from a negative effect to a positive effect, which is recorded in other operating income during the three months ended March 31, 2024 (see Note 4.3).

4.3 Other Operating Income

Other operating income recognized during the three months ended March 31, 2024 and 2023 is shown in the following table:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
Foreign exchange differences, net	17.1	—
Government grants	9.1	—
Gain on derivative instruments at fair value through profit or loss	—	41.9
Other	2.1	15.2
Total	**28.3**	**57.1**

During the three months ended March 31, 2024, other income decreased compared to the three months ended March 31, 2023, as the result on derivative instruments at fair value through profit or loss arising on foreign exchange forward contracts that did not qualify for hedge accounting changed from a gain to a loss, which is recorded in other operating expenses (see Note 4.2).

4.4 Finance Result

The finance result recognized during the three months ended March 31, 2024 and 2023 is shown in the following table:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
Finance result		
Finance income	**180.1**	**82.3**
Gains from financial instruments	174.9	82.3
Foreign exchange differences, net	5.2	—
Finance expenses	**(4.7)**	**(29.0)**
Foreign exchange differences, net	—	(27.8)
Other	(4.7)	(1.2)
Total finance result	**175.4**	**53.3**

During the three months ended March 31, 2024 and 2023, the finance result was mainly derived from interest income in relation to bank deposits and debt security investments as well as fair value adjustments of our money market funds.

5. Income Taxes

For the three months ended March 31, 2024, income taxes were calculated based on the best estimate of the weighted average annual income tax rates expected for the full financial years (estimated annual effective income tax rates) on ordinary income before tax adjusted by the tax effect of any discrete items. The income tax asset represents the portion of prepayments for corporate income taxes and trade taxes in Germany that have been paid for the first quarter of 2024 but not yet offset by income tax expenses calculated for such quarter. For the three months ended March 31, 2024, our effective income tax rate was approximately 5.0% applicable on our negative income and for the three months ended March 31, 2023, our effective income tax rate was approximately 29.0%, on our positive income. The decrease in the effective income tax rate was mainly driven by the expected negative result for 2024 and management's assessment of the requirements in IAS 12, including 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. Thus, in countries where the requirements of IAS 12 were not fulfilled, no deferred tax asset was recognized. Such assessment takes into account the

fact that there is an inherent risk of failure in pharmaceutical development and uncertainty of approvals that depend on external regulatory agencies' opinions.

As of March 31, 2024, it is considered highly probable that taxable profits for the U.S. tax group will be available against which the deferred tax assets can be utilized in the near future fulfilling the requirements set out by IAS 12.

We apply the mandatory exception to recognizing and disclosing information about deferred tax assets and liabilities arising from Pillar Two income taxes. Furthermore, we reviewed the corporate structure in light of the introduction of Pillar Two Model Rules in various jurisdictions. Since the Group's relevant effective tax rate calculated for Pillar Two Purposes is mainly above 15% in all jurisdictions in which it operates, it has been determined that the Group is not materially subject to Pillar Two "top-up" taxes. Therefore, the consolidated financial statements for the three months ended March 31, 2024, do not include information required by paragraphs 88A-88D of IAS 12.

Income taxes recognized during the three months ended March 31, 2024 and 2023 are shown in the following table:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
Current income taxes	(7.8)	243.2
Deferred taxes	(8.9)	(37.7)
Income taxes	**(16.7)**	**205.5**

6. Financial Assets and Financial Liabilities

Financial Assets and Liabilities at Amortized Cost and at Fair Value through OCI and Profit or Loss

Set out below is an overview of financial assets and liabilities at amortized cost and at fair value through OCI and profit or loss, as of the dates indicated:

March 31, 2024

(in millions €)	Category[1]	Carrying amount	Level 1 (Fair value)	Level 2 (Fair value)	Level 3 (Fair value)	Total
Financial assets measured at fair value						
Foreign exchange forward contracts	FVTPL	3.6	—	3.6	—	3.6
Money market funds	FVTPL	4,059.3	4,059.3	—	—	4,059.3
Non-listed equity investments	FVTOCI	27.1	—	—	27.1	27.1
Listed equity investments	FVTOCI	221.3	221.3	—	—	221.3
Royalty assets	FVTPL	43.3	—	—	43.3	43.3
Financial assets not measured at fair value						
Trade and other receivables	AC	1,639.8	—	—	—	1,639.8
Security investments	AC	7,962.7	—	—	—	7,962.7
Other financial assets	AC	19.1	—	—	—	19.1
Bank deposits	AC	3,865.0	—	—	—	3,865.0
Reverse Repo	AC	400.0	—	—	—	400.0
Cash at banks and on hand	AC	652.3	—	—	—	652.3
Financial liabilities measured at fair value						
Foreign exchange forward contracts	FVTPL	5.0	—	5.0	—	5.0
Contingent consideration	FVTPL	40.6	—	—	40.6	40.6
Financial liabilities not measured at fair value						
Lease liabilities	n/a	234.0	—	—	—	234.0
Loans and borrowings	AC	2.3	—	—	—	2.3
Trade payables and other payables	AC	298.8	—	—	—	298.8
Other financial liabilities	AC	147.4	—	—	—	147.4

[1] Financial assets and liabilities categorized at amortized costs mainly correspond to fair value. Fair values are not disclosed because the book values represent a reasonable approximation of fair value.

The €195.3 million increase in listed equity investments compared to year-end 2023 mainly reflects our investment in Autolus Therapeutics plc (Autolus) in February 2024.

Under the terms of the license and option agreement with Autolus we acquired a royalty asset in connection with Autolus' lead cell therapy candidate, obe-cel, and we are eligible to receive a royalty on obe-cel net sales. Autolus will retain full rights to and control of the development and commercialization of obe-cel. We deferred a day one gain amounting to €5.6 million based as the difference of the measured fair value of the instrument at initial recognition based on the present value of expected future cash flows and the transaction price.

Additional developments in our financial assets and liabilities mainly resulted from growth and reallocation of existing capital. This led to a decrease of €3,386.8 million in money market funds and increases of €1,973.0 million in security investments and €1,275.5 million in bank deposits compared to year-end 2023.

December 31, 2023

(in millions €)	Category[1]	Carrying amount	Level 1 (Fair value)	Level 2 (Fair value)	Level 3 (Fair value)	Total
Financial assets measured at fair value						
Money market funds	FVTPL	7,446.1	7,446.1	—	—	7,446.1
Non-listed equity investments	FVTOCI	27.1	—	—	27.1	27.1
Listed equity investments	FVTOCI	26.0	26.0	—	—	26.0
Financial assets not measured at fair value						
Trade and other receivables	AC	2,155.7	—	—	—	2,155.7
Security investments	AC	5,989.7		—	—	5,989.7
Other financial assets	AC	18.6	—	—	—	18.6
Bank deposits	AC	2,589.5	—	—	—	2,589.5
Reverse Repo	AC	1,175.0		—	—	1,175.0
Cash at banks and on hand	AC	453.1	—	—	—	453.1
Financial liabilities measured at fair value						
Foreign exchange forward contracts	FVTPL	0.4	—	0.4	—	0.4
Contingent consideration	FVTPL	38.8	—	—	38.8	38.8
Financial liabilities not measured at fair value						
Lease liabilities	n/a	216.7	—	—	—	216.7
Loans and borrowings	AC	2.3	—	—	—	2.3
Trade payables and other payables	AC	354.0	—	—	—	354.0
Other financial liabilities	AC	414.9	—	—	—	414.9

[1] Financial assets and liabilities categorized at amortized costs mainly correspond to fair value. We do not make a disclosure for cash and cash equivalents, trade receivables and trade payables. Fair values are not disclosed because the book values represent a reasonable approximation of fair value.

Equity investments designated at Fair Value through OCI

Financial investments in equity securities measured at fair value through other comprehensive income comprise the following effects:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
Net gain on equity instruments designated at fair value through other comprehensive income	6.9	—
Total	**6.9**	**—**

Measurement of fair values

The following table shows the valuation techniques used in measuring fair values for financial instruments in our consolidated statements of financial position, as well as the significant unobservable inputs used.

Type	Valuation technique	Significant unobservable inputs
Forward exchange contracts	Discounted cash flow using par method. Expected future cash flows based on foreign exchange forwards discounted over the respective remaining term of the contracts using the respective deposit interest rates and spot rates.	n/a
Non-listed equity investments	Quantitative and qualitative factors such as actual and forecasted results, cash position and financing round valuations.	– Actual and forecasted results – Cash position – Nature and pricing indication of latest financing round
Listed equity investments	Stock prices of the listed companies and applicable exchange rates, if the listing is in a foreign currency.	n/a
Money market funds	Quoted prices on an active market	n/a
Contingent consideration	Present value of expected future payments and reflecting changes in expected achievement of underlying performance parameters and compounding effects.	– Expected future payments – Applied cost of capital
Royalty assets	Present value of expected future cash flows	– Expected future cash flows – Applied cost of capital

Recurring Fair Values (Level 3)

The following table shows the recurring fair value measurement of contingent consideration and royalty assets as well as the effect of the measurements on our unaudited interim condensed consolidated statements of profit or loss for the current period.

	Financial assets	Financial liabilities
(in millions €)	Royalty assets	Contingent consideration
As of January 1, 2023	**—**	**(6.1)**
As of March 31, 2023	**—**	**(6.1)**
As of January 1, 2024	**—**	**(38.8)**
Purchases	37.7	—
Net effect on profit or loss - Finance income / (expense)		
Net change in fair value	—	(1.8)
Net deferred effects on other non-financial liabilities		
Net change in fair value	5.6	—
As of March 31, 2024	**43.3**	**(40.6)**

The sensitivity of the fair values of contingent consideration to the significant, unobservable, variable input factors, with all other factors remaining constant, is shown in the following table:

Contingent consideration

Input factor	Change in assumptions	Change in fair value with increasing input factor (in millions €)	Change in fair value with decreasing input factor (in millions €)
Cash flow projections	10 %	3.8	(3.8)
Discount rate	1 %	(0.9)	0.9

The sensitivity of the fair values of royalty assets to the significant, unobservable, variable input factors, with all other factors remaining constant, is shown in the following table:

Royalty assets

Input factor	Change in assumptions	Change in fair value with increasing input factor (in millions €)	Change in fair value with decreasing input factor (in millions €)
Cash flow projections	10 %	5.2	(5.2)
Discount rate	1 %	(3.7)	4.2

The estimated fair value of non-listed equity investments would, for example, increase (decrease) if the price of the latest financing round of the respective investment were to increase (decrease) and the overall company value were higher (lower).

Risk Management Activities

No changes have occurred regarding our risk management activities as disclosed in the notes to our audited consolidated financial statements included in our Annual Report on Form 20-F as of and for the year ended December 31, 2023.

7. Issued Capital and Reserves

As of March 31, 2024 and December 31, 2023, the number of shares outstanding was 237,725,735. This amount excludes 10,826,465 shares held in treasury.

8. Share-Based Payments

Expenses Arising from Share-Based Payment Arrangements

During the three months ended March 31, 2024 and 2023, the following share-based payment arrangements led to the expenses recognized for services received during the respective periods as shown in the following table:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
Expense arising from equity-settled share-based payment arrangements	15.6	10.7
Expense / (Income) arising from cash-settled share-based payment arrangements	0.7	(2.5)
Total	**16.3**	**8.2**
Recognized in:		
Cost of sales	1.9	1.5
Research and development expenses	9.8	6.5
Sales and marketing expenses	0.4	0.1
General and administrative expenses	4.2	0.1
Total	**16.3**	**8.2**

9. Contingencies

Our contingencies include, but are not limited to, intellectual property disputes and product liability and other product-related litigation. 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 intellectual property. As of March 31, 2024, none of such intellectual property-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 are subject to an increasing number of product liability claims. Such claims often involve highly complex issues related to medical causation, correctness and completeness of product information (Summary of Product Characteristics/package leaflet) as well as label warnings and reliance thereon, scientific evidence and findings, actual and provable injury, and other matters. These complexities vary from matter to matter. As of March 31, 2024, none of these claims fulfill the criteria for recording a provision. Substantially all of our contingencies are subject to significant uncertainties and, therefore, determining the likelihood of a loss and/or the measurement of any loss can be complex. Consequently, we are unable to estimate the range of reasonably possible loss. Our assessments, which result from a complex series of judgments about future events and uncertainties, are based on estimates and assumptions that have been deemed reasonable by management, but that may prove to be incomplete or inaccurate, and unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. We currently do not believe that any of these matters will have a material adverse effect on our financial position, and will continue to monitor the status of these and other claims that may arise. However, we could incur judgments, enter into settlements or revise our expectations regarding the outcome of matters, which could have a material adverse effect on our results of operations and/or our cash flows in the period in which the amounts are accrued or paid. 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.

Certain pending matters to which we are a party are discussed below.

Alnylam Proceedings

In March 2022, Alnylam Pharmaceuticals, Inc., or Alnylam, filed a lawsuit against Pfizer and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging that an existing patent owned by Alnylam, U.S. Patent No. 11,246,933, or the '933 Patent, is infringed by the cationic lipid used in *Comirnaty*, and seeking monetary relief, which is not specified in their filings. We filed a counterclaim to become party to the Alnylam proceeding, and in June 2022, Alnylam added to its claims allegations that we induced infringement of the '933 Patent. Additionally, in July 2022, Alnylam filed a lawsuit against us, our wholly owned subsidiary, BioNTech Manufacturing GmbH, Pfizer and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging that we also induced infringement of a newly issued patent, U.S. Patent No. 11,382,979, or the '979 Patent, which is a continuation of the '933 Patent. The two lawsuits were consolidated on July 28, 2022. In May 2023, Alnylam filed a third lawsuit against Pfizer Inc. and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 11,633,479; 11,633,480; 11,612,657; and 11,590,229, all of which are continuations of the '933 Patent. We filed a counterclaim to become party to the new proceeding, and in July 2023, Alnylam added to its claims allegations that we induced infringement of the four new patents. All of the proceedings have been consolidated and are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Alnylam's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

CureVac Proceedings

Infringement Proceedings – EP'122, DE'961, DE'974, DE'575, and EP'668

In July 2022, CureVac AG, or CureVac, filed a lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging *Comirnaty*'s infringement of one European patent, EP1857122B1, or the EP'122 Patent, and three Utility Models DE202015009961U1, DE202015009974U1, and DE202021003575U1. In August 2022, CureVac added European Patent EP3708668B1, or the EP'668 Patent, to its German lawsuit.

On August 15, 2023, the Düsseldorf Regional Court held a hearing on infringement with respect to all five IP rights. At the hearing, the Court suspended its infringement ruling with respect to EP'122 until December 28, 2023. On September 28, 2023, the Court issued orders suspending its infringement rulings with respect to the remaining four IP rights (DE'961, DE'974, DE'575, and EP'668) pending validity decisions in the DE'961, DE'974, and DE'575 cancellation proceedings before the German Patent and Trademark Office and in the EP'668 opposition proceedings before the Opposition Division of the European Patent Office. In the September 28th orders, the Court explained that it was suspending its infringement rulings until validity decisions are reached, while contemporaneously noting concerns regarding the validity of DE'961, DE'974, DE'575, and EP'668. On December 28, 2023, the Düsseldorf Regional Court stayed the infringement proceedings as to EP'122 until a final appellate decision is rendered as to the validity of EP 122 by the Federal Court of Justice.

Infringement Proceedings – EP'755, DE'123, and DE'130

In July 2023, CureVac SE filed a second lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging *Comirnaty*'s infringement of one European patent, EP4023755B1, or the EP'755 Patent, and two Utility Models DE202021004123U1, and DE202021004130U1.

Nullity Proceedings – EP'122

In September 2022, we filed a nullity action in the Federal Patent Court of Germany seeking a declaration that the EP'122 Patent is invalid. In April 2023, the Federal Patent Court of Germany issued a preliminary opinion in the EP'122 nullity action in support of the validity of the EP'122 Patent. The preliminary opinion did not address any infringement of the EP'122 Patent. The preliminary opinion is a preliminary assessment by the court of the merits of a claim, and is non-binding. On December 19, 2023, the Federal Patent Court held an oral hearing, after which it nullified EP'122.

Cancellation Proceedings – DE'961, DE'974, and DE'575

In November 2022, we filed cancellation actions seeking the cancellation of the three German Utility Models in the German Patent and Trademark Office. On December 27, 2023, the German Patent Office issued a preliminary opinion that DE'974 is likely to be cancelled. On January 23, 2024, the German Patent Office issued a preliminary opinion that DE'961 is likely to be cancelled. On March 7, 2024, the German Patent Office issued a preliminary opinion that DE'575 is likely to be cancelled.

United States

In July 2022, we and Pfizer filed a complaint for a declaratory judgment in the U.S. District Court for the District of Massachusetts, seeking a judgment of non-infringement by *Comirnaty* of U.S. Patent Nos. 11,135,312, 11,149,278 and 11,241,493. In May 2023, the action in the U.S. District Court for the District of Massachusetts was transferred to the U.S. District Court for the Eastern District of Virginia, where CureVac filed counterclaims asserting infringement of six additional U.S. patents, U.S. Patent Nos. 10,760,070; 11,286,492; 11,345,920; 11,471,525; 11,576,966; and 11,596,686. In July 2023, CureVac filed amended counterclaims to assert an additional U.S. patent, U.S. Patent No. 11,667,910.

