

**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 2022

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 9, 2022, BioNTech SE (the “Company”) provided a development update and reported its financial results for the three months ended March 31, 2022. 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, 2022, 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 s 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 9, 2022

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<u>Quarterly Report for the Three Months Ended March 31, 2022</u>

BIONTECH



BioNTech SE

Quarterly Report BioNTech SE for the Three Months Ended March 31, 2022

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Unaudited Interim Condensed Consolidated Financial Statements

Interim Condensed Consolidated Statements of Profit or Loss

<i>(in millions, except per share data)</i>	Note	Three months ended March 31,	
		2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>
Revenues			
Research & development revenues	3	€12.4	€20.9
Commercial revenues	3	6,362.2	2,027.5
Total revenues		€6,374.6	€2,048.4
Cost of sales	4.1	(1,294.1)	(233.1)
Research and development expenses	4.2	(285.8)	(216.2)
Sales and marketing expenses		(14.3)	(8.7)
General and administrative expenses	4.3	(90.8)	(38.9)
Other operating expenses	4.4	(71.6)	(0.6)
Other operating income	4.5	134.7	111.3
Operating income		€4,752.7	€1,662.2
Finance income	4.6	272.1	24.8
Finance expenses	4.7	(6.7)	(44.7)
Profit before tax		€5,018.1	€1,642.3
Income taxes	5	(1,319.3)	(514.2)
Profit for the period		€3,698.8	€1,128.1
Earnings per share			
Basic profit for the period per share		€15.13	€4.64
Diluted profit for the period per share		€14.24	€4.39

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

Interim Condensed Consolidated Statements of Comprehensive Income

<i>(in millions)</i>	Note	Three months ended March 31,	
		2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>
Profit for the period		€3,698.8	€1,128.1
Other comprehensive income			
<i>Other comprehensive income that may be reclassified to profit or loss in subsequent periods, net of tax</i>			
Exchange differences on translation of foreign operations		3.7	4.5
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods		€3.7	€4.5
<i>Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods, net of tax</i>			
Remeasurement loss on defined benefit plans		(0.1)	—
Net other comprehensive loss that will not be reclassified to profit or loss in subsequent periods		€(0.1)	€—
Other comprehensive income for the period, net of tax		€3.6	€4.5
Comprehensive income for the period, net of tax		€3,702.4	€1,132.6

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

Interim Condensed Consolidated Statements of Financial Position

<i>(in millions)</i>		March 31, 2022	December 31, 2021
	Note	<i>(unaudited)</i>	
Assets			
Non-current assets			
Intangible assets		€216.0	€202.4
Property, plant and equipment		358.3	322.5
Right-of-use assets		198.6	197.9
Other financial assets	6	48.4	21.3
Other assets		0.8	0.8
Deferred expenses		11.4	13.6
Total non-current assets		€833.5	€758.5
Current assets			
Inventories	7	459.3	502.5
Trade and other receivables	6	12,695.8	12,381.7
Other financial assets	6	0.9	381.6
Other assets		64.9	64.9
Income tax assets		0.4	0.4
Deferred expenses		80.7	48.5
Cash and cash equivalents		6,164.1	1,692.7
Total current assets		€19,466.1	€15,072.3
Total assets		€20,299.6	€15,830.8
Equity and liabilities			
Equity			
Share capital	8	246.8	246.3
Capital reserve	8	1,976.3	1,674.4
Treasury shares		(3.8)	(3.8)
Retained earnings		13,581.7	9,882.9
Other reserves	9	109.7	93.9
Total equity		€15,910.7	€11,893.7
Non-current liabilities			
Loans and borrowings	6	155.4	171.6
Other financial liabilities	6	6.1	6.1
Income tax liabilities	5	4.4	4.4
Provisions	10	240.0	184.9
Contract liabilities		66.4	9.0
Other liabilities		11.2	12.8
Deferred tax liabilities		50.9	66.7
Total non-current liabilities		€534.4	€455.5
Current liabilities			
Loans and borrowings	6	30.6	129.9
Trade payables	6	123.7	160.0
Other financial liabilities	6	1,381.9	1,190.4
Government grants		3.0	3.0
Refund liabilities		90.0	90.0
Income tax liabilities	5	1,614.0	1,568.9
Provisions	10	339.2	110.2
Contract liabilities		192.0	186.1
Other liabilities		80.1	43.1
Total current liabilities		€3,854.5	€3,481.6
Total liabilities		€4,388.9	€3,937.1
Total equity and liabilities		€20,299.6	€15,830.8

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

Interim Condensed Consolidated Statements of Changes in Stockholders' Equity

<i>(in millions, unaudited)</i>	Note	Share capital	Capital reserve	Treasury shares	Retained earnings	Other reserves	Total equity
As of January 1, 2021		€246.3	€1,514.5	€(4.8)	€(409.6)	€25.4	€1,371.8
Profit for the period		—	—	—	1,128.1	—	1,128.1
Other comprehensive income		—	—	—	—	4.5	4.5
Total comprehensive income		€—	€—	€—	€1,128.1	€4.5	€1,132.6
Share-based payments	9	—	—	—	—	15.2	15.2
As of March 31, 2021		€246.3	€1,514.5	€(4.8)	€718.5	€45.1	€2,519.6
As of January 1, 2022		€246.3	€1,674.4	€(3.8)	€9,882.9	€93.9	€11,893.7
Profit for the period		—	—	—	3,698.8	—	3,698.8
Other comprehensive income		—	—	—	—	3.6	3.6
Total comprehensive income		€—	€—	€—	€3,698.8	€3.6	€3,702.4
Issuance of share capital	8	0.5	67.1	—	—	—	67.6
Redemption of convertible note	6	—	234.9	—	—	—	234.9
Transaction costs		—	(0.1)	—	—	—	(0.1)
Share-based payments	9	—	—	—	—	12.2	12.2
As of March 31, 2022		€246.8	€1,976.3	€(3.8)	€13,581.7	€109.7	€15,910.7

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

Interim Condensed Consolidated Statements of Cash Flows

<i>(in millions)</i>	Three months ended March 31,	
	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>
Operating activities		
Profit for the period	€3,698.8	€1,128.1
Income taxes	1,319.3	514.2
Profit before tax	€5,018.1	€1,642.3
Adjustments to reconcile profit before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	27.6	13.0
Share-based payment expense	9.4	17.3
Net foreign exchange differences	6.1	(31.2)
Gain on disposal of property, plant and equipment	—	0.2
Finance income	(217.3)	(0.3)
Finance expense	6.7	44.7
Movements in government grants	—	(67.9)
Net loss on derivative instruments at fair value through profit or loss	(1.9)	—
Working capital adjustments:		
Increase in trade and other receivables, contract assets and other assets	(403.5)	(2,100.5)
Decrease / (increase) in inventories	43.2	(82.8)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	857.5	255.5
Interest received	0.7	0.3
Interest paid	(6.4)	(1.8)
Income tax paid	(1,290.0)	(0.1)
Net cash flows from / (used in) operating activities	€4,050.2	€(311.3)
Investing activities		
Purchase of property, plant and equipment	(44.1)	(21.7)
Proceeds from sale of property, plant and equipment	—	0.9
Purchase of intangible assets and right-of-use assets	(16.7)	(7.5)
Investment into equity instruments designated at fair value through OCI	(27.0)	—
Proceeds from maturity of other financial assets	375.2	—
Net cash flows from / (used in) investing activities	€287.4	€(28.3)
Financing activities		
Proceeds from issuance of share capital and treasury shares, net of costs	110.5	—
Repayment of loans and borrowings	(18.8)	(0.7)
Payments related to lease liabilities	(11.4)	(3.8)
Net cash flows from / (used in) financing activities	€80.3	€(4.5)
Net increase / (decrease) in cash and cash equivalents	4,417.9	(344.1)
Change in cash and cash equivalents resulting from exchange rate differences	53.5	25.4
Cash and cash equivalents at the beginning of the period	1,692.7	1,210.2
Cash and cash equivalents at March 31	€6,164.1	€891.5

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 fully integrated global biotechnology company specializing in the development of novel medicines at the intersection of immunology and synthetic biology. Since our founding in 2008, we have focused on harnessing the power of the immune system to address human diseases with unmet medical need and major health burden. Our fully-integrated model combines decades of research in immunology, translational drug discovery and development, a technology agnostic innovation engine, GMP manufacturing, and commercial capabilities to rapidly develop and commercialize potential vaccines and therapies to address a range of serious indications on a global scale. We have built a broad toolkit across multiple technology platforms, including a diverse range of potentially first-in-class therapeutic approaches. This includes mRNA vaccines, cell and gene therapies, targeted antibodies, small molecule immunomodulators, Ribologicals, and next generation immunomodulators.

In February 2022, BioNTech Innovation GmbH, Mainz, Germany, was established and is a wholly owned consolidated subsidiary of BioNTech SE.

Our unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2022 were authorized for issuance in accordance with a resolution of the audit committee on May 9, 2022.

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, 2022 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 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, 2021.

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, 2022 include BioNTech SE and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Significant Accounting Judgments, Estimates and Assumptions

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 the judgment described as “Pfizer Agreement Characteristics” in the notes to our audited consolidated financial statements as of and for the year ended December 31, 2021. 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, some of which is based on preliminary data shared between the partners. These estimated figures may change in future periods as we receive final data from our collaboration partner. Those changes in our share of the collaboration partner’s gross profit are recognized prospectively as a change in estimates. Our management continually evaluates judgments and estimates, including such related to the fair value measurement of derivatives, revenues and expenses. Management bases its judgments and estimates on parameters available 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.

Significant Accounting Policies

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, 2021, 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). Certain policies have been described further below due to the activities related to and the transactions occurred during the three months ended March 31, 2022.

Foreign Exchange Forward Contracts

Effects from foreign exchange forward contracts are either shown as other operating income or expenses on a cumulative basis and might switch between those two positions during the year-to-date reporting periods.

Standards Applied for the First Time

The IFRS standards applied for the first time as of January 1, 2022, as disclosed in the notes to the audited consolidated financial statements as of and for the year ended December 31, 2021, had no impact on our unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2022.

Operational Impacts of COVID-19

As we advance our clinical programs, we are in close contact with our principal investigators and clinical sites, and are assessing the impact on the clinical trials, expected timelines and costs on an ongoing basis. We have modified the business practices in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. In addition, for certain programs, including BNT111, BNT113, BNT122, BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines) and BNT161 (Influenza), delays in the commencement of trials were experienced, due to slowed patient enrollment and other delays as a result of the COVID-19 pandemic. After several months of delay to focus efforts on our COVID-19 vaccine in 2020, in 2021 we started four Phase 2 clinical trials: two for our FixVac product candidates BNT111 and BNT113, one each for our iNeST program BNT122 as well as for our bispecific antibody program BNT311. In addition, we have started multiple Phase 1 clinical trials that include product candidates for BNT211 (CARVac), BNT221 (NEO-PTC-01, a neoantigen-based T-cell therapy), BNT151 and BNT152+153 (RiboCytokines) and BNT141 (RiboMab). The delays, even though they were temporary, may negatively impact our operations and overall business by delaying further progress of these clinical trials and preclinical studies. Our operations, including research and manufacturing, could also be negatively impacted due to the potential impact of staff absences as a result of self-isolation procedures or extended illness. Such factors were evaluated and considered when preparing these unaudited interim condensed consolidated financial statements as of and for the three months ended March 31, 2022. We will continue to evaluate observed and potential effects of the COVID-19 pandemic.

3 Revenues from Contracts with Customers

Disaggregated information on revenues

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

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Research & development revenues from collaborations	€12.4	€20.9
Commercial revenues	€6,362.2	€2,027.5
COVID-19 vaccine revenues	6,353.2	2,015.6
<i>Sales to collaboration partners⁽¹⁾</i>	<i>603.2</i>	<i>63.9</i>
<i>Direct product sales to customers</i>	<i>1,163.1</i>	<i>199.8</i>
<i>Share of collaboration partners' gross profit and sales milestones</i>	<i>4,586.9</i>	<i>1,751.9</i>
Other sales	9.0	11.9
Total	€6,374.6	€2,048.4

⁽¹⁾ Represents sales to our collaboration partners of products manufactured by us.

Research & Development Revenues from Collaborations

During the three months ended March 31, 2022, research and development revenues were mainly derived from our collaborations with Genentech Inc., or Genentech. In addition, during the three months ended March 31, 2022, we entered into a new research, development and commercialization collaboration with Pfizer Inc., or Pfizer, to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV). Under the terms of the agreement, an amount of €67.5 million was classified as upfront payment and recognized as contract liability in our unaudited interim condensed consolidated statements of financial position. The amount is recognized as revenues upon advancement of research and development activities.

Commercial Revenues

During the three months ended March 31, 2022, commercial revenues were recognized from the supply and sales of our COVID-19 vaccine worldwide. We are the marketing authorization holder in the United States, the European Union, the United Kingdom, Canada and other countries, and holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries; submissions to pursue regulatory approvals on those countries where emergency use authorizations or equivalent were initially granted are ongoing. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Turkey. Fosun Pharma has marketing and distribution rights in China, Hong Kong special administrative region, or SAR, Macau SAR and the region of Taiwan. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal.

Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and our COVID-19 vaccine is transferred, the vaccine is sold from one partner to the other. During the three months ended March 31, 2022 and 2021, we recognized €603.2 million and €63.9 million of revenues, respectively, from selling drug product batches manufactured by us to our partners.

By supplying our territories during the three months ended March 31, 2022 and 2021, we recognized €1,163.1 million and €199.8 million of revenues, respectively, from direct COVID-19 vaccine sales in Germany and Turkey. The share of gross profit that we owe our collaboration partner Pfizer based on our sales is recognized as cost of sales.

Based on COVID-19 vaccine sales in the collaboration partners' territories, we are eligible to receive a share of their gross profit which represents a net figure and is recognized as collaboration revenues during the commercial phase together with sales milestones that are recorded once the underlying thresholds are met. During the three months ended March 31, 2022, €4,586.9 million gross profit share was recognized as revenues. During the three months ended March 31, 2021, €1,504.7 million gross profit share and €247.2 million of sales milestones were recognized as revenues. In order to determine our share of our collaboration partners' gross profits, we used certain information from the collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available. The true-up recognized prospectively during the three months ended March 31, 2022 and 2021, with respect to the previous period, was not material.

Revenues from contracts with customers were recognized as follows:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Timing of revenue recognition		
<i>Goods and services transferred at a point in time</i>	€1,773.4	€273.7
<i>Goods and services transferred over time</i>	4,601.2	1,774.7
Total	€6,374.6	€2,048.4

4 Income and Expenses

4.1 Cost of Sales

The cost of sales recognized during the three months ended March 31, 2022 and 2021 are shown in the following table:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Cost of sales related to COVID-19 vaccine revenues	€1,288.3	€223.2
Cost related to other sales	5.8	9.9
Total	€1,294.1	€233.1

4.2 Research and Development Expenses

The research and development expenses recognized during the three months ended March 31, 2022 and 2021 are shown in the following table:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Purchased services	€131.4	€141.9
Wages, benefits and social security expense	70.8	47.5
Laboratory supplies	57.6	11.4
Depreciation and amortization	10.8	7.5
Other	15.2	7.9
Total	€285.8	€216.2

4.3 General and Administrative Expenses

The general and administrative expenses recognized during the three months ended March 31, 2022 and 2021 are shown in the following table:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Purchased services	€30.3	€12.0
Wages, benefits and social security expense	27.5	14.3
IT and office equipment	11.3	2.6
Insurance premiums	6.0	4.3
Recruiting expenses	3.7	0.9
Other	12.0	4.8
Total	€90.8	€38.9

4.4 Other Operating Expenses

The other operating expenses recognized during the three months ended March 31, 2022 and 2021 are shown in the following table:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Loss on derivative instruments at fair value through profit or loss	€69.3	€—
Other	2.3	0.6
Total	€71.6	€0.6

The loss on derivative instruments at fair value through profit or loss related to foreign exchange forward contracts that did not qualify for hedge accounting (see Note 6).

4.5 Other Operating Income

The other operating income recognized during the three months ended March 31, 2022 and 2021 is shown in the following table:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Foreign exchange differences, net	€124.0	€40.7
Gain on derivative instruments at fair value through profit or loss	2.8	—
Government grants	—	67.9
Other	7.9	2.7
Total	€134.7	€111.3

The foreign exchange differences included in operating income primarily arose from valuing our U.S. dollar denominated trade receivables which mainly relate to our COVID-19 collaboration with Pfizer, U.S. dollar denominated trade payables as well as our U.S. dollar denominated other financial liabilities which mainly relate to obligations incurred from our license agreements.

4.6 Finance Income

The finance income recognized during the three months ended March 31, 2022 and 2021 is shown in the following table:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Fair value adjustments of financial instruments measured at fair value	€216.8	€—
Foreign exchange differences, net	54.8	24.5
Interest income	0.5	0.3
Total	€272.1	€24.8

The fair value adjustments were derived from remeasuring the derivative embedded in our convertible note (see Note 6) and are reflecting the change in the derivative's fair value related to the equity investment of Pfizer mainly derived from our share price development between contract signing and closing (see Note 8).