United Kingdom

In September 2022, we and Pfizer filed a declaration of non-infringement and revocation action against the EP'122 Patent and the EP'668 Patent in the Business and Property Courts of England and Wales. In October 2022, CureVac responded by filing a counterclaim alleging infringement of the EP'122 and EP'668 patents in the Business And Property Courts of England and Wales. On December 18, 2023, we amended our pleadings to further allege non-infringement and invalidity against EP'755.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and utility models and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of CureVac's claims is ongoing and complex, and we believe the ultimate outcomes remain substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Moderna Proceedings

Germany

Infringement Proceedings – EP'949 and EP'565

In August 2022, Moderna filed a lawsuit against us and Pfizer and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Manufacturing Belgium NV, Pfizer Ireland Pharmaceuticals and Pfizer Inc. in the Düsseldorf Regional Court alleging *Comirnaty*'s infringement of two European Patents, 3590949B1, or the EP'949 Patent, and 3718565B1, or the EP'565 Patent. On November 7, 2023, the European Patent Office, or the EPO, Opposition Division revoked EP'565 after a one-day oral hearing. The Opposition Division issued a preliminary opinion on December 8, 2023 noting that it believes EP'949 is likely invalid. As a result of these EPO proceedings, the Düsseldorf Regional Court postponed its hearing on infringement, originally scheduled for December 12, 2023, to January 21, 2025.

United Kingdom

In August 2022, Moderna filed a lawsuit asserting *Comirnaty*'s infringement of the EP'949 Patent and EP'565 Patent against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Limited, Pfizer Manufacturing Belgium NV and Pfizer Inc. in the Business and Property Courts of England and Wales. In September 2022, we and Pfizer filed a revocation action in the Business and Property Courts of England and Wales requesting revocation of the EP'949 Patent and EP'565 Patent.

United States

U.S. District Court Litigation

In August 2022, Moderna filed a lawsuit in the United States District Court for the District of Massachusetts against us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. and Pfizer Inc. alleging *Comirnaty*'s infringement of U.S. Patent Nos. 10,898,574, 10,702,600 and 10,933,127 and seeking monetary relief. On April 12, 2024, the United States District Court for the District of Massachusetts stayed the litigation pending resolution of the *inter partes* review of U.S. Patent Nos. 10,702,600 and 10,933,127.

Inter Partes Review

In August 2023, Pfizer and we filed petitions seeking inter partes review of U.S. Patent Nos. 10,702,600 and 10,933,127 before the United States Patent Trial and Appeal Board, or the PTAB. On March 6, 2024, the PTAB issued decisions instituting *inter partes* review proceedings on all challenged claims of U.S. Patent Nos. 10,702,600 and 10,933,127.

Netherlands

In September 2022, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH and Pfizer B.V., Pfizer Export B.V., C.P. Pharmaceuticals International C.V. and Pfizer Inc. in the District Court of The Hague alleging *Comirnaty*'s infringement of the EP '949 Patent and the EP '565 Patent. The District Court of the Hague held a hearing on October 6, 2023 on infringement and validity with respect to the EP '949 Patent. On December 6, 2023, the Court found EP'949 to be invalid. On March 5, 2024, Moderna appealed this decision. The EP'565 case has been stayed pending the outcome of Moderna's appeal of the Opposition Division's revocation of EP'565.

Ireland

In May 2023, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc., Pfizer Healthcare Ireland, Pfizer Ireland Pharmaceuticals, and C.P. Pharmaceuticals International C.V. alleging *Comirnaty*'s infringement of the EP'949 Patent and EP'565 Patent in the High Court of Ireland. On February 26, 2024, the High Court of Ireland stayed the lawsuit pending the final determination of the EPO opposition proceedings for EP'949 and EP'565 (in each case including any appeals).

Belgium

In May 2023, Moderna filed a lawsuit against us, our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc. and Pfizer Manufacturing Belgium alleging *Comirnaty*'s infringement of the EP'949 Patent and the EP'565 Patent in the Brussels Dutch-speaking Enterprise Court.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Moderna's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Arbutus and Genevant Proceedings

In April 2023, Arbutus Biopharma Corp., or Arbutus, and Genevant Sciences GmbH, or Genevant, filed a lawsuit against Pfizer and us in the U.S. District Court for the District of New Jersey alleging that Pfizer and we have infringed the following patents owned by Arbutus: U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098, through the use of Genevant's lipid nanoparticle technology and methods for producing such lipids in *Comirnaty*, and seeking monetary relief. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Arbutus and Genevant's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

GlaxoSmithKline Proceedings

In April 2024, GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC filed a lawsuit against Pfizer and us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. in the United States District Court for the District of Delaware alleging that the cationic lipid used in *Comirnaty* infringes U.S. Patent Nos. 11,638,693; 11,638,694; 11,666,534; 11,766,401; and 11,786,467; and seeking monetary relief.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of GlaxoSmithKline's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

10. Related Party Disclosures

ATHOS KG, Holzkirchen, Germany is the sole shareholder of AT Impf GmbH, Munich, Germany and a 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. The total amount of transactions with ATHOS KG or entities controlled by them had no significant impact on our unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2024, compared to the details disclosed in Note 21 to our audited consolidated financial statements included in our Annual Report on Form 20-F as of and for the year ended December 31, 2023.

11. Events after the Reporting Period

As previously disclosed, we are in discussions with the National Institutes of Health ("NIH") concerning royalties and other amounts allegedly owed under a license agreement on sales of our COVID-19 vaccine since commercialization. While we believe we have a strong legal position and disagree with the opinion being taken by the NIH, the ultimate outcome of the matter is uncertain, and we cannot guarantee that our interpretation of the license agreement will prevail.

On March 22, 2024, we received a notice of default from the NIH relating to alleged amounts owed and breaches under such license. In April 2024, we shared a non-binding proposal with the NIH to amend and restate our agreement, including a possible financial resolution of the applicable NIH claim and facilitating continued collaboration. Neither of the parties is bound by the proposal, and the ultimate outcome remains subject to significant uncertainties.

We will continue to evaluate the discussion with the NIH. As of today, we are unable to estimate a potential financial effect. If we ultimately may pay some or all of the amounts in dispute, it could cause a material adverse effect on our results of operations and/or our cash flows.

Any such assessments require management to make significant judgments, as described in Note 3 to our audited consolidated financial statements included in our Annual Report on Form 20-F as of and for the year ended December 31, 2023.

Operating and Financial Review and Prospects

In this report, unless stated or the context otherwise requires, references to the "Company", "BioNTech", "Group", "we", "us" and "our" refer to BioNTech SE and its consolidated subsidiaries. The following "Operating and Financial Review and Prospects" should be read together with the unaudited interim condensed consolidated financial statements and related notes as presented above. 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 the "Risk Factors" section further below. Please also see "Forward-Looking Statements" included elsewhere in this quarterly report for the three months ended March 31, 2024.

Operating Results

Overview

We are a global next-generation immunotherapy company pioneering novel medicines against cancer, infectious diseases and other serious diseases. Since our founding in 2008, we have focused on harnessing the power of the immune system to address human diseases with unmet medical needs and major global health burdens. Our fully integrated model combines decades of research in immunology with a multi-technology innovation engine, GMP manufacturing, translational drug discovery, clinical development, commercial capabilities, computational medicine, data science and artificial intelligence, or AI, and machine learning, or ML, capabilities to discover, develop and commercialize our marketed product and product candidates.

We have built a broad toolkit across multiple technology platforms, including a diverse range of potentially first-in-class therapeutic approaches. This includes investigational messenger ribonucleic acid, or mRNA vaccines, protein-based therapeutics (including targeted antibodies such as monoclonal, bispecific and antibody-drug conjugates, or ADCs), cell therapies and small molecules.

We expect each platform to yield a pipeline of product candidates for further development. Our multi-technology combination of platforms and product candidates positions us as pioneers in the field of individualized, patient-centric therapeutic approaches in oncology and infectious diseases. We aim to expand this status into other disease areas in the future.

In oncology, we endeavor to address the continuum of cancer patients. The root causes of cancer treatment failure are cancer heterogeneity and interindividual variability. Driven by random sequential mutations, every patient's cancer is unique and within one patient's tumor, every cell is different. Addressing these two challenges is the core of our strategy. To augment anti-tumor activity and to counteract resistance mechanisms we seek to combine compounds with non-overlapping, synergistic mechanisms of action.

In infectious diseases, our product strategy is rooted in global social responsibility and our goal of contributing to equitable access to medicine.

Our approach has generated a robust and diversified product pipeline across a range of technologies in oncology and infectious disease, and has led to the approval of our first marketed product, *Comirnaty*.

Corporate Development

A key component of our corporate strategy is strengthening our clinical pipeline, technology platforms, digital capabilities and infrastructure through select strategic partnerships and acquisitions.

In February 2024, in line with our goal of scaling up innovation, we and Autolus Therapeutics plc, or Autolus, announced a strategic collaboration aimed at advancing both companies' autologous CAR-T programs towards commercialization, pending regulatory authorizations. As part of the strategic collaboration, we have the option to access Autolus's commercial and clinical site network, manufacturing capacities in the United Kingdom, or UK, and commercial supply infrastructure in a cost-efficient set-up, allowing for the accelerated development of our product candidate BNT211.

Environmental, Social, and Governance (ESG)

BioNTech was founded out of a responsibility to patients and to society and this is still the vision that drives the Company. It gives grounds for BioNTech's enhanced responsibility: for translating the Company's science into the health of people worldwide and democratizing access to innovative medicines, for environmental and climate protection, for respecting human rights and for fostering the full potential of all employees.

In February 2024, the Company's near-term science-based emissions reduction targets were approved by the Science Based Targets initiative, or SBTi. This validation underscores the ambitious nature of BioNTech's scope 1 and scope 2 climate targets and is intended to align with the United Nations' Paris Climate Agreement to limit global warming to 1.5 degrees Celsius above pre-industrial levels.

BioNTech's performance on environmental, social, and governance matters is regularly assessed by external rating agencies. The Institutional Shareholder Services Group, or ISS, currently assigns BioNTech a "Prime" ESG rating: the Company has received an overall corporate rating of B-, which is among the top 10% of all rated companies in the pharmaceutical and biotechnology sector. In the ISS Governance Quality Score, BioNTech stands at 5 on a risk scale of 1 (low risk) to 10 (high risk). S&P Global Ratings has rated BioNTech in the S&P Corporate Sustainability Assessment 2023, or CSA, with an S&P Global CSA score of 45 (2022: 32) out of 100. Morningstar Sustainalytics has given BioNTech a Sustainalytics ESG rating of 24.1 (2022: 22.3), which corresponds to a "medium risk", the third of five risk levels (negligible, low, medium, high and severe).

In March 2024, we published our annual ESG report (Sustainability Report 2023). The report highlights the Company's progress in developing novel medicines and introducing scalable technological innovations. It describes our science-based climate goals (under SBTi review), actions and climate risk management as well as the status of our human rights strategy and due diligence. The report addresses diversity, inclusion, equity and belonging, and highlights the importance of our values and culture.

BioNTech recognizes its responsibility as a corporate citizen and is committed to supporting its local communities and beyond through donations, sponsorships and volunteer activities.

Marketed Product: *Comirnaty*, our COVID-19 Vaccine Program (BNT162)

COVID-19 vaccination has played an important role in saving lives and livelihoods across the world. Our commercial product, *Comirnaty*, was the first-ever approved mRNA-based product, and, to our knowledge, represents the fastest ever developed prophylactic vaccine from viral sampling to approval. As of December 2023, our COVID-19 vaccine products have been authorized or approved for emergency or temporary use or granted marketing authorization in more than 180 countries and regions worldwide. Our efforts have resulted in more than 4.8 billion doses shipped globally. We are now focused on preparing for vaccine adaptation to be ready to launch ahead of the upcoming 2024/2025 season, pending approvals.

Under our collaboration with Pfizer, we are the Marketing Authorization Holder in the United States, the European Union, or EU, the UK, Canada and other countries. Additionally, we are the holder of emergency use authorizations, or EUAs, or equivalents in the United States (jointly with Pfizer) and other countries for the COVID-19 vaccine program. Pfizer has marketing and distribution rights worldwide apart from Greater China, Germany, and Türkiye. We have the marketing and distribution rights to *Comirnaty* in Germany and Türkiye.

Under our collaboration with Fosun Pharmaceutical Industrial Development, Co., Ltd, or Fosun Pharma, Fosun Pharma has marketing and distribution rights in Mainland China, Hong Kong Special Administrative Region, or SAR, Macau SAR and Taiwan.

A. Commercial Updates

Our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine is available in pharmacies, hospitals, and clinics across the U.S. following a recommendation by the Centers for Disease Control and Prevention, or the CDC, for the use of the vaccine for the 2023-2024 fall and winter season. The 2023-2024 formulation for individuals 12 years of age and older can be ordered as either a pre-filled syringe or a single-dose vial.

We expect that as SARS-CoV-2 continues to evolve, and the risk of severe COVID-19 disease and deaths continues, especially for high-risk populations, there will be continued demand for vaccine boosting and vaccinations, especially for at-risk and immunocompromised groups. We also expect to continue the transition from an advanced purchase agreement environment to commercial market ordering in additional geographies, driven by regulatory recommendations to adapt COVID-19 vaccines to newly circulating variants or sublineages of SARS-CoV-2.

B. Clinical Development, Regulatory and Manufacturing Updates

A Phase 2/3 study (NCT05997290) is ongoing to investigate the safety, tolerability and immunogenicity of our Omicron XBB.1.5-adapted monovalent COVID-19 vaccine in healthy people 12 years and older. In January 2024, a manuscript was published reporting the safety and immunogenicity one month after vaccination with our monovalent Omicron XBB.1.5-adapted COVID-19 vaccine in COVID-19 experienced individuals 12 years of age and older (Gayed et al., 2024). These data support a favorable benefit-risk profile of our XBB.1.5-adapted COVID-19 vaccine. In this analysis, the XBB.1.5-adapted vaccine demonstrated a safety and tolerability profile similar to that seen with original and the BA.4/5-adapted and BA.1-adapted COVID-19 vaccines and induced substantial increases in neutralizing antibody responses against Omicron XBB.1.5 (overall geometric mean fold rises, or GMFR: 7.0), EG.5.1 (GMFR: 8.7), and BA.2.86 (GMFR: 4.5). We believe the safety and immunogenicity data support administration of the XBB.1.5-adapted BNT162b2 in vaccine-experienced individuals 12 years of age and older.

Real world data showed high vaccine effectiveness of the Omicron XBB.1.5-adapted monovalent COVID-19 vaccine against current variants of concern, with 63% (95%CI: 33-80%) vaccine effectiveness against hospitalization observed in adults aged 18 years and older approximately 30 days post vaccination in the United States against XBB.1.5, XBB.1.16, EG.5.1, and BA.2.86. Similar real world evidence trends have been reported in EU countries. In Denmark, vaccination was associated with a 75.3% reduced risk of COVID-19 hospitalization nine days post-immunization with a monovalent XBB.1.5 in people over 65 years of age. In the Netherlands, early estimates demonstrated a high vaccine effectiveness against hospitalization (70.7%) and ICU admission (73.3%) in people over 60 years of age in the two months post vaccination with XBB.1.5 vaccine.

Our and Pfizer's Omicron XBB.1.5-adapted monovalent COVID-19 vaccine received multiple regulatory approvals, including approvals, authorizations for emergency or temporary use or marketing authorizations in more than 40 countries and regions.

In 2024, BioNTech has been, and expects to continue, preparing for COVID-19 vaccine adaptation and, pending regulatory approval, commercial launch ahead of the upcoming 2024/2025 fall and winter season.

Pipeline of Product Candidates: First Quarter 2024 and Post Period-End Updates

Below is a summary of our authorized product and clinical product candidates, organized by platform and indication.