4.7 Finance Expenses

The finance expenses recognized during the three months ended March 31, 2022 and 2021 are shown in the following table:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Interest expenses related to financial assets	€3.2	€—
Amortization of financial instruments	2.6	2.5
Interest expenses related to lease liabilities	0.9	0.7
Fair value adjustments of financial instruments measured at fair value	—	41.5
Total	€6.7	€44.7

The fair value adjustments were derived from remeasuring the derivative embedded in our convertible note (see Note 6).

5 Income Tax

For the three months ended March 31, 2022 and 2021, 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 plus the tax effect of any discrete items. For the three months ended March 31, 2022 and 2021, our effective income tax rate was approximately 26.3% and 31.3%, respectively, in part due to average trade tax rates in Mainz, Marburg and Idar-Oberstein decreasing from 2022 onward. During the three months ended March 31, 2022, current income taxes were recognized with respect to the German tax group. Deferred tax effects were recognized with respect to identified discrete items. In addition, the non-tax effective fair value measurement of the convertible note was considered as permanent difference. As of March 31, 2022, we continue to maintain a valuation allowance against deferred tax assets of our U.S. tax group as there is not sufficient probability in terms of IAS 12 that there will be future taxable profits available against which the unused tax losses and temporary differences can be utilized.

The income taxes recognized during the three months ended March 31, 2022 and 2021 are shown in the following table:

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Current income taxes	€1,335.1	€495.1
Deferred taxes	(15.8)	19.1
Income taxes	€1,319.3	€514.2

6 Financial Assets and Financial Liabilities

Financial Assets

Set out below is an overview of financial assets, other than cash and cash equivalents, held as of March 31, 2022 and December 31, 2021.

<i>(in millions)</i>	March 31, 2022	December 31, 2021
Derivatives not designated as hedging instruments		
Foreign exchange forward contracts	€0.7	€5.7
Equity instruments designated at fair value through OCI		
Non-listed equity investments	46.5	19.5
Financial assets at amortized cost		
Trade and other receivables	12,695.8	12,381.7
Cash deposit with an original term of six months	—	375.2
Other financial assets	2.1	2.5
Total	€12,745.1	€12,784.6
Total current	12,696.7	12,763.3
Total non-current	48.4	21.3

Equity Instruments Designated at Fair Value through Other Comprehensive Income

Equity investments generally are made in conjunction with our existing commercial partnerships. In accordance with IFRS 9 we elected to present gains and losses on our equity investments in other comprehensive income to avoid fluctuation to be disclosed in our unaudited interim condensed consolidated statements of profit or loss. During the three months ended March 31, 2022, no material gains and losses on our equity investments have occurred.

Financial Assets at Amortized Cost

Trade and other receivables mainly remained constant and predominantly comprise trade receivables from our COVID-19 collaboration with Pfizer as well as our direct product sales to customers in our territory. The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's fiscal quarter for subsidiaries outside the United States differs from ours, it creates an additional time lag between the recognition of revenues and the payment receipt. Consequently, as of March 31, 2022, our trade receivables included trade receivables which related to the gross profit share for the fourth quarter of 2021 and the first quarter of 2022. The payment settling our gross profit share for the fourth quarter of 2021 (as defined by the contract) was received from our collaboration partner in April 2022, subsequent to the end of the reporting period. Of our trade receivables outstanding as of March 31, 2022, we had collected €5,243.8 million in cash by April 14, 2022.

Financial Liabilities

Set forth below is an overview of financial liabilities, other financial liabilities and trade payables held as of March 31, 2022 and December 31, 2021.

Loans and borrowings

<i>(in millions)</i>	Maturity	March 31, 2022	December 31, 2021
Lease liabilities		€184.7	€181.6
Convertible note – host contract	(1)	—	99.7
2.2% €10,000,000 secured bank loan	(2)	—	7.7
2.1% €9,450,000 secured bank loan	(2)	—	7.8
1.9% €3,528,892 secured bank loan	(2)	—	3.4
0.8% €1,305,167 loans (aggregated)	06/30/2027 ⁽³⁾	1.3	1.3
Total		€186.0	€301.5
Total current		30.6	129.9
Total non-current		155.4	171.6

⁽¹⁾ The convertible note was fully redeemed by exercising our early redemption option as of March 1, 2022, the redemption date.

⁽²⁾ This loan was repaid in full during the three months ended March 31, 2022.

⁽³⁾ June 30, 2027 represents the latest maturity with respect to the loans (aggregated).

Other financial liabilities

<i>(in millions)</i>		March 31, 2022	December 31, 2021
Derivatives not designated as hedging instruments			
Convertible note – embedded derivative	(1)	€—	€308.7
Foreign exchange forward contracts		56.1	63.0
Financial liabilities at fair value through profit or loss			
Contingent consideration		6.1	6.1
Total financial liabilities at fair value		€62.2	€377.8
Trade payables and other financial liabilities at amortized cost, other than loans and borrowings			
Trade payables		123.7	160.0
Other financial liabilities		1,325.8	818.7
Total trade payables and other financial liabilities at amortized cost, other than loans and borrowings		€1,449.5	€978.7
Total other financial liabilities		€1,511.7	€1,356.5
Total current		1,505.6	1,350.4
Total non-current		6.1	6.1

⁽¹⁾ The convertible note was fully redeemed by exercising our early redemption option as of March 1, 2022, the redemption date.

Total financial liabilities

<i>(in millions)</i>		March 31, 2022	December 31, 2021
Loans and borrowings		€186.0	€301.5
Other financial liabilities		1,511.7	1,356.5
Total		€1,697.7	€1,658.0
Total current		1,536.2	1,480.3
Total non-current		161.5	177.7

Loans and Borrowings and Derivatives Not Designated as Hedging Instrument*Convertible Note*

In February 2022, we gave notice to Temasek Capital Management Pte. Ltd., or Temasek, of the exercise of our early redemption option and the full redemption of our convertible note as of March 1, 2022, the redemption date. As of the redemption date, the conversion features provided for in the contract initially identified as a combined embedded derivative were finally measured at fair value through profit and loss and recognized as finance income in our unaudited interim condensed consolidated statements of profit or loss (see Note 4.6). The early redemption is fulfilled by issuing the number of our ordinary shares calculated pursuant to the early redemption provisions of the convertible note, plus paying any fractional share and accrued but unpaid interest up to (but excluding) the redemption date. As of March 31, 2022, the issuance of our ordinary shares was not yet completed but only became effective during April 2022. Hence, the convertible note host contract as well as the combined embedded derivative which previously were recognized as separate financial liabilities were reclassified into our capital reserve with an amount of €234.9 million as of March 31, 2022.

Foreign Exchange Forward Contracts

Derivatives not designated as hedging instruments reflect the fair value of those foreign exchange forward contracts that were outstanding as of March 31, 2022 and were entered into to manage some of our transaction exposures. The foreign exchange forward contracts are intended to reduce the level of foreign currency risk related to trade receivables denominated in U.S. dollar. The fair value adjustments derived from remeasuring the foreign exchange forward contracts during the three months ended March 31, 2022 were recognized as other operating expenses in our unaudited interim condensed consolidated statements of profit or loss (see Note 4.4).

Other Financial Liabilities at Amortized Cost

Other financial liabilities increased mainly due to obligations incurred from our license agreements.

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, 2021.

Fair Values

Fair values of cash and cash equivalents, trade receivables, trade payables, and other current financial assets and liabilities approximate their carrying amounts largely due to the short-term maturities of these instruments.

The fair values of financial instruments measured at fair value are reassessed on a quarterly basis. The money market funds, or MMFs, which are recognized as cash and cash equivalents in the amount of €1,697.7 million as of March 31, 2022, are valued using quoted prices on the valuation date in active markets (Level 1). The change in the derivative's fair value related to the equity investment of Pfizer (see Note 8) was derived from our share price development between contract signing and closing (Level 1). As described above, as of the redemption date, the fair value of the derivative embedded in our convertible note was finally assessed by applying the Cox-Rubinstein binomial tree model which is based on significant observable inputs (Level 2) and described in further detail in Note 12 to our audited consolidated financial statements included in our Annual Report on Form 20-F as of and for the year ended December 31, 2021. The foreign exchange forward contracts are valued using valuation techniques, which employ the use of foreign exchange spot and forward rates (Level 2). The fair values of non-listed equity investments are measured based on observable inputs e.g. based on multiple analyses (Level 2).

The initial fair value of the contingent consideration determined at acquisition was based on cash flow projections (unobservable Level 3 input factors) and remains valid since no changes of the underlying performance criteria have occurred.

7 Inventories

Set out below is an overview of inventories held as of March 31, 2022 and December 31, 2021.