Oncology

Drug class	Platform	Product candidate	Indication (target)	Phase 1	Phase 1/2	Phase 2	Phase 3	BioNTech rights[1]	Collaborator/Partner
mRNA	FixVac	BNT111	Advanced, R/R melanoma					Fully owned[2]	
		BNT113	Metastatic/ R/R HPV16+ head and neck cancer						
		BNT116	1L metastatic NSCLC						
			Advanced/metastatic NSCLC						
	iNeST	BNT122 (autogene cevumeran)	1L advanced melanoma					Collaboration	Genentech[3]
			Adjuvant colorectal cancer						
			Adjuvant pancreatic ductal adenocarcinoma						
			Multiple solid tumors						
	RiboMabs	BNT142	Multiple solid tumors (CD3×CLDN6)					Fully owned	
	RiboCytokines	BNT151	Multiple solid tumors (IL-2 variant)					Fully owned	
		BNT152 + BNT153	Multiple solid tumors (IL-7, IL-2)						
Cell therapies	CAR T cells + CARVac	BNT211	Multiple solid tumors (CLDN6)					Fully owned	
	Neoantigen-based T cells	BNT221	Refractory metastatic melanoma					Fully owned	
Protein-based therapeutics	Next-generation immune checkpoint modulators	BNT311 / GEN1046 (acasunlimab)	aPD(L)1-R/R metastatic NSCLC (PD-L1×4-1BB)					Collaboration	Genmab
			Multiple solid tumors (PD-L1×4-1BB)						
		BNT312 / GEN1042	Multiple solid tumors (CD40×4-1BB)[4]						
		BNT313 / GEN1053	Multiple solid tumors (CD27)						
		BNT314 / GEN1059	Multiple solid tumors (EpCAM×4-1BB)						
		BNT322 / GEN1056	Multiple solid tumors						
		BNT316 / ONC-392 (gotistobart)	aPD(L)1-R/R metastatic NSCLC (CTLA-4)					Collaboration	OncoC4
			Platinum-resistant ovarian cancer (CTLA-4)						
			Metastatic castration-resistant prostate cancer (CTLA-4)						
			Multiple solid tumors (CTLA-4)						
	Targeted cancer antibodies	BNT321	Adjuvant pancreatic ductal adenocarcinoma (sLea)					Fully owned	
			Metastatic pancreatic cancer (sLea)						
	Antibody-drug conjugates	BNT323 / DB-1303	2L+, HR+/HER2-low metastatic breast cancer (HER2)					Collaboration	Duality Biologics
			Multiple solid tumors (HER2)						
		BNT324 / DB-1311	Multiple solid tumors (B7H3)						
		BNT325 / DB-1305	Multiple solid tumors (TROP2)						
		BNT326 / YL202	Multiple solid tumors (HER3)					Collaboration	MediLink Therapeutics
SMI[5]	Toll-like receptor binding	BNT411	Multiple solid tumors (TLR7)					Fully owned	

Infectious Diseases

Drug class	Product candidate	Indication (target)	Phase 1	Phase 1/2	Phase 2	Phase 3	Commercial	BioNTech rights	Collaborator/Partner
mRNA	BNT162b2								
	BNT162b2+BNT162b4 (T-cell enhancing)	COVID-19						Collaboration	Pfizer Fosun Pharma
	BNT162b5/6/7 (Stabilized spike antigen)								
	BNT162b2+BNT161[6]	COVID-19 – Influenza combination						Collaboration	Pfizer
	BNT161	Influenza						Collaboration[7]	Pfizer
	BNT163	HSV						Collaboration	University of Pennsylvania
	BNT164	Tuberculosis[8]						Fully owned	Funded by Bill & Melinda Gates Foundation
	BNT165	Malaria[9]						Fully owned	
	BNT166	Mpox						Fully owned	Funded by CEPI[10]
	BNT167	Shingles						Collaboration	Pfizer

(1) For further details about BioNTech's rights see quarterly reports under https://investors.biontech.de/financials-filings/quarterly-reports.

(2) *FixVac* platform is fully owned by BioNTech. The BNT111 and BNT116 Phase 2 trials are jointly conducted with Regeneron as part of a cost-sharing strategic collaboration.

(3) A member of the Roche group.

(4) Two Phase 1/2 clinical trials in patients with solid tumors are ongoing in combination with ICI+/- chemotherapy.

(5) Small Molecule Immunomodulators.

(6) The COVID-19-Influenza combination is a Phase 3 trial in partnership with Pfizer. Further development is subject to entering into a definitive agreement.

(7) Out-licensed to Pfizer.

(8) Two Phase 1 clinical trials are ongoing (NCT05537038, Germany and NCT05547464, Republic of South Africa).

(9) A Phase 1 clinical trial (NCT05581641) and a Phase 1/2 clinical trial (NCT06069544) are ongoing.

(10) Coalition for Epidemic Preparedness Innovations ("CEPI").

A. Oncology Programs

1. mRNA Product Candidates in Oncology

a) FixVac

FixVac is our wholly owned, systemic, off-the-shelf mRNA-based cancer immunotherapy approach, from which we are developing several first-in-human and potential first-in-class product candidates. *FixVac* product candidates contain our non-nucleoside optimized uridine-RNA delivered in our proprietary RNA-LPX formulation for intravenous administration. Proprietary RNA-LPX is designed to deliver RNA to dendritic cells, or DCs, and protects RNA from degradation by RNAse and is designed for RNA delivery into antigen-presenting cells in lymphoid organs. *FixVac* candidates are designed to target shared antigens that have been identified to be frequently expressed across patients with a specific cancer type. These product candidates are designed to trigger both innate and adaptive immune responses.

BNT111 in advanced melanoma.

- A global, randomized three-arm Phase 2 clinical trial (NCT04526899) is being conducted in collaboration with Regeneron Pharmaceuticals Inc., or Regeneron, and is evaluating BNT111 in combination with cemiplimab (Regeneron's Libtayo) versus both agents as monotherapy in 184 enrolled patients with anti-PD-1-/anti-PD-L1 refractory/relapsed, unresectable Stage III or IV melanoma. The primary endpoint is objective response rate, or ORR. Secondary endpoints include duration of response, or DOR, disease control rate, or DCR, time to response, or TTR, progression-free survival, or PFS, overall survival, or OS, and safety.

BNT112 in prostate cancer.

- A first-in-human Phase 1/2a, open-label dose titration and expansion clinical trial (NCT04382898) to evaluate the safety, immunogenicity and preliminary efficacy of BNT112 monotherapy and in combination with cemiplimab in patients with metastatic castration resistant prostate cancer, or mCRPC, and high-risk localized prostate cancer, or LPC, who are eligible for treatment with androgen deprivation therapy, or ADT, followed by radical prostatectomy has been discontinued and the follow-up period ended in January 2024. Final data of the trial are being gathered and evaluated and are expected to be compiled into a clinical study report.

BNT113 in Human Papilloma Virus, or HPV16+ head and neck cancer.

- A global, randomized Phase 2 clinical trial (NCT04534205) evaluating BNT113 in combination with pembrolizumab (Merck & Co., Inc.'s Keytruda) versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma expressing PD-L1 is ongoing. Part A comprises the completed non-randomized run-in portion designed to demonstrate the safety of the combination of BNT113 and pembrolizumab. Part B is the randomized portion of the trial designed to generate efficacy and safety data and which is recruiting patients. The trial plans to enroll a total of 285 participants.

BNT116 in advanced non-small-cell lung cancer, or NSCLC.

- A randomized, controlled Phase 2 clinical trial (NCT05557591) is ongoing to evaluate BNT116 in combination with cemiplimab (Regeneron's Libtayo) versus cemiplimab alone as first-line treatment of

patients with advanced NSCLC whose tumors express PD-L1 in ≥ 50% of their tumor cells. The primary objective of the Phase 2 trial is to assess the ORR per blinded-independent review committee. Secondary endpoints include other measures of clinical activity per investigator assessment, overall survival, or OS, and safety.

- A Phase 1 clinical trial (NCT05142189) is ongoing to evaluate the safety, tolerability and preliminary efficacy of BNT116 alone and in combination with cemiplimab (Regeneron's Libtayo) in patients who have progressed on prior PD-1 inhibitor treatment or are not eligible for chemotherapy, in combination with docetaxel in patients who have received prior PD-1 inhibitor therapy and platinum-based chemotherapy, in patients with unresectable Stage III NSCLC who have undergone chemoradiotherapy and also in the neoadjuvant and adjuvant settings in patients with resectable Stage II and III NSCLC.

- In April 2024, data from cohort 3 of the Phase 1 trial described above were presented at the Annual Meeting of the American Association for Cancer Research, or AACR. Patients were treated with BNT116 in combination with docetaxel after progression on a PD-1/PD-L1 inhibitor and a platinum-based chemotherapy. Preliminary data of BNT116 in combination with docetaxel show encouraging antitumor activity, consistent induction of immune responses, a manageable safety profile, and no signs of additive toxicity. Combination therapy with BNT116 and docetaxel was observed to have an ORR of 30% and a DCR of 85%.

b) Autogene Cevumeran (BNT122), an Individualized Neoantigen Specific Immunotherapy, or iNeST

Autogene cevumeran (BNT122) is an individualized cancer immunotherapy product candidate based on specific neoantigens that are present on a patient's tumor. Similar to our *FixVac* programs, our iNeST approach is also based on a pharmacologically optimized-backbone equipped uridine mRNA, or uRNA, delivered in our proprietary RNA-LPX formulation. Proprietary RNA-LPX is designed to deliver RNA to DCs and protects RNA from degradation by RNAse and is designed for RNA delivery into antigen-presenting cells in lymphoid organs. Each patient is treated with a vaccine informed by the mutation profile of their unique cancer and manufactured on-demand. The RNA encodes a unique composition of the patient's own tumor mutations and results in generation of neoantigen specific CD4+ and CD8+ T-cell responses. Each autogene cevumeran dose includes up to 20 different neoantigens selected on a patient-by-patient basis (up to 10 neoantigens on 1 RNA). We believe this modality may be well-suited for use in the adjuvant setting. iNeST is partnered with Genentech as part of a 50:50 collaboration in which development costs and future profits are shared.

Autogene Cevumeran (BNT122) in adjuvant colorectal cancer.

- A randomized, multi-site, open-label Phase 2 clinical trial (NCT04486378) evaluating autogene cevumeran as an adjuvant treatment of circulating tumor DNA, or ctDNA, positive, surgically resected Stage II (high risk)/Stage III colorectal cancer, or CRC, is ongoing. The trial is expected 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, or DFS. Secondary objectives include OS and safety. The trial is currently enrolling in the United States, Germany, Spain, Belgium, Sweden and the UK. Epidemiologic data, including post-operative ctDNA prevalence and prognostic value, from an observational study (NCT04813627) in patients with resected high-risk Stage II/III CRC is expected to be presented at the 2024 Annual Meeting of the American Society of Clinical Oncology, or ASCO.

Autogene Cevumeran (BNT122) in pancreatic ductal adenocarcinoma, or PDAC.

- A randomized Phase 2 clinical trial (NCT05968326) evaluating the safety and efficacy of autogene cevumeran in combination with atezolizumab (Genentech's Tecentriq) followed by standard-of-care chemotherapy (mFOLFIRINOX) in patients with resected PDAC compared to chemotherapy alone is recruiting. The Phase 2 study is expected to enroll 260 patients with resected PDAC who have not received prior systemic anti-cancer treatment and showed no evidence of disease after surgery. The primary endpoint is DFS. Secondary endpoints include OS and safety. The trial has been initiated in the United States and enrollment is planned in approximately 10 countries in total.

- In April 2024, at the AACR Annual Meeting, long-term follow-up data were presented from an investigator-initiated Phase 1 trial (NCT04161755) in patients with resected PDAC indicating that the individualized mRNA cancer vaccine candidate autogene cevumeran continues to show polyspecific T cell responses up to three years after vaccination and that vaccine response correlates with delayed tumor

recurrence. At three years, autogene cevumeran was observed to induce *de novo* neoantigen-specific, functional and durable CD8 T cells at substantial magnitudes for multiple neoantigens. After a median follow-up of three years, eight patients with vaccine-induced T-cell responses continued to have longer median recurrence-free survival (not reached) compared with those who did not experience an immune response (13.4 months). The investigator-initiated, single center Phase 1 trial evaluated the safety of autogene cevumeran in sequential combination with the anti-PD-L1 immune checkpoint inhibitor atezolizumab and standard-of-care chemotherapy in 16 patients with resected PDAC. Data from the 1.5-year median follow-up had been previously published in Nature (Rojas, L.A et al. 2023).

Autogene Cevumeran (BNT122) in first-line melanoma.

- A randomized Phase 2 clinical trial (NCT03815058) evaluating the efficacy and safety of autogene cevumeran in combination with pembrolizumab versus pembrolizumab alone as first-line in patients with previously untreated advanced melanoma is fully enrolled and follow-up is ongoing. The primary endpoint is PFS and is events-based. Secondary endpoints include ORR, OS, DOR and safety.

Autogene Cevumeran (BNT122) in multiple solid tumors.

- An open-label Phase 1a monotherapy/1b in combination with atezolizumab clinical trial (NCT03289962) of autogene cevumeran in patients with locally advanced or metastatic solid tumors, including patients with melanoma, NSCLC, bladder cancer, colorectal cancer, triple negative breast cancer, or TNBC, renal cancer, head and neck cancer and sarcomas as well as other solid tumors is fully enrolled and follow-up is ongoing.

c) RiboMab

Our *RiboMab* product candidate is an mRNA that encodes cancer cell targeting antibodies. This fully-owned product candidate leverages our proprietary optimized mRNA technology combining nucleoside modifications to minimize immunogenicity with our improved mRNA backbone designs with the aim of maximizing protein expression. Our *RiboMab* product candidate is formulated using liver-targeting lipid nanoparticles, or LNPs, for intravenous delivery.

BNT142 encodes a T cell engaging bispecific antibody targeting Claudin 6, or CLDN6.

BNT142 in multiple solid tumors.

- An ongoing, open-label, multi-center Phase 1/2 clinical trial (NCT05262530) in patients with CLDN6-positive advanced solid tumors that have exhausted available standard therapy or are not eligible for such available therapy is ongoing. The study is actively recruiting patients in the EU, the UK, the United States and Singapore.

d) RiboCytokines

Our *RiboCytokine* product candidates are designed to address the limitations of recombinantly expressed cytokines, including limited serum half-life and production costs. BNT151 and BNT152+153 are nucleoside-modified mRNAs encoding human cytokines fused to human serum albumin. The modified mRNA is formulated with liver-targeting LNPs for intravenous delivery. BNT151 encodes an IL-2 variant, BNT152 encodes IL-7, and BNT153 encodes IL-2.

BNT151 in multiple solid tumors.

- A first-in-human, open-label, multi-center Phase 1/2 clinical trial (NCT04455620) in multiple solid tumor indications has been discontinued after the completion of enrollment for the Part 1 monotherapy dose escalation. The follow-up phase for enrolled patients is expected to be completed this year, after which the clinical data of the trial are expected to be evaluated and reported accordingly.

BNT152+BNT153 in multiple solid tumors.

- An open-label, multi-site, first-in-human Phase 1 clinical trial (NCT04710043) in multiple solid tumor indications is ongoing to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity of a combination of BNT152 and BNT153. The clinical trial consists of two parts: Part 1, the separate mono dose escalation of BNT152 and BNT153, was completed in May 2023, in which a maximum tolerated dose, or MTD, was defined for each product. Part 2 is currently investigating the

combination treatment of BNT152 and BNT153. Since September 2023, clinical sites in the United States and Czechia have been enrolling patients to evaluate the combination of BNT152 and BNT153.

2. Oncology Cell Therapy Product Candidates

a) Chimeric antigen receptor, or CAR, T-cell therapy – CAR-T

BNT211 consists of two investigational medicinal products: our first CAR-T-cell product candidate, which targets CLDN6-positive solid tumors, in combination with an mRNA named CARVac encoding CLDN6. The CAR-T cells are equipped with a second-generation CAR of high sensitivity and specificity for the tumor-specific carcino-embryonic antigen CLDN6. CARVac is intended to support in vivo expansion of transferred CAR-T cells to increase their persistence and efficacy. As with *FixVac* and iNeST, CARVac is also based on a pharmacologically optimized-backbone equipped uRNA delivered in our proprietary RNA-LPX formulation. BNT211 has been granted Priority Medicines, or PRIME, designation by the European Medicines Agency, or EMA for the third- or later-line treatment of testicular germ cell tumors.

- A first-in-human, open-label, multi-center Phase 1/2 dose escalation and dose expansion basket trial (NCT04503278) evaluating CLDN6 CAR-T cells as monotherapy or in combination with CLDN6 CARVac in patients with CLDN6-positive relapsed or refractory solid tumors, including ovarian and testicular cancers, is ongoing. The primary outcome measure of the trial is safety, with secondary efficacy outcome measures to include ORR, DCR and DOR. After determination of the recommended Phase 2 dose, we plan to initiate a pivotal trial in patients with germ cell tumors. We plan to present real world evidence of overall survival and treatment patterns of this patient population in the U.S. at the 2024 ASCO Annual Meeting.

b) Neoantigen-Targeting T-Cell therapy

BNT221 is our autologous, fully individualized, polyspecific T-cell therapy directed against selected sets of individual neoantigens. BNT221 is based on expanded neoantigen-specific memory T cells and induced naive T cells.

- A first-in-human Phase 1 dose escalation clinical trial (NCT04625205) in patients with checkpoint inhibitor unresponsive or refractory metastatic melanoma is ongoing. The first portion of the trial consists of a monotherapy dose escalation of BNT221, for which recruitment and treatment of patients is complete. Currently, BNT221 is being 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, as well as evaluations of immunogenicity and preliminary efficacy.

3. Antibody Product Candidates in Oncology

a) Next-Generation Immune Checkpoint Modulators

We are developing, in collaboration with Genmab A/S, or Genmab, antibodies that are designed to function as tumor-targeted and dual immunomodulators, applying Genmab's proprietary technologies in combination with our joint target identification and product concept expertise.