<i>(in millions)</i>	March 31, 2022	December 31, 2021
Raw materials and supplies	€279.4	€248.3
Unfinished goods	83.1	84.5
Finished goods	96.8	169.7
Total	€459.3	€502.5

During the three months ended March 31, 2022 and 2021, inventory write-offs and reserves related to our COVID-19 vaccine amounting to €156.0 million and nil, respectively, and were recognized in cost of sales as a result of the introduction of a new COVID-19 vaccine formulation.

8 Issued Capital and Reserves

In January 2022, we announced a new research, development and commercialization collaboration with Pfizer to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV). In connection with this collaboration, Pfizer has agreed to make an equity investment and acquired 497,727 ordinary shares paying a total amount of €110.6 million. The issuance of 497,727 ordinary shares with the nominal amount of €0.5 million was registered with the commercial register (*Handelsregister*) on March 24, 2022. The equity investment which was issued in a foreign currency represents a derivative from the date of signing until the date of closing of the transaction. From the fair value measurement of this derivative €43.0 million were recognized in finance income in our unaudited interim condensed consolidated statements of profit or loss during the three months ended March 31, 2022. At closing date, in February 2022, this derivative and the agreed investment amount were recognized in our capital reserve and, taking an increase in share capital of €0.5 million into account, led to a net increase of the capital reserve of €67.1 million in our unaudited interim condensed consolidated statements of financial position.

In March 2022, we redeemed our convertible note by exercising our early redemption option. The convertible note host contract as well as the embedded derivative which previously were recognized as separate financial liabilities were reclassified into our capital reserve with an amount of €234.9 million. The increase in share capital will be reflected upon issuance (see Note 6).

In March 2022, our Management Board and Supervisory Board authorized a share repurchase program of American Depositary Shares, or ADSs, pursuant to which we may repurchase ADSs in the amount of up to \$1.5 billion over the next two years. During the three months ended March 31, 2022, no repurchases were made. We expect to use all or a portion of the ADSs we repurchase and hold in treasury to satisfy upcoming settlement obligations under our share-based payment arrangements.

9 Share-Based Payments

Expenses Arising from Share-Based Payment Arrangements

During the three months ended March 31, 2022 and 2021, the following share-based payment arrangements led to the expenses recognized for services received during the respective periods as shown in the following table:

(in millions)	Three months ended March 31,	
	2022	2021
Expense arising from equity-settled share-based payment arrangements	€12.2	€15.2
<i>Employee Stock Ownership Plan</i>	4.7	4.5
<i>Chief Executive Officer Grant</i>	0.9	1.7
<i>Management Board Grant</i>	1.0	0.5
<i>BioNTech 2020 Employee Equity Plan for Employees Based Outside North America</i>	5.6	8.5
(Income) / expense arising from cash-settled share-based payment arrangements	(2.0)	2.1
<i>Employee Stock Ownership Plan</i>	(0.2)	—
<i>Management Board Grant</i>	(0.8)	0.1
<i>BioNTech Restricted Stock Unit Plan for North America Employees</i>	(1.0)	2.0
Total	€10.2	€17.3
Cost of sales	€0.8	€1.7
Research and development expenses	7.3	12.1
Sales and marketing expenses	0.1	—
General and administrative expenses	2.0	3.5
Total	€10.2	€17.3

Changes in Share-Based Payment Arrangements

New share-based payment arrangements and material changes to arrangements that occurred during the three months ended March 31, 2022 are shown below. A detailed description of our share-based payment arrangements is included in Note 17 to our audited consolidated financial statements included in our Annual Report on Form 20-F as of and for the year ended December 31, 2021.

BioNTech 2020 Employee Equity Plan for Employees Based Outside North America (Equity-Settled)

In December 2020, we approved the BioNTech 2020 Employee Equity Plan for employees based outside North America, or the European Plan. Under the European Plan, Restricted Cash Units, or RSUs, are offered to our employees. Following the initial issuance of RSUs for the calendar year 2020 in what we refer to as the LTI 2020 program, and, for employees who did not participate in the Employee Stock Ownership Plan, or ESOP, the LTI-plus program, as of the grant date in January 2022, the European Plan was implemented again for the calendar year 2021 by entering into award agreements with our employees, which we refer to as the LTI 2021 program. RSUs issued under the LTI 2021 program vest annually in equal installments after four years commencing in December 2021. As we have the ability to determine the method of settlement, the program was classified as equity-settled. The cost of the awards will be recognized over the service period, applying the graded vesting method.

Set out below is an overview of the RSUs granted and subsequent changes to RSUs outstanding during the three months ended March 31, 2022.

	Restricted stock units	Weighted average fair value (€)
Outstanding under LTI 2020 and LTI-plus program as of January 1, 2022	614,427	78.61
Granted under LTI 2021 program	109,202	203.22
Forfeited	(4,179)	203.22
As of March 31, 2022	719,450	97.37

The fair value of the awards is based upon the price of our ADSs representing ordinary shares at grant date. A retention assumption is applied when estimating the number of equity instruments for which service conditions are

expected to be satisfied and will be revised in case material differences arise. Ultimately, a true-up to the number satisfied until settlement date will be recorded.

Management Board Grant (partly Equity-Settled, partly Cash-Settled)

With effect as of March 1, 2022, the service agreement with Prof. Özlem Türeci, M.D. was renewed until May 31, 2025. The short-term and long-term incentive compensation provided for by the extended term of the service agreement is in line with the provisions of the original term and those of our other Management Board members as described in further detail in Note 17 to our audited consolidated financial statements included in our Annual Report on Form 20-F as of and for the year ended December 31, 2021 and has been reflected when accounting for the share-based payment arrangements during the three months ended March 31, 2022.

10 Provisions and Contingencies

Provisions

As of March 31, 2022, certain claims were pending or threatened against us, mainly related to purported obligations arising out of use or alleged use of third party intellectual property. Our best estimate of potential outflow of economic resources from such proceedings amounts to €232.8 million as of March 31, 2022 (€177.9 million as of December 31, 2021), which is not expected to be settled within the next twelve months and is therefore included in non-current provisions in our consolidated statements of financial position and was recognized in cost of sales in our unaudited interim condensed consolidated statements of profit or loss. This assessment is based on assumptions deemed reasonable by management including those about future events and uncertainties. The outcome of these matters is ultimately uncertain, such that unanticipated events and circumstances might occur that might cause us to change those assumptions and give rise to a material adverse effect on our financial position in the future.

As of March 31, 2022, our current provisions include €212.5 million (nil as of December 31, 2021) obligations for production capacities derived from contracts with Contract Manufacturing Organizations, or CMOs, that became redundant as a direct result of the introduction of a new COVID-19 vaccine formulation and due to increased internal manufacturing capacities during the three months ended March 31, 2022. The related expenses were recognized in cost of sales in our unaudited interim condensed consolidated statements of profit or loss.

As of March 31, 2022, our current provisions include €69.2 million (€58.5 million as of December 31, 2021) of international trade obligations, including customs value calculation, customs tariff number classification and other related securities requirements. The majority of related expenses related to our commercial sales and were recognized as cost of sales in our unaudited interim condensed financial statements as of and for the three months ended March 31, 2022.

As of March 31, 2022, our current provisions include €45.4 million (€35.4 million as of December 31, 2021) of estimated deferred expenses in the form of inventor remuneration, which represents compensation used to honor service inventions made by employees related to our COVID-19 vaccine development, and was recognized as research and development expenses in our unaudited interim condensed consolidated statements of profit or loss for the three months ending March 31, 2022. The inventor's compensation is determined on the basis of the so-called license analogy and is therefore related to our revenues.

Contingencies

In addition to the above, from time to time, in the normal course and conduct of our business, we may be involved in discussions with third parties about considering, for example, the use and/or remuneration for use of such third party's intellectual property. As of March 31, 2022, 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 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. We do not believe it is currently practical to estimate the potential liability, if any.

11 Related Party Disclosures

ATHOS KG, Holzkirchen, Germany is the sole shareholder of AT Impf GmbH, Munich, Germany and beneficial owner of our ordinary shares. Entities controlled by ATHOS KG mainly provide rental and property management activities and sell property, plant and equipment to us. 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, 2022 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, 2021.

12 Events after the Reporting Period

- With effect as of April 1, 2022, the service agreement with Sean Marett (Chief Business Officer (CBO) and Chief Commercial Officer (CCO)) was renewed until December 31, 2024.
- In April 2022, the issuance of ordinary shares to fulfill the early redemption of our convertible note became effective.
- On May 2, 2022, the first tranche of our share repurchase program of ADSs, with a value of up to \$1.0 billion commenced. For further detail see Note 8.

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, 2022.