BNT311/GEN1046 (acasunlimab) is our jointly owned PD-L1x4-1BB product candidate, a potential first-in-class bispecific antibody combining PD-L1 checkpoint inhibition with 4-1BB stimulation. BNT311/GEN1046 (acasunlimab) is being developed for the treatment of solid tumors using Genmab's proprietary DuoBody technology platform. We and Genmab are currently evaluating BNT311/GEN1046 (acasunlimab) in multiple clinical trials.

- A Phase 2, multi-center, randomized, open-label clinical trial (NCT05117242) of BNT311/GEN1046 (acasunlimab) as monotherapy and in combination with pembrolizumab in patients with relapsed/refractory metastatic NSCLC and a tumor PD-L1 expression of tumor proportion score, or TPS, of ≥1% after treatment with standard of care therapy with an immune checkpoint inhibitor is ongoing. The primary endpoint is ORR according to Response Evaluation Criteria in Solid Tumors, or RECIST v1.1. Secondary endpoints include DOR, TTR, PFS, OS and safety. Data from this trial are expected to be presented at the 2024 ASCO Annual Meeting.

- An open-label, single-arm Phase 1/2 clinical trial (NCT03917381) with multiple expansion cohorts evaluating BNT311/GEN1046 (acasunlimab) as monotherapy and in combination therapies in patients with solid tumors is ongoing.

- A Phase 1 open-label, dose escalation clinical trial (NCT04937153) in Japan evaluating the safety and pharmacokinetics of BNT311/GEN1046 (acasunlimab) as monotherapy and in combination with pembrolizumab in patients with multiple solid tumors is ongoing.

BNT312/GEN1042 is a jointly owned, novel, agonistic, bispecific antibody that combines targeting and conditional activation of the costimulatory molecules CD40 and 4-1BB on immune cells. BNT312/GEN1042 is being developed for the treatment of solid cancers using Genmab's proprietary DuoBody technology platform and our CD40 and 4-1BB antibodies. We and Genmab are currently evaluating BNT312/GEN1042 in multiple clinical trials. We and Genmab anticipate having the data needed to determine next steps for this program this year.

- Two Phase 1/2 clinical trials (NCT05491317; NCT04083599) in patients with solid tumors are ongoing evaluating BNT312/GEN1042 in combination with pembrolizumab (Merck's Keytruda) with or without chemotherapy. We continue to actively recruit patients into the expansion cohorts across a range of solid tumors.

- A Phase 1 clinical trial (NCT06057038) is ongoing in Japan to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and antitumor activity of BNT312/GEN1042 monotherapy and in combination with pembrolizumab with or without chemotherapy in patients with multiple solid tumors

BNT313/GEN1053 is a novel CD27 antibody with an IgG Fc domain engineered to induce clustering of CD27 on the plasma membrane of T cells with the aim of enhancing T-cell activation, proliferation and differentiation without depleting T cells. In preclinical studies, BNT313/GEN1053 was observed to increase T-cell activation, proliferation, cytokine secretion and cytotoxic activity.

- A Phase 1/2 clinical trial (NCT05435339) evaluating the safety, tolerability, and preliminary efficacy of CD27-targeting antibody BNT313/GEN1053 on solid tumors as monotherapy is ongoing.

BNT314/GEN1059 is a potential first-in-class bispecific antibody product candidate designed to boost antitumor immune responses through EpCAM-dependent 4-1BB agonistic activity.

- In January 2024, the first patient was dosed in a first-in-human Phase 1/2 clinical trial (NCT06150183), which we are sponsoring, to investigate the safety and preliminary antitumor activity of BNT314/GEN1059 in patients with advanced or metastatic solid tumors.

BNT322/GEN1056 is an antibody product candidate being co-developed with Genmab for the treatment of solid tumors and for use in combination with other products.

- A first-in-human Phase 1 clinical trial (NCT05586321) in patients with advanced solid tumors is ongoing.

BNT311/GEN1046, BNT312/GEN1042, BNT313/GEN1053, BNT314/GEN1059 and BNT322/GEN1056 are partnered with Genmab as part of a 50:50 collaboration in which development costs and future profits are shared.

BNT327/PM8002 is an anti-vascular endothelial growth factor A, or VEGF-A, antibody candidate fused to a humanized anti-PD-L1 VHH being developed in collaboration with Biotheus Inc, or Biotheus. BNT327/PM8002 is currently being evaluated in Phase 1 and Phase 2/3 clinical trials in China to assess the efficacy and safety of the candidate as monotherapy or in combination with chemotherapy in various indications. An Investigational New Drug application has been accepted by the U.S. Food and Drug Administration, or FDA, for further studies in the United States and global trials are planned to start this year. Monotherapy data from Phase 1/2 trials are planned to be presented at the 2024 ASCO Annual Meeting. More data readouts, both in monotherapy and combination, are expected across a range of solid tumors in 2024.

BNT316/ONC-392 (gotistobart) is an anti-cytotoxic T-lymphocyte associated protein 4, or CTLA-4, monoclonal antibody candidate being developed in collaboration with OncoC4, Inc., or OncoC4. BNT316/ONC-392 (gotistobart) is designed to offer a differentiated safety profile that may allow for higher dosing and longer duration of treatment both as monotherapy and in combination with other therapies. The program received Fast Track Designation from the U.S. FDA in 2022.

- A two-stage, open-label, randomized Phase 3 clinical trial, PRESERVE-003 (NCT05671510), to evaluate the efficacy and safety of BNT316/ONC-392 (gotistobart) as monotherapy in metastatic NSCLC patients who have progressed on anti-PD-1/PD-L1 antibody-based therapy compared to standard-of-care

chemotherapy (docetaxel) is ongoing. The trial initiation followed the U.S. FDA Fast Track Designation granted in 2022 and is based on Phase 1/2 safety and efficacy data for the monotherapy in metastatic, immunotherapy-resistant NSCLC. The two-stage Phase 3 clinical trial will assess the efficacy and safety of BNT316/ONC-392 (gotistobart) as monotherapy compared to the standard-of-care chemotherapy (docetaxel) in patients with metastatic NSCLC that progressed under previous PD-(L)1-inhibitor treatment. The primary endpoint is OS. Secondary endpoints include ORR, PFS and safety. Approximately 600 patients are planned to be enrolled at clinical sites in the United States, China, Australia, South Korea, Türkiye, Canada, the UK and the EU countries Germany, Spain, Italy, Belgium and the Netherlands.

- A Phase 2 clinical trial (NCT05446298) evaluating BNT316/ONC-392 (gotistobart) therapy in combination with pembrolizumab in platinum-resistant ovarian cancer is ongoing. The clinical trial is evaluating two doses of BNT316/ONC-392 (gotistobart) in combination with a fixed dose of pembrolizumab in participants with ovarian cancer who are resistant to platinum-based chemotherapy and have disease progression after one line of therapy containing bevacizumab. The primary endpoints are ORR and safety. Secondary endpoints include DOR, DCR, PFS and OS.

- A Phase 2 clinical trial (NCT05682443) to evaluate the safety and efficacy of BNT316/ONC-392 (gotistobart) in combination with lutetium Lu-177 vipivotide tetraxetan (Novartis's Pluvicto) in metastatic castration resistant prostate cancer patients who have disease progressed on androgen receptor pathway inhibition is recruiting. The trial is expected to enroll approximately 144 patients at clinical trial sites in the United States. The primary endpoint is PFS.

- A first-in-human Phase 1/2 open-label dose escalation clinical trial (NCT04140526) evaluating BNT316/ONC-392 (gotistobart) as a single agent and in combination with pembrolizumab in patients with advanced or metastatic solid tumors is ongoing.

b) Targeted Cancer Antibodies & Antibody-Drug Conjugates

BNT321 is a fully human immunoglobulin G1, or IgG1, monoclonal antibody product candidate targeting sialyl Lewis A, or sLea, an epitope on CA19-9 that is expressed in pancreatic and other solid tumors that plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

- An open-label, multi-center, non-randomized dose escalation and expansion Phase 1 clinical trial (NCT02672917) of BNT321 monotherapy and in combination with modified FOLFIRINOX in pancreatic cancer and other CA19-9 expressing solid tumors is ongoing. Data from the trial were presented at the ASCO Gastrointestinal Cancer Symposium 2024. Preclinically, BNT321 binding was observed to be highly specific and restricted to cancer tissues with sLea expression. The most frequent dose-limiting toxicities, or DLTs, for both monotherapy and for mFOLFIRINOX combination therapy were hepatic transaminase elevations. DLTs generally occurred in cycle 1 and did not preclude subsequent BNT321 administration at reduced doses. BNT321 in combination with mFOLFIRINOX was tolerable for multiple cycles. Clinical activity (27% PR, RECIST) was observed in patients receiving the combination as first or subsequent line therapy for advanced disease.

- In April 2024, the first patient was dosed in a Phase 1/2 trial (NCT06069778) evaluating the safety, tolerability, and efficacy of BNT321 in combination with mFOLFIRINOX as an adjuvant therapy following curative resection in patients with PDAC.

BNT323/DB-1303 is a topoisomerase-1 inhibitor-based HER2-targeted ADC candidate being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd., or DualityBio. The program has been granted Breakthrough Therapy Designation by the U.S. FDA or the treatment of advanced endometrial cancer in patients who progressed on or after treatment with immune checkpoint inhibitors.

- An ongoing randomized, multi-center, open-label Phase 3 clinical trial (NCT06018337) is recruiting to evaluate BNT323/DB1303 versus the investigator's choice of chemotherapy in advanced or metastatic HR+, HER2-low breast cancer subjects whose disease has progressed on at least two lines of prior endocrine therapy or within six months of first-line endocrine therapy + cyclin-dependent 4/6 (CDK4/6) inhibitor and no prior chemotherapy. The first patient was dosed in January 2024. The trial aims to enroll

approximately 532 patients. The primary endpoint is PFS. Secondary endpoints include OS, ORR, DCR, DOR and safety, as well as patient-reported outcomes.

- BNT323/DB-1303 is being evaluated in an ongoing multicenter, non-randomized, open-label, multiple dose, first-in-human Phase 1/2 clinical trial (NCT05150691) in patients with advanced/unresectable, recurrent, or metastatic HER2-expressing solid tumors. A potential registrational cohort is enrolling HER2-expressing (IHC3+, 2+, 1+ or ISH-positive) patients with advanced/recurrent endometrial carcinoma and aims to recruit 140 patients. A confirmatory Phase 3 trial (NCT06340568) in this patient population is planned to start this year.

BNT324/DB-1311 is a topoisomerase-1 inhibitor-based B7H3-directed ADC candidate being developed in collaboration with DualityBio.

- A first-in-human, open-label Phase 1/2a clinical trial (NCT05914116) evaluating BNT324/DB-1311 in patients with advanced solid tumors is ongoing.

BNT325/DB-1305 is a topoisomerase-1 inhibitor-based TROP2-targeted ADC candidate being developed in collaboration with DualityBio.

- A Phase 1/2a clinical trial (NCT05438329) evaluating BNT325/DB-1305 in patients with advanced solid tumors is ongoing.

- In January 2024, we and DualityBio received Fast Track designation for BNT325/DB-1305 from the U.S. FDA for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens.

BNT326/YL202 is a topoisomerase-1 inhibitor-based HER3-targeted ADC candidate being developed in collaboration with MediLink Therapeutics (Suzhou) Co., Ltd. HER3 is a target that is overexpressed in various cancer types, such as NSCLC and breast cancer and is closely associated with tumor metastasis and disease progression. Furthermore, HER3 expression is upregulated after frontline drug therapy, making it an adequate target for cancer treatment resistance.

- A multicenter, open-label, first-in-human Phase 1 clinical trial (NCT05653752) evaluating BNT326/YL202 as a later-line treatment in patients with locally advanced or metastatic epidermal growth factor receptor, or EGFR, -mutated NSCLC or hormone receptor, or HR, -positive and HER2-negative breast cancer is ongoing in the United States and China. Preliminary data from this study are expected to be presented at the 2024 ASCO Annual Meeting.

4. Small Molecule Immunomodulator Candidates in Oncology

BNT411 is a small molecule TLR7 agonist product candidate. BNT411 is designed to activate both the adaptive and innate immune system through the TLR7 pathway.

- A Phase 1/2, first-in-human, open-label, dose escalation trial (NCT04101357) with expansion cohorts evaluating safety, pharmacokinetics, progression of disease and preliminary efficacy of BNT411 as monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve ES-SCLC is ongoing.

B. Infectious Disease Programs

1. Next-generation COVID-19 Vaccine

BNT162b5/6/7 – This is one of multiple vaccine candidates with an engineered design aimed to increase the magnitude and breadth of antibody neutralization response to better protect against COVID-19.

- A randomized, active controlled, observer-blind Phase 2 clinical trial (NCT04368728) to evaluate the safety, tolerability and immunogenicity of a stabilized spike antigen vaccine candidate has been completed and data are being gathered.

BNT162b2 + BNT162b4 – The aim of this program is to develop a vaccine candidate that enhances and broadens SARS-CoV-2 T-cell responses. BNT162b4 is a next-generation COVID-19 vaccine candidate component designed to

elicit T-cell immunity across epitopes. BNT162b4 encodes variant-conserved, immunogenic segments of the SARS-CoV-2 nucleocapsid, membrane, and ORF1ab proteins, targeting diverse human leukocyte antigen, or HLA, alleles.

- A Phase 1 clinical trial (NCT05541861) to evaluate the safety, tolerability and immunogenicity of BNT162b4 in combination with BNT162b2 is ongoing.

Both programs are being developed in collaboration with Pfizer.

2. Combination Vaccine Programs

We and Pfizer are investigating respiratory combination vaccine approaches that aim to simplify immunization practices for health care providers and recipients, helping to reduce the burden of these diseases. Combination vaccines have been an effective approach in overcoming barriers to vaccination by allowing for simple scheduling and fewer injections compared to vaccinations administered separately and/or at different visits to healthcare providers.

COVID-19 – Influenza Combination mRNA Vaccine Program – BNT162b2 + BNT161

In October 2022, we and Pfizer initiated a Phase 1/2 open-label, dose-finding trial (NCT05596734) to evaluate the safety, tolerability and immunogenicity of a combination of the COVID-19 and influenza mRNA vaccines in 180 healthy adults 18 to 64 years of age. The combination vaccine consists of our Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine and Pfizer's quadrivalent modified RNA (modRNA) influenza vaccine.

In December 2022, we and Pfizer announced that the companies received Fast Track Designation from the U.S. FDA for the mRNA-based combination vaccine candidate for influenza and COVID-19.

In October 2023, we and Pfizer announced top-line results from a Phase 1/2 clinical trial (NCT05596734) evaluating the safety, tolerability and immunogenicity of mRNA-based combination vaccine candidates for influenza and COVID-19 among healthy adults 18 to 64 years of age. In the clinical trial, the vaccine candidates were compared to licensed influenza vaccines and the Pfizer-BioNTech COVID-19 Omicron BA.4-5 adapted bivalent vaccine given separately at the same visit. The data from the trial demonstrated robust immune responses to influenza A, influenza B and SARS-CoV-2 strains, as well as a safety profile consistent with the safety profile of the companies' COVID-19 vaccine.

A pivotal Phase 3 clinical trial (NCT06178991) was initiated in December 2023 and aims to enroll 9,000 healthy subjects 18 to 64 years old of age. Further development of this product candidate is subject to our entering into a definitive agreement with Pfizer.

3. Influenza Vaccine Program – BNT161

In 2018, we and Pfizer entered into an agreement to collaborate on an mRNA program in influenza for an initial period of three years, which ended in 2021. Pfizer has since had the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products related to the program. Upon potential approval and commercialization, BioNTech is eligible to receive a royalty on Pfizer's sales.

- A Pfizer-initiated randomized Phase 3 clinical trial (NCT05540522) to evaluate the efficacy, safety, tolerability and immunogenicity of a quadrivalent modRNA influenza vaccine candidate has been completed.

4. Herpes Simplex Virus, or HSV, Vaccine Program – BNT163

We have a research collaboration with the University of Pennsylvania under which we have the exclusive option to develop and commercialize mRNA vaccine candidates against up to 10 infectious disease indications. As part of this collaboration, we are developing an HSV vaccine candidate.

- A first-in-human, controlled, dose-escalation Phase 1 clinical trial (NCT05432583) evaluating the safety, tolerability and immunogenicity of BNT163, an HSV vaccine candidate for the prevention of genital lesions caused by HSV-2 and potentially HSV-1, is ongoing. Dose escalation Part A has been completed and Part B (safety and dose evaluation) is enrolling across sites in the United States.

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.

- Two randomized, controlled, dose-finding Phase 1 clinical trials (NCT05537038, Germany and NCT05547464, Republic of South Africa) evaluating BNT164 are ongoing. Both clinical trials are designed to assess the safety, reactogenicity, and immunogenicity of mRNA vaccine candidates against tuberculosis. This program is run in partnership with the Bill & Melinda Gates Foundation.

6. Malaria Vaccine Program – BNT165

Our Malaria program aims to develop a well-tolerated and highly effective mRNA vaccine with durable immunity to prevent blood-stage malaria infection, thereby reducing morbidity and mortality as well as onward transmission. We plan to assess several vaccine candidates, featuring known targets such as circumsporozoite protein, or CSP, conserved, immunogenic segments of liver stage-expressed proteins as well as other antigens.

- A first-in-human Phase 1 clinical trial (NCT05581641) to evaluate the safety, tolerability and exploratory immunogenicity of the vaccine candidate BNT165b1, the first candidate from our BNT165 program, is fully enrolled and follow-up is ongoing.

- A randomized, dose escalation Phase 1/2 trial (NCT06069544) to evaluate the safety, tolerability, immunogenicity and efficacy of a second investigational RNA-based vaccine candidate in a controlled human malaria infection model is recruiting.

7. Mpox Vaccine Program – BNT166

Our fully-owned BNT166 program aims to deliver an effective, well-tolerated and accessible vaccine for the prevention of mpox. The multivalent BNT166 mRNA vaccine candidates encode surface antigens that are expressed in the two infectious forms of the monkeypox virus to efficiently fight virus replication and infectivity. The program is supported through a partnership with the Coalition for Epidemic Preparedness Innovations, or CEPI, to provide equitable access to the vaccine, if successfully developed and approved, in low- and middle-income countries.

- A Phase 1/2 trial clinical trial (NCT05988203) evaluating the safety, tolerability, reactogenicity and immunogenicity of two mRNA-based multivalent vaccine candidates is ongoing. The trial aims to enroll 64 healthy participants with and without prior history of known or suspected smallpox vaccination.

8. Shingles Vaccine Program – BNT167

We are collaborating with Pfizer to develop the first mRNA-based vaccine candidate against shingles (also known as herpes zoster). While there are currently approved vaccines for shingles, the goal is to develop an mRNA vaccine candidate that potentially shows high efficacy and better tolerability and is more efficient to produce globally.

- A randomized, controlled, dose-selection Phase 1/2 clinical trial (NCT05703607) to evaluate the safety, tolerability, and immunogenicity of BNT167 in up to 900 healthy volunteers 50 through 69 years of age is ongoing.

9. Anti-bacterial Programs

BioNTech R&D (Austria) GmbH, a wholly owned subsidiary of BioNTech SE, is focused on developing novel anti-bacterial drugs to treat persistent bacterial infections. Its development programs are based on our proprietary LysinBuilder platform, which allows for the targeted development of precision anti-bacterials. Our development pipeline focuses on chronic bacterial infections where antibiotics fail to cure or destroy the natural microbiomes.

Financial Operations Overview

The following table shows our unaudited interim condensed consolidated statements of profit or loss for each period presented:

	Three months ended March 31,	
	2024	**2023**
(in millions €, except per share data)	*(unaudited)*	*(unaudited)*
Revenues	187.6	1,277.0
Cost of sales	(59.1)	(96.0)
Research and development expenses	(507.5)	(334.0)
Sales and marketing expenses	(15.6)	(12.2)
General and administrative expenses [(1)]	(117.0)	(111.8)
Other operating expenses [(1)]	(23.9)	(125.7)
Other operating income	28.3	57.1
Operating income / (loss)	**(507.2)**	**654.4**
Finance income	180.1	82.3
Finance expenses	(4.7)	(29.0)
Profit / (Loss) before tax	**(331.8)**	**707.7**
Income taxes	16.7	(205.5)
Profit / (Loss) for the period	**(315.1)**	**502.2**
Earnings / (Loss) per share		
Basic earnings / (loss) for the period per share	(1.31)	2.07
Diluted earnings / (loss) for the period per share	(1.31)	2.05

[(1)] Adjustments to prior-year figures due to change in functional allocation of general and administrative expenses and other operating expenses (please see Note 4.2 for further details).

Important financial and operating terms and concepts are described in Item 5 of our Annual Report on Form 20-F as of and for the year ended December 31, 2023.

Comparison of the three months ended March 31, 2024 and 2023

Revenues

	Three months ended March 31,		Change	
(in millions €)	**2024**	**2023**	**€**	**%**
COVID-19 vaccine revenues	124.2	1,263.5	(1,139.3)	(90)
Other revenues	63.4	13.5	49.9	370
Total revenues	**187.6**	**1,277.0**	**(1,089.4)**	**(85)**

COVID-19 Vaccine Revenues

From the three months ended March 31, 2023, compared to the three months ended March 31, 2024, COVID-19 vaccine revenues decreased by €1,139.3 million, or 90%, from €1,263.5 million to €124.2 million, in line with lower sales demand during the three months ended March 31, 2024. three months ended March 31, 2023 were favorably impacted by contractual purchasing obligations (e.g., of the European Commission) and approvals of BA4/5 variant-adapted vaccines in upper middle income countries later than anticipated, which led to an increase in sales in the prior year period.

Other Revenues

During the three months ended March 31, 2024, our other revenues were mainly derived from a pandemic preparedness contract effectively supplemented in the first quarter of 2024 with the German government.

Cost of Sales

From the three months ended March 31, 2023, to the three months ended March 31, 2024, cost of sales decreased by €36.9 million or 38% from €96.0 million to €59.1 million, mainly due to recognizing lower cost of sales from our decreased COVID-19 vaccine sales, which included the share of gross profit that we owe our collaboration partner, Pfizer, and royalty expenses based on our sales. In addition, cost of sales was impacted by expenses arising from inventory write-downs to net realizable value due to inventories expected to be unsellable, not fulfilling the specification defined by our quality standards, shelf-life expiry or destruction of inventory amounting to €36.0 million, compared to €73.7 million in the previous period. The inventories valued at net realizable value in our consolidated statement of financial position as of March 31, 2024, take contractual compensation payments into consideration.

Research and Development Expenses

	Three months ended March 31,		Change	
(in millions €)	**2024**	**2023**	**€**	**%**
Research and development expenses				
COVID-19 vaccine	56.6	87.6	(31.0)	(35)
Non-COVID-19 vaccine	450.9	246.4	204.5	83
Total research and development expenses	**507.5**	**334.0**	**173.5**	**52**

From the three months ended March 31, 2023, compared to the three months ended March 31, 2024, research and development expenses increased by €173.5 million, or 52%, from €334.0 million to €507.5 million, mainly influenced by progressing clinical studies for pipeline candidates and our newly acquired clinical stage antibody drug conjugate (ADC) and antibody product candidates which further expand our oncology pipeline. Further contributions to the increase coming from wages, benefits and social security expenses resulting from a significant increase in headcount.

General and Administrative Expenses

From the three months ended March 31, 2023, compared to the three months ended March 31, 2024, our general and administrative expenses increased by €5.2 million, or 5%, from €111.8 million to €117.0 million, primarily driven by increased expenses for IT environment and wages, benefits, and social security expenses resulting from a significant increase in headcount.

Other Operating Income / Expenses

From the three months ended March 31, 2023, compared to the three months ended March 31, 2024, our total other operating result increased by €73.0 million from a negative operating result of €68.6 million to a positive operating result of €4.4 million. This is mainly due to the previous year including net negative foreign exchange differences offset by recording the change in fair value of foreign exchange forward contracts that were entered to manage some of our transaction exposures but were not designated as hedging instruments under IFRS.

Finance Income / Expenses

From the three months ended March 31, 2023, compared to the three months ended March 31, 2024, our total finance result increased by €122.1 million from €53.3 million to €175.4 million. During the three months ended March 31, 2024, our finance result mainly derived from interest income in relation to bank deposits and debt security investments as well as fair value adjustments of our money market funds. During the three months ended March 31, 2023, our finance result was driven by interest income mainly derived from our bank deposits and the fair value adjustments which were derived from remeasuring our money market funds as well as offsetting foreign exchange differences arising on financing items (i.e. U.S. dollar denominated cash and cash equivalents).

Income Taxes

For the three months ended March 31, 2024, income taxes were calculated based on the best estimate of the weighted average annual income tax rates expected for the full financial years (estimated annual effective income tax rates) on ordinary income before tax adjusted by the tax effect of any discrete items. The income tax asset represents the portion of prepayments for corporate income taxes and trade taxes in Germany that have been paid for the first quarter of 2024

but not yet offset by income tax expenses calculated for such quarter. For the three months ended March 31, 2024, our effective income tax rate was approximately 5.0% applicable on our negative income and for the three months ended March 31, 2023, our effective income tax rate was approximately 29.0%, on our positive income. The decrease in the effective income tax rate was mainly driven by the expected negative result for 2024 and management's assessment of the requirements in IAS 12, including 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. Thus, in countries where the requirements of IAS 12 were not fulfilled, no deferred tax asset was recognized. Such assessment takes into account the fact that there is an inherent risk of failure in pharmaceutical development and uncertainty of approvals that depend on external regulatory agencies' opinions.

As of March 31, 2024, it is considered highly probable that taxable profits for the U.S. tax group will be available against which the deferred tax assets can be utilized in the near future fulfilling the requirements set out by IAS 12.

We apply the mandatory exception to recognizing and disclosing information about deferred tax assets and liabilities arising from Pillar Two income taxes. Furthermore, we reviewed the corporate structure in light of the introduction of Pillar Two Model Rules in various jurisdictions. Since the Group's relevant effective tax rate calculated for Pillar Two Purposes is mainly above 15% in all jurisdictions in which it operates, it has been determined that the Group is not materially subject to Pillar Two "top-up" taxes. Therefore, the consolidated financial statements three months ended March 31, 2024, do not include information required by paragraphs 88A-88D of IAS 12.

Related Party Transactions

Related party transactions that occurred during the three months ended March 31, 2024 and 2023 are explained in Note 10 to the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report.

Critical Accounting Policies and Use of Estimates

Our unaudited interim condensed consolidated financial statements for the three months ended March 31, 2024, have been prepared in accordance with IAS 34 Interim Financial Reporting.

Our critical accounting policies and the use of estimates are explained in Note 2 to the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report and further discussed in Note 3 to our audited consolidated financial statements of our Annual Report on Form 20-F as of and for the year ended December 31, 2023.

Legal Proceedings

Our contingencies include, but are not limited to, intellectual property disputes and product liability and other product-related litigation. 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 intellectual property. As of March 31, 2024, none of such intellectual property-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 are subject to an increasing number of product liability claims. Such claims often involve highly complex issues related to medical causation, correctness and completeness of product information (Summary of Product Characteristics/package leaflet) as well as label warnings and reliance thereon, scientific evidence and findings, actual and provable injury, and other matters. These complexities vary from matter to matter. As of March 31, 2024, none of these claims fulfill the criteria for recording a provision. Substantially all of our contingencies are subject to significant uncertainties and, therefore, determining the likelihood of a loss and/or the measurement of any loss can be complex. Consequently, we are unable to estimate the range of reasonably possible loss. Our assessments, which result from a complex series of judgments about future events and uncertainties, are based on estimates and assumptions that have been deemed reasonable by management, but that may prove to be incomplete or inaccurate, and unanticipated events and circumstances may occur that might cause us to change those estimates and assumptions. We currently do not believe that any of these matters will have a material adverse effect on our financial position, and will continue to monitor the status of these and other claims that may arise. However, we could incur judgments, enter into settlements or revise our expectations regarding the outcome of matters, which could have a material adverse effect on our results of operations and/or our cash flows in the period in which the amounts are accrued or paid. 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.

Certain pending matters to which we are a party are discussed below.

Alnylam Proceedings

In March 2022, Alnylam Pharmaceuticals, Inc., or Alnylam, filed a lawsuit against Pfizer and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging that an existing patent owned by Alnylam, U.S. Patent No. 11,246,933, or the '933 Patent, is infringed by the cationic lipid used in Comirnaty, and seeking monetary relief, which is not specified in their filings. We filed a counterclaim to become party to the Alnylam proceeding, and in June 2022, Alnylam added to its claims allegations that we induced infringement of the '933 Patent. Additionally, in July 2022, Alnylam filed a lawsuit against us, our wholly owned subsidiary, BioNTech Manufacturing GmbH, Pfizer and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging that we also induced infringement of a newly issued patent, U.S. Patent No. 11,382,979, or the '979 Patent, which is a continuation of the '933 Patent. The two lawsuits were consolidated on July 28, 2022. In May 2023, Alnylam filed a third lawsuit against Pfizer Inc. and Pharmacia & Upjohn Co. LLC in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 11,633,479; 11,633,480; 11,612,657; and 11,590,229, all of which are continuations of the '933 Patent. We filed a counterclaim to become party to the new proceeding, and in July 2023, Alnylam added to its claims allegations that we induced infringement of the four new patents. All of the proceedings have been consolidated and are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Alnylam's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

CureVac Proceedings

Infringement Proceedings – EP'122, DE'961, DE'974, DE'575, and EP'668

In July 2022, CureVac AG, or CureVac, filed a lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging *Comirnaty*'s infringement of one European patent, EP1857122B1, or the EP'122 Patent, and three Utility Models DE202015009961U1, DE202015009974U1, and DE202021003575U1. In August 2022, CureVac added European Patent EP3708668B1, or the EP'668 Patent, to its German lawsuit.

On August 15, 2023, the Düsseldorf Regional Court held a hearing on infringement with respect to all five IP rights. At the hearing, the Court suspended its infringement ruling with respect to EP'122 until December 28, 2023. On September 28, 2023, the Court issued orders suspending its infringement rulings with respect to the remaining four IP rights (DE'961, DE'974, DE'575, and EP'668) pending validity decisions in the DE'961, DE'974, and DE'575 cancellation proceedings before the German Patent and Trademark Office and in the EP'668 opposition proceedings before the Opposition Division of the European Patent Office. In the September 28th orders, the Court explained that it was suspending its infringement rulings until validity decisions are reached, while contemporaneously noting concerns regarding the validity of DE'961, DE'974, DE'575, and EP'668. On December 28, 2023, the Düsseldorf Regional Court stayed the infringement proceedings as to EP'122 until a final appellate decision is rendered as to the validity of EP 122 by the Federal Court of Justice.

Infringement Proceedings – EP'755, DE'123, and DE'130

In July 2023, CureVac SE filed a second lawsuit against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH and BioNTech Manufacturing Marburg GmbH, in the Düsseldorf Regional Court, alleging *Comirnaty*'s infringement of one European patent, EP4023755B1, or the EP'755 Patent, and two Utility Models DE202021004123U1, and DE202021004130U1.

Nullity Proceedings – EP'122

In September 2022, we filed a nullity action in the Federal Patent Court of Germany seeking a declaration that the EP'122 Patent is invalid. In April 2023, the Federal Patent Court of Germany issued a preliminary opinion in the EP'122 nullity action in support of the validity of the EP'122 Patent. The preliminary opinion did not address any infringement of the EP'122 Patent. The preliminary opinion is a preliminary assessment by the court of the merits of a

claim, and is non-binding. On December 19, 2023, the Federal Patent Court held an oral hearing, after which it nullified EP'122.

Cancellation Proceedings – DE'961, DE'974, and DE'575

In November 2022, we filed cancellation actions seeking the cancellation of the three German Utility Models in the German Patent and Trademark Office. On December 27, 2023, the German Patent Office issued a preliminary opinion that DE'974 is likely to be cancelled. On January 23, 2024, the German Patent Office issued a preliminary opinion that DE'961 is likely to be cancelled. On March 7, 2024, the German Patent Office issued a preliminary opinion that DE'575 is likely to be cancelled.

United States

In July 2022, we and Pfizer filed a complaint for a declaratory judgment in the U.S. District Court for the District of Massachusetts, seeking a judgment of non-infringement by *Comirnaty* of U.S. Patent Nos. 11,135,312, 11,149,278 and 11,241,493. In May 2023, the action in the U.S. District Court for the District of Massachusetts was transferred to the U.S. District Court for the Eastern District of Virginia, where CureVac filed counterclaims asserting infringement of six additional U.S. patents, U.S. Patent Nos. 10,760,070; 11,286,492; 11,345,920; 11,471,525; 11,576,966; and 11,596,686. In July 2023, CureVac filed amended counterclaims to assert an additional U.S. patent, U.S. Patent No. 11,667,910.

United Kingdom

In September 2022, we and Pfizer filed a declaration of non-infringement and revocation action against the EP'122 Patent and the EP'668 Patent in the Business and Property Courts of England and Wales. In October 2022, CureVac responded by filing a counterclaim alleging infringement of the EP'122 and EP'668 patents in the Business And Property Courts of England and Wales. On December 18, 2023, we amended our pleadings to further allege non-infringement and invalidity against EP'755.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and utility models and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of CureVac's claims is ongoing and complex, and we believe the ultimate outcomes remain substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Moderna Proceedings

Germany

Infringement Proceedings – EP'949 and EP'565

In August 2022, Moderna filed a lawsuit against us and Pfizer and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Manufacturing Belgium NV, Pfizer Ireland Pharmaceuticals and Pfizer Inc. in the Düsseldorf Regional Court alleging *Comirnaty*'s infringement of two European Patents, 3590949B1, or the EP'949 Patent, and 3718565B1, or the EP'565 Patent. On November 7, 2023, the European Patent Office, or the EPO, Opposition Division revoked EP'565 after a one-day oral hearing. The Opposition Division issued a preliminary opinion on December 8, 2023 noting that it believes EP'949 is likely invalid. As a result of these EPO proceedings, the Düsseldorf Regional Court postponed its hearing on infringement, originally scheduled for December 12, 2023, to January 21, 2025.