Operating Results

Overview

BioNTech was founded in 2008 with the goal to develop treatments for patients that address diseases with high unmet medical need. As a next generation immunotherapy company, it is our vision to harness the power of the immune system to develop novel therapies against cancer and infectious diseases. To realize this vision, we combine decades of groundbreaking research in immunology, a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals.

We have built a broad toolkit across multiple technology platforms, including a diverse range of potentially first-in-class therapeutic approaches. This includes mRNA vaccines, cell and gene therapies, targeted antibodies, small molecule immunomodulators, Ribologicals, and next generation immunomodulators. Our approach has created a robust and diversified product pipeline across infectious disease and oncology, comprised of our first commercial product, BNT162b2 (COMIRNATY), the first ever approved mRNA therapy, over 17 clinical stage product candidates and more than 30 research programs.

We believe our successful development of a first-in-class COVID-19 mRNA vaccine in less than one year validates our execution capabilities and the power of our technologies to change lives. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient’s immune system to address the unique molecular signature of each patient’s underlying disease.

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

On the research and development front, we are focused on developing next-generation COVID-19 vaccines to maintain leadership and strengthen pandemic preparedness as well as broaden the label of and access to the vaccine.

Additionally, we are accelerating clinical development, bolstering mid- and late-stage oncology presence and broadening our pipeline through the start of new programs in oncology and infectious diseases. In addition, 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. Moreover, we plan to invest to build out our global development organization bringing in talent with clinical and regulatory experts needed to rapidly advance our diversified clinical pipeline.

Mergers and acquisitions activity and business development efforts are focused on strengthening technology platforms and digital capabilities through selected strategic partnerships and acquisitions. We also plan to enhance capabilities through complementary acquisitions, technologies, infrastructure and manufacturing.

Corporate Development

- In February 2022, BioNTech Innovation GmbH, Mainz, Germany, was established and is a wholly owned consolidated subsidiary of BioNTech SE.

A key component of our corporate strategy is strengthening our technology platforms, digital capabilities and infrastructure through selected strategic partnerships and acquisitions. In the first quarter of 2022, we entered into new collaborations and research agreements, as previously reported in our full year 2021 Corporate Update. These included a collaboration with InstaDeep to develop an early warning system for new SARS-CoV-2 variants, a multi-target discovery collaboration with Crescendo Biologics Ltd., and an asset purchase and option agreement with MediGene AG to develop novel T cell receptor-based immunotherapies against cancer.

- In April 2022, we were granted a pandemic preparedness contract by the Federal Republic of Germany. The framework agreement is aimed at pandemic preparedness including manufacturing and supply of mRNA vaccines in emergency situations in Germany. Under the preparedness agreement, which has an initial term of five years, we will reserve and maintain manufacturing capabilities to produce at least 80 million mRNA-based vaccine doses per year.
- In April 2022, we entered into an exclusive research collaboration with Matinas Biopharma to evaluate the combination of mRNA formats and Matinas' proprietary Lipid Nanocrystal, or LNC, platform technology, including a potential formulation for oral vaccines.

Key Pipeline Updates

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

Pipeline overview

Infectious Diseases

Drug Class	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Rights/Collaborator	Milestones 2022	
mRNA	BNT162b2	COVID-19	[Progress bar: Pre-clinical to Phase 1]						Fosun Pharma (China), Pfizer (Global, excl. China)	Multiple updates
	BNT161	Influenza (mod mRNA)	[Progress bar: Pre-clinical to Phase 1]					Pfizer	Data update: 2022	
	Un-named program	Influenza (sa mRNA)	[Progress bar: Pre-clinical]					Pfizer		
	Un-named program	Shingles	[Progress bar: Pre-clinical]					Pfizer	Phase 1 start: 2H 2022	
	Un-named program	Malaria	[Progress bar: Pre-clinical]					Fully-owned	Phase 1 start: 2H 2022	
	BNT164	Tuberculosis ¹	[Progress bar: Pre-clinical]					Bill & Melinda Gates Foundation	Phase 1 start: 2H 2022	
	Un-named program	HSV 2	[Progress bar: Pre-clinical]					Fully-owned	Phase 1 start: 2H 2022	
	Un-named program	HIV ¹	[Progress bar: Pre-clinical]					Bill & Melinda Gates Foundation		
	Undisclosed programs	Additional mRNA vaccine programs ²	[Progress bar: Pre-clinical]					Fully-owned		
	Undisclosed programs	Precision antibacterials	[Progress bar: Pre-clinical]					Fully-owned		

¹ Collaboration with Bill & Melinda Gates Foundation. BioNTech holds worldwide distribution rights except developing countries where BMG holds distribution rights

² University of Pennsylvania collaboration

Oncology

Drug Class	Platform	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Rights/Collaborator	Milestones 2022
mRNA	FixVac (fixed combination of shared cancer antigens)	BNT111	Advanced melanoma	█	█	█		Fully-owned	Phase 1 start: 2H 2022
		BNT112	Prostate cancer	█	█				
		BNT113	HPV16+ head and neck cancer	█	█				
		BNT115	Ovarian cancer ¹	█	█				
		BNT116	NSCLC	█					
	iNeST (patient specific cancer antigen immunotherapy)	autogene cevumeran (BNT122)	1L melanoma Adjuvant colorectal cancer Solid tumors	█	█	█		Genentech (global 50:50 profit/loss share)	Data update: 2H 2022
		SAR441000 (BNT131)	Solid tumors (IL-12sc, IL-15sushi, GM-CSF, IFNα)	█	█		Sanofi (global profit/loss share)		
	RiboMabs (mRNA-encoded antibodies)	BNT141	Multiple solid tumors (CLDN18.2)	█	█			Fully-owned	Phase 1 start: 1H 2022
		BNT142	Multiple solid tumors (CD3+CLDN6)	█					
	RiboCytokines (mRNA-encoded cytokines)	BNT151	Multiple solid tumors (Optimized IL-2)	█	█			Fully-owned	
BNT152, BNT153		Multiple solid tumors (IL-7, IL-2)	█	█					
Cell Therapies	CAR-T Cells + CarVac	BNT211	Multiple solid tumors (CLDN6)	█	█			Fully-owned	Data update: 2H 2022
		BNT212	Pancreatic, other cancers (CLDN18.2)	█					
	Neoantigen-based T cells	BNT221 (NEO-PTC-01)	Multiple solid tumors	█	█			Fully-owned	
	TCR engineered T cells	To be selected	All tumors	█				Fully-owned	
Antibodies	Next-Gen CP Immunomodulators	GEN1046 (BNT311)	Metastatic NSCLC (PD-L1×4-1BB)	█	█	█		Genmab (global 50:50 profit/loss share)	
		GEN1046 (BNT311)	Multiple solid tumors (PD-L1×4-1BB)	█	█				
		GEN1042 (BNT312)	Multiple solid tumors (CD40×4-1BB)	█	█				
	Targeted Cancer Antibodies	BNT321 (MVT-5873)	Pancreatic cancer (sLea)	█	█			Fully-owned	
SMIM	Toll-Like Receptor Binding	BNT411	Solid tumors (TLR7)	█	█			Fully-owned	

¹ Investigator-initiated Phase 1 trial
FPD, First Patient Dosed; mod, modified; sa, self amplifying; CP, Checkpoint inhibitor; SMIM, Small Molecule Immunomodulators

Infectious Disease

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

COVID-19 Vaccine Program – BNT162

BNT162b2, the first ever approved mRNA-based product, has paved the way for a new class of medicines. We and Pfizer continue to execute on plans for global COVID-19 vaccine leadership with multiple new product launches, including label expansions, pediatric dosages, and development of follow-on and next generation vaccine candidates.

Commercial updates

In the first quarter of 2022, we and Pfizer have invoiced approximately 750 million COVID-19 vaccine doses. As of end-April 2022, we and Pfizer have signed orders for approximately 2.4 billion doses in 2022. As part of our pledge to equitable access to medicines, we and Pfizer are on track to deliver a total of more than two billion doses of COVID-19 vaccine to low- and middle-income countries by the end of 2022.

Manufacturing updates

Our and Pfizer’s global COVID-19 vaccine supply chain and manufacturing network includes 20 manufacturing facilities spanning four continents. In February 2022, we announced our turnkey manufacturing solution, named “BioNTainer,” which is designed to enable scalable mRNA vaccine production in bulk. The novel approach utilizes a modular manufacturing unit made up of state-of-the-art manufacturing containers. BioNTainers are designed and equipped to manufacture a range of mRNA-

based vaccines, for example COVID-19 vaccine doses. With their scalable and modular approach, BioNTainers are intended to enable the production of high-quality mRNA vaccines worldwide. The establishment of the first modular mRNA manufacturing facility in the African Union is expected to start in the second half of 2022.