United Kingdom

In August 2022, Moderna filed a lawsuit asserting *Comirnaty*'s infringement of the EP'949 Patent and EP'565 Patent against us and our wholly owned subsidiaries, BioNTech Manufacturing GmbH, BioNTech Europe GmbH and BioNTech Manufacturing Marburg GmbH, Pfizer Limited, Pfizer Manufacturing Belgium NV and Pfizer Inc. in the

Business and Property Courts of England and Wales. In September 2022, we and Pfizer filed a revocation action in the Business and Property Courts of England and Wales requesting revocation of the EP'949 Patent and EP'565 Patent.

United States

U.S. District Court Litigation

In August 2022, Moderna filed a lawsuit in the United States District Court for the District of Massachusetts against us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. and Pfizer Inc. alleging *Comirnaty*'s infringement of U.S. Patent Nos. 10,898,574, 10,702,600 and 10,933,127 and seeking monetary relief. On April 12, 2024, the United States District Court for the District of Massachusetts stayed the litigation pending resolution of the *inter partes* review of U.S. Patent Nos. 10,702,600 and 10,933,127.

Inter Partes Review

In August 2023, Pfizer and we filed petitions seeking inter partes review of U.S. Patent Nos. 10,702,600 and 10,933,127 before the United States Patent Trial and Appeal Board, or the PTAB. On March 6, 2024, the PTAB issued decisions instituting *inter partes* review proceedings on all challenged claims of U.S. Patent Nos. 10,702,600 and 10,933,127.

Netherlands

In September 2022, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH and Pfizer B.V., Pfizer Export B.V., C.P. Pharmaceuticals International C.V. and Pfizer Inc. in the District Court of The Hague alleging *Comirnaty*'s infringement of the EP '949 Patent and the EP '565 Patent. The District Court of the Hague held a hearing on October 6, 2023 on infringement and validity with respect to the EP '949 Patent. On December 6, 2023, the Court found EP'949 to be invalid. On March 5, 2024, Moderna appealed this decision. The EP'565 case has been stayed pending the outcome of Moderna's appeal of the Opposition Division's revocation of EP'565.

Ireland

In May 2023, Moderna filed a lawsuit against us and our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc., Pfizer Healthcare Ireland, Pfizer Ireland Pharmaceuticals, and C.P. Pharmaceuticals International C.V. alleging *Comirnaty*'s infringement of the EP'949 Patent and EP'565 Patent in the High Court of Ireland. On February 26, 2024, the High Court of Ireland stayed the lawsuit pending the final determination of the EPO opposition proceedings for EP'949 and EP'565 (in each case including any appeals).

Belgium

In May 2023, Moderna filed a lawsuit against us, our wholly owned subsidiary BioNTech Manufacturing GmbH, Pfizer Inc. and Pfizer Manufacturing Belgium alleging *Comirnaty*'s infringement of the EP'949 Patent and the EP'565 Patent in the Brussels Dutch-speaking Enterprise Court.

All of the above proceedings are currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the proceedings mentioned above. However, our analysis of Moderna's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Arbutus and Genevant Proceedings

In April 2023, Arbutus Biopharma Corp., or Arbutus, and Genevant Sciences GmbH, or Genevant, filed a lawsuit against Pfizer and us in the U.S. District Court for the District of New Jersey alleging that Pfizer and we have infringed the following patents owned by Arbutus: U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098, through the use of Genevant's lipid nanoparticle technology and methods for producing such lipids in *Comirnaty*, and seeking monetary relief. This proceeding is currently pending.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of Arbutus and Genevant's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the

balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

GlaxoSmithKline Proceedings

In April 2024, GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC filed a lawsuit against Pfizer and us and our wholly owned subsidiaries BioNTech Manufacturing GmbH and BioNTech US Inc. in the United States District Court for the District of Delaware alleging that the cationic lipid used in *Comirnaty* infringes U.S. Patent Nos. 11,638,693; 11,638,694; 11,666,534; 11,766,401; and 11,786,467; and seeking monetary relief.

We believe we have strong defenses against the allegations claimed relative to each of the patents and intend to vigorously defend ourselves in the lawsuit mentioned above. However, our analysis of GlaxoSmithKline's claims is ongoing and complex, and we believe the outcome of the suit remains substantially uncertain. Taking into account discussions with our external lawyers, we do not consider the probability of an outflow of resources to be sufficient to recognize a provision at the balance sheet date. In our opinion, these matters constitute contingent liabilities as of the balance sheet date. However, it is currently impractical for us to estimate with sufficient reliability the respective contingent liabilities.

Liquidity and Capital Resources

Overview

Given our strong financial, scientific and operational accomplishments, we believe we have the resources to diligently allocate our current capital to drive a multi-platform strategy and deliver a fully integrated global biotechnology company. We focus our research and development, or R&D, on rapidly advancing our diversified clinical oncology pipeline with synergistic potential, developing next generation COVID-19 vaccines to maintain leadership and pandemic preparedness, as well as broadening the label of and access to the existing vaccine. We also plan to invest heavily to build out our global development organization, bringing in talent with clinical and regulatory expertise needed to accelerate our pipeline development. We are also diversifying 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 a science and innovation driven company, we will continue to focus investments on R&D and scaling the business for commercial readiness in oncology in multiple countries by the end of 2025.

As of March 31, 2024, we had cash and cash equivalents of €8,976.6 million and security investments of €7,962.7 million, accumulating to €16,939.3 million in cash, cash equivalents and security investments.

Cash and cash equivalents and financial securities are invested in accordance with our asset management and investment policy, primarily with a focus on liquidity and capital preservation, and consist primarily of cash in bank accounts and on hand as well as long- and short-term financial investments.

Cash Flow

The following table summarizes the primary sources and uses of cash for each period presented:

	Three months ended March 31,	
(in millions €)	**2024**	**2023**
Net cash flows used in:		
Operating activities	(317.3)	(677.4)
Investing activities	(2,304.4)	(735.4)
Financing activities	(7.8)	(291.3)
Total cash outflow	**(2,629.5)**	**(1,704.1)**

Operating Activities

We derive cash flows from operations primarily from the sale of products and services rendered. Our cash flows from operating activities are significantly influenced by cash we generated as settlement payments of our gross profit as well as our use of cash for operating expenses and working capital to support the business.

Net cash used in operating activities for the three months ended March 31, 2024, was €317.3 million, comprising a loss before tax of €331.8 million, negative non-cash adjustments of €151.7 million, and a net positive change in assets and liabilities of €222.5 million. Non-cash items primarily included finance income as well as depreciation of property, plant and equipment and other intangible assets without cash-effect. The net positive change in assets and liabilities was primarily due to a decrease in trade receivables related to our COVID-19 vaccine collaboration with Pfizer which developed in line with our revenues, as described in Note 3 to the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report.

Net cash used from operating activities for the three months ended March 31, 2023, was €677.4 million, comprising a profit before tax of €707.7 million, positive non-cash adjustments of €85.4 million, a net positive change in assets and liabilities of €47.7 million and income taxes paid of €844.9 million. Non-cash items primarily included net foreign exchange differences as well as fair value adjustments of derivatives without cash-effect. The net positive change in assets and liabilities was primarily due to a decrease in other financial liabilities and other liabilities mainly including wage tax and social security payments from our share-based payment settlement and royalty payments.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2024 was €2,304.4 million. The amount includes €2,167.5 million mainly spent on security investments. The capital expenditures supporting our operating activities amounted to €62.5 million, whereof the majority was related to investments in building our laboratory and office facilities in Mainz, Germany.

Net cash used in investing activities for the three months ended March 31, 2023 was €735.4 million, mainly attributable to financial security investments in accordance with our asset management and investment policy.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2024 was €7.8 million, mainly related to our lease payments.

During the three months ended March 31, 2023, net cash used in financing activities was €291.3 million, primarily in connection with to our share repurchase program.

Operation and Funding Requirements

As part of our capital allocation strategy, 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 new and expanded sites 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 contract research organizations, or CROs, for clinical trials

and clinical and commercial supply manufacturing, and with vendors for preclinical research studies and for other services and products for operating purposes. We work together with contract manufacturing organizations, or 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 within the remaining months in 2024 is related to lease payments amounting to €38.6 million and commitments under purchase agreements and contractual obligations amounting to €356.5 million. Further, we have lease payment obligation with an amount of €226.3 million and commitments under purchase agreements and contractual obligations of €1,472.7 million for the years 2025 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;
- 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; and
- the terms of any ADS repurchases we make.

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 such 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.

Risk Factor Summary

- Demand for our COVID-19 vaccine, though difficult to predict, is expected to continue to decrease in the near future. Changing market dynamics will impact our revenue, which currently depends heavily on sales of our COVID-19 vaccine, and result in challenges relating to production of our COVID-19 vaccine.
- Our reported commercial revenue is partially 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.
- 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.
- 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. Since commercialization, we have received, and expect to continue to receive, product liability claims related to our COVID-19 vaccine.
- 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, or that negatively affect our results of operations.
- 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.
- 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.
- If we identify material weaknesses in our internal control over financial reporting and fail to remediate such material weaknesses, 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 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.
- 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.

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

Demand for our COVID-19 vaccine, though difficult to predict, is expected to continue to decrease in the near future. Changing market dynamics will impact our revenue, which currently depends heavily on sales of our COVID-19 vaccine, and result in challenges relating to production of our COVID-19 vaccine.

Prior to the commercialization of our COVID-19 vaccine, we had not sold or marketed any products in our pipeline. As a result, a majority of our total revenues to date are attributable to sales of our COVID-19 vaccine. However, we have experienced and we expect to continue to experience increasing reductions in demand for COVID-19 vaccination generally, including for our vaccine, as the virus becomes endemic and as a growing proportion of the population becomes vaccinated. We expect that future revenues from sales of our COVID-19 vaccine will decrease as demand for vaccination wanes. Such revenues will depend on numerous factors, including:

- the extent to which a COVID-19 vaccine, including any booster shot, continues to be necessary as COVID-19 becomes an endemic virus;
- 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;
- our ability to successfully and timely develop effective vaccines targeting new variants and mutations of COVID-19;
- 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 reimbursement negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments, including the transition towards ordinary-course insurance coverage in the public and private sectors;
- 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 undesirable effects or increased incidence or severity of known undesirable effects are identified with our COVID-19 vaccine;
- intellectual property litigation involving our COVID-19 vaccine and COVID-19 vaccines in general; and
- our manufacturing and distribution capabilities for our COVID-19 vaccine.

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, and we cannot ensure it will maintain its competitive position. Uncertainty in the demand for our COVID-19 vaccine and difficulties in targeting appropriate supply of our COVID-19 vaccines have in the past resulted, and may in the future result, in significant inventory write-downs and cancellations of contract manufacturing orders. Our business and financial condition could be materially affected by

lowered COVID-19 vaccine revenues resulting from any of the above factors, or by production and supply chain difficulties. In addition, if our revenues or market share of, or other financial metrics relating to, 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.

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 includes preliminary estimates in part due to a difference in Pfizer's financial quarter for subsidiaries outside the United States, which consequently creates an additional time lag between the recognition of revenues and the receipt of payment. 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 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.

Pfizer has historically provided us with 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 has also provided estimated profits for COVID-19 vaccine sales outside of the United States that were preliminary in nature for the last month of a quarter, as Pfizer's subsidiaries outside of the United States have a different reporting cycle than ours. These estimated figures have changed, and in the future such estimated figures are likely to change, as we receive final data from Pfizer for the applicable period in accordance with the reporting cycle of Pfizer's 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 estimate and judgment. Any changes to the preliminary data we report herein may have an impact on our reported revenues and expenses, profitability or financial position.

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 and our ability to continue to generate income from sales of our COVID-19 vaccine is uncertain.

The COVID-19 disease itself is unpredictable and each variant comes with varying levels of transmissibility 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 individual and public health perspectives.

Our COVID-19 vaccine was initially developed based upon the genetic sequence of the original 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 original virus. While we continue to monitor emerging SARS-CoV-2 strains, undertake investigations into the immunogenicity of our COVID-19 vaccine against new variants as they emerge and develop modified versions of our COVID-19 vaccine against new variants, these efforts may be unsuccessful, and failure to timely and successfully 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 certain variants of the SARS-CoV-2 virus, but that a market for adapted vaccines does not develop for one or more variants or that 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 the new vaccine, new variants continue to emerge and any adapted vaccine may not be as effective in protecting against such future variant strains.

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. Billions of doses of our COVID-19 vaccination have now been delivered worldwide, and our COVID-19 vaccine is being more widely used by patients as an authorized product than it was used in clinical trials. As a result, undesirable effects and other problems may be observed 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, and we have received, and expect to continue to receive, product liability claims relating to our COVID-19 vaccine. 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 clinical trials 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. Safety events that arise outside of a clinical trial setting are difficult to monitor, and given the widespread use of our COVID-19 vaccine, we have experienced difficulty tracking potential treatment-related adverse events on a global basis. Any 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, or 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. We and 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. FDA and other regulatory authorities. If problems are identified during a review or inspection, we or our collaborators may be the subject of adverse regulatory action, including the issuance of untitled or warning letters, which 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.

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 to 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 for 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. The Inflation Reduction Act, or IRA, enacted in August 2022 allows the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D. The IRA's negotiation program will apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics), among other negotiation selection criteria. The negotiated prices, which will become effective in 2026 for the first round of selected drugs, will be capped at a statutorily-determined ceiling price. The IRA also penalizes drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These IRA provisions will take effect progressively starting in 2023, although the drug negotiation provisions of the IRA are currently the subject of legal challenges. The effects of the IRA on our business and the healthcare industry in general are not yet known. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our products for which we may obtain regulatory approval or the frequency with which any such product is prescribed or used. 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 importing 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, 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.

Government policies, including relating to manufacturing or export controls, and negative public perception regarding vaccines and mRNA-based therapeutics could severely and adversely impact the manufacturing and sales of our COVID-19 vaccine and other product candidates we may develop, if approved.

There is a heightened risk that vaccines could be subject to export controls, adverse emergency actions or supply requirements by governmental and other authorities. In the past, 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, which could have prohibited us from delivering our COVID-19 vaccine to other jurisdictions. Vaccines are also at risk of being subject to adverse emergency actions taken by governmental entities in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions, such as the requirement that specific quantities of vaccine doses be set aside for designated purposes or geographic areas.

Furthermore, public sentiment regarding commercialization of vaccines, the safety and efficacy of our COVID-19 vaccine, other COVID-19 vaccines and treatments, and other public perceptions and misinformation relating to COVID-19, mRNA technology, and our and other COVID-19 vaccines may limit our ability to generate income from sales of our COVID-19 vaccine and other product candidates we may develop and sell, and cause reputational damage.

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 more than thirty other vaccines have been authorized for emergency use or approved in various countries, including vaccines developed by Moderna, Inc., Johnson & Johnson and University of Oxford/AstraZeneca plc. 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 continue successful commercialization of 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 undesirable 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 12 years and older, emergency or limited use authorization in a number of countries and in the United States for individuals 6 months to 12 years of age and approval for use in certain other countries. Our COVID-19 vaccine has not yet received full approval by regulatory authorities in certain countries where it has been authorized for emergency or temporary use. We and Pfizer intend to continue to observe our COVID-19 vaccine, including vaccine candidates that we may develop for other variants of COVID-19, 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 or marketing or conditional marketing approval or that concerns about 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.

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 materially harm our financial condition.

We are developing other product candidates and services 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 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 continue to face intense competition from products that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop products in the future. We also expect to face competition from new products that enter the market. There are a number of products 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 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.

Following our acquisition of InstaDeep Ltd., we also face competition in the rapidly growing and developing artificial intelligence industry. Our competitors may develop or commercialize products and services 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, biotechnology or technology companies, providing them with an advantage over us. Our competitors therefore may be more successful in commercializing their products and services than we are, which could adversely affect our competitive position and

business. Competitive products and services may make any products and services we develop obsolete or non-competitive before we can recover the expenses of developing and commercializing such products, if approved, and services.

The market opportunities for some 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 be unable to achieve or maintain profitability in future periods without obtaining regulatory approval for additional indications.

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 for some 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 be unable to achieve or maintain profitability in future periods without obtaining regulatory approval for additional indications.

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 sufficient product sales revenue.

We have only relatively recently developed our sales, distribution or marketing capabilities in Germany and Türkiye, 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. In addition, with respect to our COVID-19 vaccine, we rely heavily on the sales, distribution, and marketing capabilities of our partners, except in Germany and Türkiye. To successfully commercialize any other products that may result from our development programs, several of which are undergoing pivotal clinical trials, 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 further 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 compete with many companies that currently have extensive and well-funded marketing and sales operations. Without continuing to grow our internal team or obtaining the support of third parties to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our ability to achieve or maintain profitability in future periods 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 achieve or maintain profitability in future periods 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, particularly in 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 epidemics, pandemics and other public health developments, such as COVID-19, 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 research involving mRNA 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 in future periods. 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 undesirable effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any undesirable effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered;
- the 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, for our products that are approved for marketing, we and/or our collaborator are 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 certain of 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.

In August 2022, the IRA was enacted, which sets forth meaningful changes to drug product reimbursement by Medicare. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products in the United States, among other effects. Any reduction in reimbursement from Medicare resulting from the IRA or other legislative or policy changes, or from other government programs may result in a similar reduction in payments from private payers. We cannot be sure whether additional legislative changes will be enacted, or the effect of forthcoming guidance implementing the IRA, or what the impact of such changes on our products and product candidates may be.

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 products and 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 product candidates 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 our approved products and 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.

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

Our COVID-19 vaccine is currently approved in the United States, the European Union, and other jurisdictions, and we intend to seek approval to market other product candidates in the United States, the European Union and other selected jurisdictions. If we obtain approval for our products or 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 products or 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

Long-term sustainable profitability is difficult to achieve and maintain over time and is highly dependent on various factors.

Our ability to continue to generate revenue and achieve and maintain long-term sustainable 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 transactions, we expect that future revenues from sales of our COVID-19 vaccine will decrease as demand for vaccination wanes. 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 pharmaceutical product sales and sales of our other products and services 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 approved products and product candidates, if approved;
- obtaining market acceptance of our approved products and product candidates as a treatment option;
- launching and commercializing products 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;
- managing our expenses;
- 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 European Medicines Agency, or 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 ability to achieve and maintain profitability.

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 ordinary 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 and spending;

- our ability to 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, including take-or-pay or similar obligations;
- the extent to which we repurchase outstanding ADSs under any share repurchase plans we may enter in the future;
- 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, testing difficulties or decreased demand, and our ability to write down certain inventory;
- 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;
- our ability to use our net operating loss carryforwards to offset future taxable income;
- risks of counterparty defaults within our asset management portfolio; and
- increased or unpredictable pricing for the commodities we rely on, including as a result of inflation.

Each of the factors listed above may be affected by the changing impact of COVID-19 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 our 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.

We have incurred significant losses in the past and we may incur significant losses in the future.

Prior to the first full year of commercialization of our COVID-19 vaccine, and for the three months ended March 31, 2024, 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, and funded our operations primarily from private placements or issuances of ordinary shares (including in the form of ADSs) in connection with our public offerings, generation of proceeds under our collaboration agreements, secured bank loans and issuance of a convertible note.

We have experienced, and we expect to continue to experience, increasing reductions in demand for COVID-19 vaccination generally, including for our vaccine. We expect that future revenues from sales of our COVID-19 vaccine will decrease as demand for vaccination wanes. We plan to continue to invest heavily in research and development 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 or may obtain regulatory approval or emergency use authorization, our future revenues will depend upon the size of any markets in which such products 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 revenue from commercial sales, equity or debt financings, sales of assets, collaborations or grants.

As part of our capital allocation strategy, 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 new and expanded sites 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.

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 German tax loss carryforwards for corporate taxes for German group entities with pre tax group losses, though we have not recognized deferred tax assets related to such loss carryforwards for IFRS reporting purposes as of March 31, 2024. 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 incurred significant net losses in every year since our inception other than 2018, 2021, 2022 and 2023 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 other 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. After a significant volume of service providers were engaged to assist with research, development, manufacturing and supply of our COVID-19 vaccine, we discovered after internal review that we and certain of our subsidiaries did not withhold, report and remit certain German wage taxes and social security contributions in connection with certain contract service providers engaged in a manner comparable to internal employees, which we notified tax authorities about. If we do not properly and timely make required payments in the future, we could be subjected to fees, administrative offenses or other proceedings or penalties.

It is not possible to seek the refund of these wage taxes or social security contributions from either the German tax authorities or 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 are considered non-deductible and must be repaid to the German tax authorities. It is possible to reclaim the VAT repaid to the German tax authorities from the service provider. 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.

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 products or 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, including the development of modular production and clinical facilities in various markets via our BioNTainer network; 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. While we are currently generating product sales and royalty revenue to finance our operations, we cannot be certain that we will continue to generate sufficient revenue from product sales

and royalties to finance our operations. If we were to seek financing from outside sources, that additional funding may not be available on favorable terms, or at all. Should our revenues from product sales sufficiently decrease 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 shift of COVID-19 towards an endemic phase and other global events, such as political upheavals and economic downturns, 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 the ADSs representing our ordinary 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 or ADSs, share ownership interests will be diluted. 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 may encounter difficulties in developing and expanding our company and managing such 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 and/or 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 incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to 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 U.S. 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.

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.

If we identify material weaknesses in our internal control over financial reporting 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 identified a material weakness in our internal control which has been fully remediated, but there can be no guarantee that we will not identify additional material weaknesses in the future.

If we are unable to successfully remediate any future 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 discovered in the future that 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

have in the past discovered that certain of our and our subsidiaries' customs value calculations were not applied correctly, following which we notified the customs authorities of potential late payments.

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. If we do not properly address our international trade and customs requirements, we could be subjected to penalties and fees.

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 financial 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 employees and the 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.

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 and other public health developments, 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 conflicts in the Middle East and in Ukraine, and 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.

For example, the ongoing conflict between Russia and Ukraine and the conflicts in the Middle East, and resulting sanctions and other economic actions, have contributed to, and are expected to continue to contribute to, rising prices and shortages of crude oil and natural gas. Prolonged or expanded conflict between Russia and Ukraine and in the Middle East, and political responses to global actions, could further reduce oil and gas supplies, increase energy volatility and have severe adverse effects on regional and global supply chains and economies and our business. Our commercial production of our COVID-19 vaccine is currently run on natural gas, although we believe our production could be powered by alternative fuel sources if needed. Additionally, we continue to evaluate the impacts that a growing or subsequent energy shortage may have on our partners, suppliers and service providers. Were any of these parties to experience significant impacts from this or any other energy shortage, our business could be materially harmed. We cannot predict with certainty the impact a continuing or more severe natural gas shortage would have on our or their operations, including on the manufacturing of our COVID-19 vaccine and the manufacturing and testing of our product candidates.

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, negatively impact our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate, 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 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.

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, business interruption, transportation, product liability, cyber matters, clinical trials, and several other areas of coverage. We are dedicating resources to exploring additional avenues for more adequate coverage as our business evolves. However, 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.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, such as actual events or concerns involving liquidity, defaults or non-performance, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, a bank which we previously used to support operations in the United States, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver.

While a statement by the U.S. Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day following the date of closure and we received such access on March 13, 2023, and neither the amount in question nor any delays in access were material to our operations, uncertainty and liquidity concerns in the broader financial services industry remain. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments. However, widespread demands for customer withdrawals or other needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions in a timely fashion or at all.

While we maintain our cash and cash equivalents in multiple financial institutions worldwide, our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, any of which could have material adverse impacts on our operations and liquidity.

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 their 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 and/or regulatory approvals in certain countries, it is possible 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. We expect to submit initial BLAs/MAAs for our mRNA-based product candidates in the United States, the European Union and in other countries globally. In some of these jurisdictions, mRNA-based medicinal products may be classified in different ways and may be subject to specific

requirements. Securing regulatory approval requires the submission of extensive quality, 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. Benefit and risk are regularly assessed, and 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 carries substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.

To our knowledge, other than our and Moderna, Inc.'s COVID-19 vaccines, no mRNA immunotherapies have been approved or received emergency use authorization or conditional marketing authorization to date by the FDA or the EMA. 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.

For administrative purposes, mRNA products are classified together with gene therapy products by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and may cause certain side effects, mRNA is highly unlikely to localize to the nucleus, be reverse transcribed or integrated into the genome. 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 many other jurisdictions for approval is uncertain. Our COVID-19 vaccine is not currently classified as a gene therapy. The regulatory pathway for an individualized therapy, such as our iNeST mRNA-based immunotherapy where each patient receives a different combination of mRNAs, remains undetermined. 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 advanced medicinal 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 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 undesirable 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 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. 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. The centers using our products, if and when approved, could also have difficulty managing any adverse effects of our products, or use medicines that do not adequately control such undesirable effects or that have a detrimental impact on the efficacy of the treatment.

In addition, even if we successfully advance 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 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 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, risks related to COVID-19 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. 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 related to the spread of COVID-19; 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. Each of the foregoing risks may continue to be affected by the spread of seasonal viral infections, including COVID-19, as well as the potential for any new pandemic caused by an as-yet-unknown agent.

We, our collaborators, and other third parties on whom we rely conduct various activities, including research, clinical trials, manufacturing and, where approved, marketing, in jurisdictions across the globe. Such activities are subject to a variety of risks which could materially and adversely affect our business.

Our activities increasingly span different jurisdictions. For example, 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;
- restrictions on transfers of information, including certain technologies and personal data;
- 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.

As part of our global operations, we and our collaborators rely on relationships with entities based in various jurisdictions, including for clinical research and manufacturing activities and other regional operational needs. Such relationships may involve the use of our or others' intellectual property. We expect to continue to rely on such entities, which include locally-based CMOs and CROs, in the future. For example, we and our collaborators rely on WuXi Biologics Co., Ltd. and its affiliates for outsourcing activities related to manufacturing and the supply chain, research and development, certain IP, and commercialization readiness for certain of our product candidates. Such entities are subject to evolving local regulatory requirements, and may also be subject to U.S. and EU legislation, including the proposed U.S. BIOSECURE Act, sanctions, trade restrictions, and/or other regulations. Such requirements could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, or have an adverse affect on our ability to secure significant commitments from governments to purchase our potential therapies.

The extent to which the COVID-19 virus continues to impact our operations, including our clinical trial operations, as it becomes endemic will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including new outbreaks, 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.

As noted above, we and our partners have conducted and are expecting in the future to conduct clinical trials for our product candidates at clinical sites located outside of the United States. Although the FDA may accept data from clinical trials outside the United States that are not conducted under an IND, acceptance of this data in support of a marketing application or IND requires the clinical trial to have been conducted in accordance with GCPs, and that FDA is able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are considered applicable to the U.S. patient population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an onsite inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an onsite inspection or other appropriate means. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States in support of a marketing application. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of a product candidate.

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.

Many 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 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, manufacturing, and AI, 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, and the failure to succeed in preclinical studies or clinical trials or in 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, to provide accurate information to the FDA, the EMA and other regulatory authorities, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to 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.

Employment-related disputes, including employee litigation and unfavorable publicity, could negatively affect our future business.

From time to time we may be subject to claims by our employees or regulatory authorities with respect to employment and workplace matters, including lawsuits or proceedings 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, or, if approved, our other product candidates, 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 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, or, if approved, our other product candidates. 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 or, if approved, our other product candidates, 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 of 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 or in other jurisdictions. 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, in December 2020, we were informed by the EMA that the agency was subject to a cyberattack 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.

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. We have received product liability claims against our COVID-19 vaccine, and expect to receive additional product liability claims in the future. If we cannot successfully defend ourselves against claims that our products and/or our product candidates have caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product or 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 products or product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

We carry clinical trial insurance and product liability insurance, which we believe to be sufficient in light of our current clinical programs and commercial operations; however, the amount of coverage we have obtained may not be adequate and 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. 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 ADSs 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 or 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 products or, if approved, 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.

Issues in the development and use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business.

We are investing in AI technology systems, including through our acquisition of InstaDeep, and such systems are complex and rapidly changing. We face significant competition from other companies with respect to our AI and machine learning services, along with an evolving regulatory landscape. The introduction of AI into the development and manufacturing of our product candidates, or the provision of services relating to AI technologies and applications, may result in new or enhanced governmental or regulatory scrutiny, litigation, intellectual property risks, confidentiality or security risks, ethical concerns or other complications that could harm our business, reputation or financial condition.

Uncertainty around AI may require additional investment in the development and maintenance of proprietary datasets and development of appropriate protections and safeguards for handling the use of customer data with AI technologies, which may be costly and could impact our expenses. In addition, AI may create content that appears correct but is inaccurate or flawed, and if created by third parties, may be mistakenly attributed to us. Our customers or others may rely on or use this flawed content to their detriment, which may expose us to brand or reputational harm, competitive harm or legal liability.

Our ability to effectively monitor and respond to the rapid and ongoing developments and expectations relating to environmental, social and governance, or 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 price of ADSs representing our ordinary 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 own operations and our supply chain, and human resource development, which may result in increased regulatory, social or other scrutiny on us.

We believe we must 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. To this end, we have set ourselves near-term scienced-based emissions reduction targets for our own operations (scope 1, 2) and for our supply chain (supplier engagement target for scope 3), validated by the SBTi in early February 2024.

Additionally, we are addressing increasingly complex regulatory requirements with respect to human rights risks, including German legislation (for example, the Act on Corporate Due Diligence Obligations for the Prevention of Human Rights Violations in Supply Chains ("Lieferkettensorgfaltspflichtengesetz – LkSG")), potential legislative planning by the European Union and local or regional regulations. We are expected by regulation to identify, prevent, mitigate and ideally end the extent of any potential adverse impacts or violations throughout our own operations and value chain.

Finally, we are faced with increasing ESG related transparency and reporting obligations. These requirements arise, for example, from the EU CSRD regulation and the ESRS sustainability standards, from specific human right reporting regulations (e.g. section 10 of the German LkSG), the recently-announced SEC rules that will require registrants to provide additional climate-related disclosures in future periods, and other possible obligations.

Should we fail to meet our climate protection targets or 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 have to pay substantial fines, forego 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 price of ADSs representing our ordinary 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, the price of ADSs representing our ordinary shares, 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 COVID-19 vaccine 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.

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 the recency of our 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 products or 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 in Hong Kong, Fosun Pharma, 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 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 in the future 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 different from our manufacturing sites. Export restrictions could lead to unplanned interruptions in manufacturing, 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 products and 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 products or 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 products or 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 transport intermediate products with holding times in refrigeration (TIR) and allowed times out of refrigeration (TOR) across long distances and crossing borders, 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 such product candidates for clinical trials or, if approved, products for patients 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, we may not be able to supply this expanded need reliably without significant investments due to the custom nature of the equipment and single-use assemblies. 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 individualized 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.

For those of our product candidates that are manufactured for each individual patient, we are required to maintain a chain of identity with respect to each patient's tissue sample, the sequenced data derived from such tissue sample, the results of such patient's genomic analysis and the custom manufactured product for such 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 or appropriate quantities of our COVID-19 vaccine or any of our product candidates, or our failure to comply with applicable regulatory requirements, could 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, the construction of a novel modular manufacturing facility that we refer to as a "BioNTainer," and the construction of a facility to support manufacturing of our Individualized Vaccines Against Cancer (IVAC) candidates. 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, including our BioNTainer units, 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.

We and our collaboration partner also have experienced, and continue to face the risk of, inventory write-downs or redundant production capacities with respect to our COVID-19 vaccine. Planned new formulations of our COVID-19 vaccine, including versions that could protect against new variants of COVID-19, have resulted or may result in significant research and development expense that was not or may not be recouped. In addition, we have experienced in the past, and may experience in the future, redundant production capacities under our agreements with CMOs due to planned new formulations, adaptations of our COVID-19 vaccine and increased internal manufacturing capacities. Significant inventory write-downs or redundant manufacturing expenses would negatively impact our results of operations.

Our facilities are subject to various regulatory requirements and may be subject to announced or unannounced inspections by the FDA or other regulatory authorities at any time during the development or commercialization phase. 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 or our external CMOs' facilities inadequate for the manufacture of our COVID-19 vaccine or our product candidates or otherwise deficient, including as a result of a site inspection, such facilities may be the subject of adverse regulatory action, including the issuance of untitled or warning letters. 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 delay or otherwise 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, labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients in clinical trials, or to provide approved products for the treatment of patients, 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 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 a 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 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 continue to establish additional manufacturing capabilities in different jurisdictions, 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 required personnel, and/or generally manage our growth effectively, the development and production of our products or 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 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 or at all, which could have a material adverse impact on our business.

We are subject to significant regulatory oversight with respect to manufacturing our products and 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 fail to provide sufficient quality assurance or control, approval to continue delivery of our commercial product or to commercialize our product candidates may not be granted. Inspections by regulatory authorities may be announced or unannounced and may occur at any time during the development or commercialization phase. 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 result in adverse regulatory action, including the issuance of untitled or warning letters, which could influence our ability, or the ability of our third-party manufacturers or suppliers, to fulfill supply obligations, impacting or delaying supply or delaying programs. Our failure, or the failure

of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including, but not limited to, 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.

The manufacturing process for any product is subject to the FDA's, the EMA's and other regulatory authorities' approval processes, and we may need to contract with manufacturers whom 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, and could result in the sanctions and other adverse outcomes described above. Our potential future dependence upon others for the manufacture of our products, product candidates and raw materials may adversely affect our future operating results 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 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. Furthermore, 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 are also required to register ongoing clinical trials and post the results of completed clinical trials on a U.S. 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 are also 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;
- make 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 continues to be affected by the spread of COVID-19 globally, even as the virus begins to enter an endemic phase.

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 products and 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 products and product candidates. We expect to enter into additional collaborations to access additional funding, capabilities and/or 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 and products 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 (for example, we are aware that there have been allegations that Fosun International Ltd., an affiliate of our collaboration partner Fosun Pharma, is facing liquidity risks), 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 Germany or 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, or otherwise yield the expected benefits under the collaborations. As a result, our development of product candidates and commercialization efforts could be delayed and we may need additional resources to develop and commercialize our product candidates. 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 Acuitas 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 certain program milestones being achieved or 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.