Clinical development and regulatory updates

Our and Pfizer's COVID-19 vaccine has received multiple regulatory approvals including expansions of authorizations for booster and pediatric vaccinations, and updated storage conditions.

Label expansions achieved in the first quarter of 2022 include approvals in multiple geographies of a booster dose in individuals 12 years and older, which were supported by real-world vaccine efficacy data.

The U.S. Food and Drug Administration, or FDA, also expanded the Emergency Use Authorization, or EUA, in the first quarter of 2022 to include a second booster (fourth dose) for both individuals aged 50 years and older and individuals aged 12 years and older with certain immunocompromised conditions, who have previously received a booster of any authorized or approved COVID-19 vaccine.

We and Pfizer are continuing a robust booster development program to address waning efficacy and partial escape variants and to provide continued protection by the vaccine.

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

Real-world data from Israel suggest a fourth dose of BNT162b2 increases immunogenicity and lowers rates of confirmed infections and severe illness in the elderly population. A real-world study conducted by the Israeli Ministry of Health showed that in individuals over 60 years of age, confirmed infection and severe disease after a fourth dose was lower compared to individuals who did not receive a fourth dose (Bar-On YM, et al MedRxiv. Protection by 4th dose of BNT162b2 against Omicron in Israel; February 1, 2022).

We and Pfizer are evaluating follow-on COVID-19 vaccines, including an Omicron-adapted candidate and bivalent vaccines directed against the Omicron and other strains of SARS-CoV-2, as well as novel next-generation vaccine concepts. The studies are part of the ongoing effort to develop next generation COVID-19 vaccines designed to provide a broad protection against emerging variants of concern.

In a recent preprint publication (bioRxiv.Omicron breakthrough infection drives cross-variant neutralization and memory B cell formation; April 1, 2022) we showed that Omicron breakthrough infection in BNT162b2 vaccinated individuals results in strong neutralizing activity against both Omicron and previous SARS-CoV-2 variants of concern. *In vitro* analyses of blood sera samples from individuals double- and triple-vaccinated with BNT162b2 demonstrated that Omicron breakthrough infection mediated a broad B cell recall response primarily through expanded preformed memory B cells that recognize antigens shared broadly by different variants, rather than inducing new B cells against strictly Omicron-specific antigens. These observations suggest that a vaccine adapted to the Omicron strain spike could similarly reshape the B-cell memory repertoire and may be more beneficial than an extended series of boosters with the existing vaccines directed against the ancestral strain.

- In January 2022, we and Pfizer announced the initiation of clinical trials to evaluate the safety, tolerability, and immunogenicity of an Omicron-adapted vaccine in healthy adults 18 to less than 56 years of age and adults greater than 55 years of age. The study is evaluating approximately 2,150 participants across multiple cohorts examining different regimens of the current COVID-19 vaccine or an Omicron-adapted vaccine in both vaccine experienced and naive subjects. The study also includes cohorts evaluating a bivalent Omicron-adapted vaccine. A data update is now expected in the coming weeks and will be shared with regulatory agencies.
- In February 2022, following a request from the U.S. FDA, we and Pfizer initiated a rolling submission seeking to amend the EUA to include children six months to less than five years of age in response to the urgent public health need in this population. The Phase 1/2/3 trial for this patient population was designed to evaluate safety, tolerability, and immunogenicity. Following study amendments, we and Pfizer are evaluating a three-dose regimen of 3 µg per dose in children six months to less than five years of age. The data are now expected in the coming weeks.

- In April 2022, multiple regulatory agencies, including the EMA and U.S. FDA, authorized the extension of the shelf-life of the vaccine from nine months to twelve months when stored at -90°C to -60°C.
- In April 2022, we and Pfizer announced data from a Phase 2/3 clinical trial demonstrating high immune response following a booster (third) dose of BNT162b2 in 140 healthy children five through 11 years of age. Data demonstrated that a booster dose given approximately six months after the second dose of the 10-µg primary series increased neutralizing antibodies by six-fold against the SARS-CoV-2 wild-type strain compared to levels seen after two doses. Also, data from a subanalysis of 30 sera showed a 36-fold increase in SARS-CoV-2 Omicron neutralizing titers following a booster dose. The vaccine was well tolerated with no new safety signals observed. We and Pfizer submitted these data to the U.S. FDA at the end of April 2022. Additional submissions to other regulatory agencies worldwide are ongoing.
- In May, the European Commission approved the reduction of the interval between the primary course and booster vaccination from six months to three months in individuals 12 years of age and older.

Additional Infectious Disease programs

Prevention and treatment of infectious diseases is a long-term growth pillar for us, and our objective is to be a leader in mRNA vaccines for infectious diseases. With investments in multiple programs to address diseases with major impact on global population health and on people in lower income countries, we are advancing our pipeline of mRNA vaccines and therapeutics to address multiple high-need indications. We are on track to initiate four first-in-human clinical trials in the second half of 2022.

Influenza Vaccine Program

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

- BNT161 – A Phase 1 clinical trial of BNT161, an mRNA vaccine, to evaluate the safety, tolerability and immunogenicity of a single dose quadrivalent mRNA influenza vaccine is ongoing. A data update is expected in 2022.
- We and Pfizer also plan to start a clinical study to develop a self-amplifying mRNA, or saRNA, influenza vaccine. This planned dose-finding study will evaluate safety, tolerability, and immunogenicity in healthy adults 18 to less than 50 years of age.

Shingles Vaccine Program

We are collaborating with Pfizer to develop the first mRNA-based shingles vaccine candidate. The goal is to develop an mRNA vaccine candidate with a favorable safety profile and high efficacy, utilizing a scalable manufacturing technology to support global access.

- Clinical trials are expected to start in the second half of 2022.

Malaria Vaccine Program

We are developing an mRNA vaccine candidate to potentially prevent malaria and disease-associated mortality. We will assess several vaccine candidates, featuring known targets such as circumsporozoite protein (CSP) as well as other antigens.

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

Tuberculosis Vaccine Program

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

- A clinical trial for one such candidate, BNT164, is planned to start in the second half of 2022.

Research collaboration with University of Pennsylvania

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

HSV 2 Vaccine Program

As part of this collaboration with the University of Pennsylvania, we are developing an Herpes Simplex Virus Type 2 (HSV 2) vaccine candidate.

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

Oncology

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

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

Our clinical pipeline includes a total of 16 product candidates in 20 ongoing clinical trials. The clinical stage oncology pipeline now includes five randomized Phase 2 clinical trials: two FixVac programs (BNT111 and BNT113), two indications for our iNeST product candidate, autogene cevumeran (BNT122/RO7198457), and the bispecific antibody checkpoint immunomodulator BNT311 (GEN1046). A first-in-human trial of our novel CAR-T cell therapy candidate, BNT211, is continuing to show encouraging clinical data, an important proof-point of our scientific innovation engine.

We expect continued pipeline advancement and expansion, as well as further data readouts from the ongoing trials in 2022.

FixVac

Our off-the-shelf cancer immunotherapy approach, FixVac, leverages our proprietary uridine mRNA (uRNA) backbone that encodes cancer-specific shared antigens for intravenous administration using the proprietary RNA-lipoplex, or RNA-LPX, formulation and is optimized for induction of strong antigen-specific immune responses.

FixVac product candidates are designed to trigger both innate and adaptive immune responses and may be of clinical utility in combination with anti-PD1 in patients with a lower mutational burden tumors, including those who have already experienced checkpoint inhibitor, or CPI, therapy.

- **BNT111** in advanced melanoma.
 - A global, three-arm Phase 2 trial evaluating BNT111 in combination with cemiplimab (Regeneron and Sanofi's Libtayo[®]), versus both agents as monotherapy, in patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV melanoma, is ongoing. The primary endpoint is overall response rate of BNT111 in combination with cemiplimab. Secondary endpoints include overall response rate in the single agent arms, duration of response, and safety. The trial is being conducted in collaboration with Regeneron.
 - BNT111 is also in an ongoing Phase 1 trial for the treatment of advanced melanoma.
- **BNT112** is in an ongoing Phase 1/2 trial for the treatment of prostate cancer.
- **BNT113** in HPV16+ head and neck cancer.
 - A randomized Phase 2 trial evaluating BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma, or HNSCC, expressing PD-L1 is ongoing. Primary endpoints include safety, overall survival and objective response rate. Secondary endpoints include progression free survival, durable complete responses, duration of response, patient reported outcomes and quality of life measures.
 - An investigator sponsored Phase 1/2 dose escalation trial of BNT113 in patients with HPV16+ head and neck and other cancers is ongoing.