We and our collaborators 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 where available, we also rely on outside vendors to manufacture supplies and process our product candidates. We only manufacture our COVID-19 vaccine on a commercial scale and may not be able to achieve commercial-scale manufacturing and processing for our other 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.

Certain of our collaborators currently rely on CMOs located outside of the United States to manufacture their clinical materials, and we expect to rely on CMOs located outside of the United States in the future. Such ex-U.S. CMOs may be subject to or affected by U.S. legislation, executive orders, regulations, or investigations, including but not limited to the proposed BIOSECURE Act, the Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, sanctions, trade restrictions and other U.S. and other regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies and adversely affect our financial condition and business prospects.

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 vaccine 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 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 European Union, the United States and elsewhere 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 products, 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, 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 other 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. or EU 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. 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 spread of COVID-19.

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 products, product candidates and other technology and any other products, product candidates and technology that we may 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, 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 they have filed and will continue to file patent applications claiming inventions in the fields in the United States and elsewhere. This may limit, interfere with or eliminate our 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. In the United States, 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.

Additionally, we face ongoing COVID-19 vaccine-related patent litigation. Alnylam Pharmaceuticals Inc. has brought litigation against us and Pfizer regarding U.S. Patent Nos. 11,245,933; 11,382,979; 11,633,479; 11,633,480; 11,612,657; and 11,590,229, the latter five of which are continuations of the '933 Patent. In addition, CureVac SE initiated litigation against us regarding European patents 1857122B1 and 3708668B1 (EP'122 and EP'668 Patents), and three German utility models, or the CureVac IP, in Germany, and then a subsequent litigation was brought by us and Pfizer in the United States regarding U.S. Patent Nos. 11,135,312, 11,149,278 and 11,241,493 that are "U.S. counterparts" to the CureVac IP. CureVac responded with counterclaims asserting infringement of seven additional

U.S. patents, U.S. Patent Nos. 10,760,070; 11,286,492; 11,345,920; 11,471,525; 11,576,966; 11,596,686, and 11,667,910. BioNTech and Pfizer also initiated proceedings seeking the revocation of the EP'122 and EP'668 Patents in the Business and Property Courts of England and Wales. In addition, BioNTech filed a nullity action in the Federal Patent Court of Germany seeking a declaration that the EP'122 Patent is invalid, initiated cancellation actions against the CureVac IP in the German Patent and Trademark Office, and filed an opposition proceeding in the European Patent Office seeking the revocation of EP'668. CureVac initiated a second litigation against us in Germany regarding European patent EP4023755B1 (EP'755 Patent), and two Utility Models DE202021004123U1 and DE202021004130U1. BioNTech filed an opposition proceeding seeing the revocation of EP'755 and cancellation actions against DE'123 and DE'130. ModernaTX, Inc., or Moderna, has brought litigation against us and Pfizer regarding European patents 3590949B1 and 3718565B1 (EP'949 and EP'565 Patents) in Germany, England and Wales, the Netherlands, Ireland, and Belgium, and regarding U.S. Patent Nos. 10,898,574, 10,702,600, and 10,933,127 in the United States. BioNTech and Pfizer also initiated proceedings seeking the revocation of the EP'949 and EP'565 Patents in the Business and Property Courts of England and Wales and have filed opposition proceedings in the European Patent Office seeking the revocation of the EP'949 and EP'565 Patents. BioNTech and Pfizer have filed petitions for inter partes review before the Patent Trial and Appeal Board in the U.S. with respect to U.S. Patent Nos. 10,702,600 and 10,933,127. Arbutus Biopharma Corp. and Genevant Sciences GmbH have brought litigation against us and Pfizer in the United States regarding U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098. Promosome initiated litigation against us and Pfizer in the United States regarding U.S. Patent No. 8,853,179; it has since been dismissed with prejudice. GlaxoSmithKline has brought litigation against us and Pfizer in the United States regarding U.S. Patent Nos. 11,638,693; 11,638,694; 11,666,534; 11,766,401; and 11,786,467. We cannot guarantee that we will not become subject to additional COVID-19 vaccine patent infringement lawsuits in the future. In addition, should Pfizer not prevail in any of the ongoing COVID-19 vaccine patent infringement lawsuits to which it is a party, 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 in which it does not prevail. We believe we have strong defenses against each of these claims and intend to vigorously defend ourselves in each proceeding, but we can make no assurances regarding the ultimate outcome of any of these matters.

We expect that we will continue to be subject to similar proceedings or priority disputes, including oppositions, in Europe or other 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, Pfizer and us, there may be additional 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 and 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 activities may involve additional product candidates or services 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 other 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 candidates, including not being able to prevent a competitor or other third party from developing the same product(s) or product candidates 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, we may disagree from time to time with licensors or collaborators regarding, among other things, the interpretation of each party's obligations or the amounts payable under our agreements. For example, we are in ongoing discussions with the University of Pennsylvania and the National Institutes of Health, or NIH, concerning royalties and other related amounts allegedly owed on sales of our COVID-19 vaccine since commercialization. We and the NIH have exchanged detailed characterizations of our positions and the NIH has delivered a notice of default relating to alleged amounts owed and breaches under such license. While we disagree with the positions being taken by the University of Pennsylvania and the NIH, the ultimate outcome of these matters is uncertain and we cannot guarantee that our interpretation of these license agreements will prevail, or that we will not ultimately need to pay some or all of the royalty and other related amounts in dispute.

If we are found to have failed to satisfy obligations or materially breached any of our agreements, such as licenses to third-party intellectual or any disagreements between us and our licensors, a licensor could potentially have the right or reason to terminate the license, 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 rightfully 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, and our licensors may be able to seek additional judicial remedies. 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. Failure to prevail with respect to any contractual disagreements could result in a material adverse effect on our competitive position, business, financial conditions, results of operations or prospects, particularly if discussions result in legal or other dispute resolution proceedings.

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 NIH, Genevant, and Cellscript, have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. 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 such inventions or produced through the use of any such 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 or our licensors 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 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.

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 candidates, 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, after such submission (including for certain formulations of our COVID-19 vaccine), 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 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 such 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, licenses could not be available on commercially reasonable terms or at all, and design-around could be prohibitively expensive or impossible.

Additionally, with respect to our products, product candidates and related technologies that may play a role in addressing a pandemic or other public health emergency, it is unclear whether governments around the world will protect vaccine manufacturers for liability from infringement of third party intellectual property, at least during the period of such public health emergency. 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 was deemed protected from infringement during the period of the pandemic crisis, now that various global and U.S. agencies have declared an end to the global COVID-19 public health emergency, 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. We have a number of opposition proceedings ongoing at the European Patent Office against third-party patents related to mRNA technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products, product candidates and services 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. For example, BioNTech SE and certain of our wholly owned subsidiaries are defendants in litigations initiated by CureVac SE, Alnylam Pharmaceuticals, Inc., ModernaTX, Inc., Arbutus Biopharma Corp. and Genevant Sciences GmbH regarding Comirnaty. See "Legal Proceedings." 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 to 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 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 proceedings adequately. Some of our competitors may be able to sustain the costs of such 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, the price of the ADSs representing our ordinary shares could decline.

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-license. 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 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 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 or 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 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, particularly those in Asia, including China, 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 Europe and 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. In particular, the validity, enforceability and scope of protection of intellectual property in China, where we derive net sales and maintain collaboration partnership including licensing, are still evolving and historically, have not protected and may not protect in the future, intellectual property rights to the same extent as laws developed in Europe, including Germany, and the United States. Consequently, the time required to enforce our intellectual property rights in the legal regime of China may be lengthy and delay our recovery.

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 appropriately or at all, 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 individualized 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 changed in May 2022 when a new EU regulation with stricter regulatory requirements for in vitro diagnostics became 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 jurisdictions 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 U.S. 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, be reverse transcribed or integrated into the genome. Consequently, we expect that our products or 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 products and product candidates to address safety concerns that are not available to other products or product candidates classified as gene therapies, such as lowering the dose of our products or 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. 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 potential future clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly

could 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 approved mRNA products or 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 products or 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 certain markets or to obtain and maintain required approvals, or if regulatory approvals in certain markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Certain jurisdictions may have submission requirements for drug clinical trial and marketing applications that require us or our partners to submit substantial detailed materials related to non-clinical and clinical development and manufacturing and quality control to drug regulators or testing laboratories. This can include executed batch records for the production of biological products or other records or documents that set forth detailed information about the manufacturing process. If these records are disclosed, lost, or diverted to third parties or competitors during the application preparation process, this could negatively affect our ability to protect our intellectual property.

Our partners in different countries are subject to local regulatory requirements on the manufacturing and distribution of drugs and the implementation of clinical and non-clinical research. These include but are not limited to good manufacturing, distribution, laboratory, and clinical practice rules. If these companies do not comply with applicable standards, they could become the subjects of investigations and enforcement, including orders to cease the activities pending remediation that is acceptable to the government. Such an order or other similar enforcement could interfere with our clinical development activities both in that jurisdiction and others, if it impacts supply or the quality and transfer of data.

A third-party investigational product candidate 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 product candidates. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing products, 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 product used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing products. If the products or product candidates 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 product candidates 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 product candidate if that unapproved product candidate does not ultimately obtain marketing approval. In addition, unapproved product candidates 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 product candidates or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the products or product candidates 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 products or 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 products or product candidates cause undesirable side effects, it could delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval. Products or 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 products or 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, if approved, 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.

Upon the successful approval of a product candidate, we will continue to face significant regulatory oversight of its manufacturing and distribution. 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. Our operations may 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 U.S. 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 U.S. 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 U.S. 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;

- U.S. 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. In particular, in China, where some of our clinical data are originated, the cybersecurity, data privacy, data protection, or

other data-related laws and regulations, including the Human Genetic Resources Regulation (which now only regulates transfer human genetic data generated in clinical research to foreign or foreign controlled parties), are relatively new and evolving, and their interpretation and application may be uncertain. In the United States, we may be subject to restrictions and requirements under the Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, signed on February 28, 2024. Practices regarding the collection, use, storage, transmission and security of personal information by companies have also been subject to increasing regulatory focus. As such, we cannot assure you that we will be compliant with such new regulations in all respects, and we may be ordered to rectify and terminate any actions that are deemed illegal by the government authorities and become subject to fines and other government sanctions, which may materially and adversely affect our business, financial condition, and results of operations. In addition, the uncertainties regarding further interpretation and implementation of these laws and regulations may adversely affect the secure storage of documented work as well as the cross-border transfer of important data and personal information originated from our clinical trial activities, which are critical to the development of our pipelines.

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 such as BioNTech SE that are developing potential therapeutics and vaccines to combat COVID-19, as well as conducting mRNA-based research in oncology and infectious disease more generally, 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 and commercialization activities. For example, during 2023, the closing sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market ranged from $88.00 to $156.28, with significant volatility occurring, for example, shortly after announcements by us or others related to regulatory matters, to our COVID-19 vaccine, to other COVID-19 vaccines, to development and commercialization pipelines in oncology and infectious disease, and to our transactions with third parties. Additionally, we have observed the trading price of the ADSs respond significantly to news and statements by us, government agencies, other vaccine developers, financial analysts or others relating to our business as well as to other COVID-19 vaccines and COVID-19 therapeutics and the spread of COVID-19 generally, even in cases in which we believe the news does not affect our business or vaccine specifically. Given the attention being paid to COVID-19 worldwide and the public scrutiny of COVID-19 development and commercialization announcements, and given that our COVID-19 vaccine is currently among the primary vaccines being used worldwide, any news regarding manufacturing, supply 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, as a result, the price of the ADSs representing our ordinary shares likely will continue to be volatile. In addition, volatility in the overall market and in the market price of a particular company's securities can result in securities litigation, including shareholder class action lawsuits. Any securities litigation can result in substantial costs and a diversion of our management's attention and resources.

Acquisitions, joint ventures and collaborations 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. For example, in July 2023, we acquired InstaDeep, a leading global technology company in the field of AI and machine learning, for upfront consideration of cash and BioNTech shares, and potential future milestone payments. Although we believe that AI and machine learning technology has the potential to accelerate the development of therapeutic programs and further optimize manufacturing and supply chain processes, it is possible that our use of the acquired technology will not achieve the desired results, and that we will not be able to retain and grow InstaDeep's business around the world. If demand for the services developed by InstaDeep does not continue, or if we are unable to improve our AI and machine learning technology in a timely, effective and competitive manner, we may not be able realize the expected outcomes from the InstaDeep acquisition. There is no guarantee that we will realize any anticipated benefits of this or future acquisitions, or that the diversification of our business through acquired technology or products will be successful.

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.

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 any ADS repurchase program we conduct in the future 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 the applicable repurchase plan. These purposes may 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 any ADS repurchase program. Additionally, we may enter into a Rule 10b5-1 trading plan governing the repurchases, and if we do, we would have no discretion over the particular purchases made and would only be 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, 2023, 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 registration statements 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 have become, and any other registration statements on Form S-8 we file in the future will 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 have included, and we may in the future make sales including, 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.

If we are a "passive foreign investment company" for U.S. federal income tax purposes, there may be adverse U.S. federal income tax consequences to U.S. investors.

Based on our income and assets, we believe that we should be treated as a PFIC for the preceding taxable year. However, the determination of our PFIC status is made annually based on the factual tests described below. Consequently, while we may be a PFIC in future years, we cannot estimate with certainty at this stage whether or not we are likely to be treated as a PFIC in the current taxable year or any future taxable years. Generally, if, for any taxable year, at least 75 percent of our gross income is "passive income" or at least 50 percent 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, we will be characterized as a PFIC for U.S. federal income tax purposes. 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 should not be considered passive income for purposes of the PFIC test. For example, if we were to be characterized as a PFIC for U.S. federal income tax purposes in any taxable year during which a U.S. Holder (as defined in "Taxation —Material United States federal income tax considerations" in our Annual Report on Form 10-K for the year ended December 31, 2023) holds ordinary shares or ADSs, such U.S. Holder could be subject to additional taxes and interest charges upon certain distributions by us and any gain recognized on a sale, exchange or other disposition of our shares, whether or not we continue to be characterized as a PFIC. Certain adverse consequences of PFIC status can be mitigated if a U.S. Holder makes a "mark to market" election or a "Qualified Electing Fund" (QEF) election. We intend to provide U.S. holders with the information necessary to make and maintain a QEF election for any taxable year in which we are treated as a PFIC. See "Taxation —Material United States federal income tax considerations —Passive foreign investment company considerations" in our Annual Report on Form 10-K for the year ended December 31, 2023.

Whether we are a PFIC for any taxable year will depend on the composition of our income and the composition and value of our assets from time to time. Each U.S. Holder is strongly urged to consult its tax advisor regarding these issues and any available elections to mitigate such tax consequences.

Disclaimer

Forward-Looking Statements

This quarterly report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: our expected revenues and net profit/(loss) related to sales of our COVID-19 vaccine, referred to as *Comirnaty* where approved for use under full or conditional marketing authorization, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners; the rate and degree of market acceptance of our COVID-19 vaccine and, if approved, our investigational medicines; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of our research and development programs, including our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; the targeted timing and number of potentially registrational trials, and the registrational potential of any trial we may initiate; discussions with regulatory agencies; our expectations with respect to intellectual property; the impact of our acquisition of InstaDeep Ltd. and our collaboration and licensing agreements; the development, nature and feasibility of sustainable vaccine production and supply solutions; and our expectations with respect to legal claims and proceedings. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

The forward-looking statements in this quarterly report are based on our current expectations and beliefs of future events, and are neither promises nor guarantees. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control and which could cause actual results to differ materially and adversely from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this report, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; our pricing and coverage negotiations regarding our COVID-19 vaccines with governmental authorities, private health insurers and other third-party payors; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; 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, side-effect profile and durability of immune response; the timing of and our ability to obtain and maintain regulatory approval for our product candidates; the ability of our COVID-19 vaccine to prevent COVID-19 caused by emerging virus variants; our and our counterparties' ability to manage and source necessary energy resources; our ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines; the impact of COVID-19 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 ability and that of our collaborators to commercialize and market our COVID-19 vaccine and, if approved, our product candidates; our ability to manage our development and expansion and related expenses; regulatory developments in the United States and other countries; our ability to effectively scale our production capabilities and manufacture our products, including our target COVID-19 vaccine production levels, and our product candidates; risks relating to the global financial system and markets; and other factors not known to us at this time. You should review the risks and uncertainties described under the heading "Risk Factors" in this quarterly report for the three months ended March 31, 2024, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at https://www.sec.gov/. These forward-looking statements speak only as of the date hereof. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this quarterly report in the event of new information, future developments or otherwise.

General Information

This quarterly report contains references to our trademarks and to trademarks belong to other entities. Solely for convenience, trademarks and trade names referred to, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Our trademark portfolio includes, but is not limited to, *Comirnaty*, *BioNTainer*, *FixVac*, *RiboCytokine* and *RiboMab*, including logo versions of some of these trademarks. Brand names appearing in italics throughout this report are trademarks owned by BioNTech. All other trademarks are the property of their respective owners.