- **BNT115** is in an ongoing investigator-initiated Phase 1 trial for the treatment of ovarian cancer.
- **BNT116** in advanced non-small-cell lung cancer, or NSCLC.
 - The first-in-human clinical trial to evaluate the safety, tolerability and preliminary efficacy of BNT116 is expected to be initiated in the second half of 2022.
 - In March 2022, we announced the expansion of our strategic collaboration with Regeneron. Under the agreement, the combination of BNT116 and cemiplimab (Regeneron and Sanofi's Libtayo®) is expected to be advanced into clinical development for the treatment of advanced NSCLC.

Individualized Neoantigen Specific Immunotherapies (iNeST)

Our individualized cancer immunotherapy approach (iNeST) is also based on our pharmacologically optimized uRNA delivered in our proprietary RNA-LPX formulation.

Individual mRNA cancer vaccines encode the patient's own tumor mutations, against which they generate neoantigen specific CD4 and CD8 T cell responses in vivo. We believe this modality is well-suited for use in early-stage cancers and the adjuvant setting.

Autogene cevumeran (BNT122) – Our lead iNeST product candidate, autogene cevumeran, is being developed as part of a co-development and co-commercialization collaboration with Genentech.

- An open-label Phase 2 trial evaluating the efficacy and safety of autogene cevumeran in combination with pembrolizumab versus pembrolizumab alone in patients with previously untreated advanced melanoma is ongoing. The primary endpoint is progression-free survival, or PFS, of patients treated with autogene cevumeran compared with patients receiving pembrolizumab alone, according to RECIST v1.1. Secondary endpoints include objective response rate, or ORR, overall survival, or OS, duration of response, or DOR, and safety.

A data update is expected in the second half of 2022.

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

- An open-label Phase 1a/1b trial evaluating the safety, tolerability, immune response and pharmacokinetics of autogene cevumeran (BNT122) as a single agent and in combination with atezolizumab in patients with locally advanced or metastatic solid tumors (basket trial) is ongoing.

mRNA Intratumoral Immunotherapy

We, in collaboration with Sanofi, are developing intratumoral immunotherapies utilizing our proprietary mRNA technology. The product candidate SAR441000 (BNT131) consists of modified mRNA encoding immunomodulatory cytokines for direct intratumoral injection.

SAR441000 (BNT131) – A Sanofi-sponsored Phase 1 clinical trial as monotherapy and in combination with an anti-PD-1 checkpoint inhibitor in patients with advanced solid tumors is ongoing.

RiboCytokines

BNT151 and BNT152+153 are nucleoside-modified mRNAs encoding human cytokines fused to human serum albumin. The modified mRNA is formulated with liver-targeting lipid nanoparticles, or LNP, for intravenous delivery BNT151 encodes an IL-2 variant, BNT152 encodes IL-7 and BNT153 encodes IL-2.

Our RiboCytokine product candidates are designed to address the limitations of recombinantly expressed cytokines, including limited serum half-life and production costs.

- **BNT151** – A first-in-human, open-label, multicenter Phase 1/2 trial in multiple solid tumor indications is ongoing. Part 1 of the trial is the monotherapy dose escalation and will enroll patients with tumors that are metastatic or unresectable with no available standard therapy likely to confer clinical benefit. In the combined treatment dose escalation, patients with different solid tumors will be enrolled and treated with BNT151 and other potential combination agents.
- **BNT152+153** – A first-in-human Phase 1/2 trial evaluating a combination of BNT152 (encoding IL-7) and BNT153 (encoding IL-2) in patients with various solid tumors is ongoing. In parallel, BNT152 and BNT153 monotherapy dose escalation in Part 1 will determine the Part 2 starting dose of each compound in combination. Part 2 will be the combination dose finding of BNT152 and BNT153.

RiboMabs

Our RiboMab product candidates, BNT141 and BNT142, are designed to encode cancer cell targeting antibodies. These product candidates leverage our proprietary optimized mRNA technology combining nucleoside modifications to minimize immunogenicity with our modifications in the mRNA backbone to maximize protein expression.

RiboMabs may address the limitations of recombinant antibodies, including costly manufacturing processes and unfavorable pharmacokinetics, such as short plasma half-life.

BNT141 encodes an antibody targeting Claudin-18.2, expressed in high unmet medical need tumors, including multiple epithelial solid tumors, such as gastric and pancreatic cancers. BNT142 encodes a bispecific T cell engaging antibody that targets CD3, a T cell receptor component, and Claudin-6 (CLDN6), an oncofetal cell surface antigen found in solid tumors.

- **BNT141** – In January 2022, the first participant was dosed in an open-label, multi-site, Phase 1/2 dose escalation, safety, and pharmacokinetic trial of BNT141 followed by expansion cohorts in patients with Claudin 18.2, or CLDN18.2, -positive tumors. The trial evaluates dose escalation as monotherapy in patients with unresectable or metastatic cancers, followed by dose escalation in combination with standard of care in patients with advanced unresectable or metastatic CLDN18.2-positive pancreatic adenocarcinoma or cholangiocarcinoma who are eligible for treatment with standard of care. After dose escalation, expansion cohorts will be evaluated
- **BNT142** - We plan to start a Phase 1 clinical trial for BNT142 in the first half of 2022.

CAR-T Cell Immunotherapy

BNT211, our first chimeric antigen receptor, or CAR-T cell product candidate, targets CLDN6-positive solid tumors in combination with a CAR-T cell-amplifying RNA vaccine, or CARVac, encoding CLDN6. CARVac is also based on our pharmacologically optimized uRNA backbone delivered in our proprietary RNA-LPX formulation. CLDN6 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 designed to drive *in vivo* expansion of transferred CAR-T cells, increasing their persistence and efficacy. BNT211 is designed to overcome CAR-T cell therapy limitations in patients with solid tumors.

- A first-in-human Phase 1/2 open-label dose escalation and dose expansion trial evaluating BNT211 in patients with CLDN6 positive solid tumors is ongoing. The trial evaluates CLDN6 CAR-T cells dosed as monotherapy and in combination with CLDN6 CARVac.

Data from the ongoing trial were presented at the American Association for Cancer Research (AACR) Conference 2022. The presentation included data from 16 patients who received CLDN6 CAR-T cells at two dose levels alone or combined with CARVac. Tumor indications included testicular cancer (8 patients), ovarian cancer (4 patients), endometrial cancer, fallopian tube cancer, sarcoma, and gastric cancer (1 patient each).

The preliminary efficacy data showed encouraging signs of clinical activity with a disease control rate of 86% and an overall response rate of 43%. All 16 patients showed robust CAR-T cell engraftment with peak expansion 10 to 17 days after infusion reaching cell frequencies of 10^9 total cell counts or above at the higher dose level. At the first efficacy assessment 6 weeks post infusion, six of 14 evaluable patients showed a partial response, or PR, and five patients had stable disease, or SD, with shrinkage of target lesions. Responses were seen in four testicular and two ovarian cancer patients. At 12 weeks, four of the six patients with a PR showed deepening and durability of responses with one patient reaching a complete response 18 weeks after infusion. All four testicular cancer patients in the higher dose level had disease control and three of these patients showed objective responses. In addition, one testicular cancer patient showed partial response after infusion of

the lowest CAR-T dose level in combination with CARVac. Antitumor activity tended to be higher at the higher CAR-T dose and when combined with the vaccine, with four of five patients in the CARVac combination group showing a partial response.

The results also demonstrated an encouraging safety profile as adverse events and dose limiting toxicities were manageable.

Another data update from the ongoing Phase 1/2 trial is expected in the second half of 2022.

Neoantigen-Targeting T Cell Therapy

BNT221 (NEO-PTC-01) is our individualized neoantigen-targeting T cell therapy for the treatment of cancer. BNT221 targets selected sets of individualized neoantigens.

- A first-in-human Phase 1 dose escalation trial evaluating BNT221 in patients with checkpoint inhibitor unresponsive or refractory metastatic melanoma is ongoing. Part 1 of the trial consists of a monotherapy dose escalation of BNT221. In Part 2, BNT221 will be dosed in combination with anti-PD1 therapy after first-line treatment.

Next-Generation Checkpoint Immunomodulators

We are developing, in collaboration with Genmab, bispecific antibodies that function as tumor-targeted and dual immunomodulators, applying Genmab's proprietary DuoBody technology in combination with our joint target identification and product concept expertise.

These next-generation checkpoint immunomodulators are designed to prime and activate anti-tumor T-cell and Natural Killer cell function.

BNT311 and BNT312 are partnered with Genmab as part of a 50/50 collaboration in which development costs and future profit are shared.

BNT311 (GEN1046) is a potential first-in-class bispecific antibody combining PD-L1 checkpoint inhibition with 4-1BB checkpoint activation. **BNT312 (GEN1042)** is a potential first-in-class bispecific antibody designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells.

- BNT311 (GEN1046) – A Phase 2, multicenter, randomized, open-label trial of BNT311 as monotherapy and in combination with pembrolizumab in subjects with relapsed/refractory metastatic NSCLC after treatment with standard of care therapy with an immune checkpoint inhibitor is ongoing. The primary endpoint of the study is ORR according to RECIST v1.1. Secondary endpoints include DOR, time to response, PFS, OS, and safety.

A Phase 1/2 dose escalation trial with multiple expansion cohorts in patients with solid tumors is ongoing.

- BNT312 (GEN1042) - A Phase 1/2 trial with expansion cohorts in patients with solid tumors is ongoing. Currently 10 expansion cohorts are ongoing, including patients with NSCLC, triple negative breast cancer (TNBC), urothelial cancer, squamous cell carcinoma of the head and neck (SCCHN), and cervical cancer.

Targeted Cancer Antibodies

BNT321 (MVT-5873) is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLea), an epitope on CA19-9 that is expressed in pancreatic and other solid tumors that plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

- BNT321 is currently in Phase 1 clinical development in pancreatic cancer.

Small Molecule Immunomodulators

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

- A Phase 1/2 dose-escalation trial of BNT411 as a monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer, or ES-SCLC, is ongoing.

Rare Disease Protein Replacement Therapies

We are collaborating with Genevant in order to combine our mRNA technology with Genevant's LNP delivery technology, to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. Currently, we have placed the programs on hold in order to focus on other disease areas.

Financial Operations Overview

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

<i>(in millions, except per share data)</i>	Three months ended March 31,	
	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>
Revenues		
Research & development revenues	€12.4	€20.9
Commercial revenues	6,362.2	2,027.5
Total revenues	€6,374.6	€2,048.4
Cost of sales	(1,294.1)	(233.1)
Research and development expenses	(285.8)	(216.2)
Sales and marketing expenses	(14.3)	(8.7)
General and administrative expenses	(90.8)	(38.9)
Other operating expenses	(71.6)	(0.6)
Other operating income	134.7	111.3
Operating income	€4,752.7	€1,662.2
Finance income	272.1	24.8
Finance expenses	(6.7)	(44.7)
Profit before tax	€5,018.1	€1,642.3
Income taxes	(1,319.3)	(514.2)
Profit for the period	€3,698.8	€1,128.1
Earnings per share		
Basic profit for the period per share	€15.13	€4.64
Diluted profit for the period per share	€14.24	€4.39

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, 2021.

Operational Impacts of COVID-19

The impact of COVID-19 during the three months ended March 31, 2022 is explained in Note 2 to the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report.

COVID-19 Collaborations

In response to the COVID-19 pandemic, we initiated our COVID-19 vaccine development program, BNT162, in late January 2020, leveraging our proprietary mRNA platform, and assembled a global consortium of partners including Pfizer (marketing and distribution rights worldwide with the exception of China, Germany and Turkey) and Fosun Pharma (marketing and distribution rights in China, Hong Kong special administrative region, or SAR, Macau SAR and the region of Taiwan).

Details about our COVID-19 collaborations are described further in our Key Pipeline Updates above, Items 4 and 5 of our Annual Report on Form 20-F as of and for the year ended December 31, 2021, as well as the notes to our audited consolidated financial statements included in that Annual Report.

Comparison of the three months ended March 31, 2022 and 2021

Revenues

The following is a summary of revenues recognized for the periods indicated:

<i>(in millions)</i>	Three months ended March 31,		Change	
	2022	2021	€	%
Revenues				
Research & development revenues from collaborations	€12.4	€20.9	€(8.5)	(41)
Commercial revenues	€6,362.2	€2,027.5	€4,334.7	214
COVID-19 vaccine revenues	6,353.2	2,015.6	4,337.6	215
<i>Sales to collaboration partners⁽¹⁾</i>	<i>603.2</i>	<i>63.9</i>	<i>539.3</i>	<i>844</i>
<i>Direct product sales to customers</i>	<i>1,163.1</i>	<i>199.8</i>	<i>963.3</i>	<i>482</i>
<i>Share of collaboration partners' gross profit and sales milestones</i>	<i>4,586.9</i>	<i>1,751.9</i>	<i>2,835.0</i>	<i>162</i>
Other sales	9.0	11.9	(2.9)	(24)
Total revenues	€6,374.6	€2,048.4	€4,326.2	211

⁽¹⁾ Represents sales to our collaboration partners of products manufactured by us.

From the three months ended March 31, 2021 compared to the three months ended March 31, 2022, our total revenues from contracts with customers increased by €4,326.2 million from €2,048.4 million to €6,374.6 million mainly due to increasing our commercial revenues from the supply and sales of our COVID-19 vaccine worldwide.

We are the marketing authorization holder in the United States, the European Union, the United Kingdom, Canada and other countries, and holder of emergency use authorizations or equivalents in the United States (jointly with Pfizer) and other countries; submissions to pursue regulatory approvals on those countries where emergency use authorizations or equivalent were initially granted are ongoing. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Turkey. Fosun Pharma has marketing and distribution rights in China, Hong Kong special administrative region, or SAR, Macau SAR and the region of Taiwan. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal.

Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and our COVID-19 vaccine is transferred, the vaccine is sold from one partner to the other. During the three months ended March 31, 2022 and 2021, we recognized €603.2 million and €63.9 million of revenues, respectively, from selling drug product batches manufactured by us to our partners.

By supplying our territories during the three months ended March 31, 2022 and 2021, we recognized €1,163.1 million and €199.8 million of revenues, respectively, from direct COVID-19 vaccine sales in Germany and Turkey. The share of gross profit that we owe our collaboration partner Pfizer based on our sales is recognized as cost of sales.

Based on COVID-19 vaccine sales in the collaboration partners' territories, we are eligible to receive a share of their gross profit which represents a net figure and is recognized as collaboration revenues during the commercial phase together with sales milestones that are recorded once the underlying thresholds are met. During the three months ended March 31, 2022, €4,586.9 million gross profit share was recognized as revenues. During the three months ended March 31, 2021, €1,751.9 million gross profit share and €247.2 million of sales milestones were recognized as revenues. In order to determine our share of our collaboration partners' gross profits, we used certain information from the collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available. The true-up recognized prospectively during the three months ended March 31, 2022 and 2021, with respect to the previous period, was not material.

Cost of Sales

The following table summarizes our cost of sales for the periods indicated:

<i>(in millions)</i>	Three months ended March 31,		Change	
	2022	2021	€	%
Cost of sales				
Cost of sales related to COVID-19 vaccine revenues	€1,288.3	€223.2	€1,065.1	477
Cost related to other sales	5.8	9.9	(4.1)	(41)
Total cost of sales	€1,294.1	€233.1	€1,061.0	455

From the three months ended March 31, 2021 compared to the three months ended March 31, 2022, our cost of sales increased by €1,061.0 million from €233.1 million to €1,294.1 million. The increase in cost of sales resulted mainly from the recognition of costs related to our COVID-19 vaccine revenues which included the share of gross profit owed to our collaboration partner Pfizer. This increase in cost of sales is additionally attributed to expenses arising from inventory write-offs and for production capacities derived from contracts with Contract Manufacturing Organizations, or CMOs, that became redundant as a direct result of the introduction of a new COVID-19 vaccine formulation and due to increased internal manufacturing capacities during the three months ended March 31, 2022.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

<i>(in millions)</i>	Three months ended March 31,		Change	
	2022	2021	€	%
Research and development expenses				
Purchased services	€131.4	€141.9	€(10.5)	(7)
Wages, benefits and social security expense	70.8	47.5	23.3	49
Laboratory supplies	57.6	11.4	46.2	405
Depreciation and amortization	10.8	7.5	3.3	44
Other	15.2	7.9	7.3	92
Total research and development expenses	€285.8	€216.2	€69.6	32

From the three months ended March 31, 2021 compared to the three months ended March 31, 2022, our research and development expenses increased by €69.6 million or 32% from €216.2 million to €285.8 million, mainly due to recognizing costs related to the production of pre-launch Omicron vaccine products as research and development expenses in the period incurred and an increase in wages, benefits and social security expenses resulting from an increase in headcount. The increase was partly offset by lower research and development expenses related to our COVID-19 vaccine program as compared to the prior year period.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated:

<i>(in millions)</i>	Three months ended March 31,		Change	
	2022	2021	€	%
General and administrative expenses				
Purchased services	€30.3	€12.0	€18.3	153
Wages, benefits and social security expense	27.5	14.3	13.2	92
IT and office equipment	11.3	2.6	8.7	335
Insurance premiums	6.0	4.3	1.7	40
Recruiting expenses	3.7	0.9	2.8	311
Other	12.0	4.8	7.2	150
Total general and administrative expenses	€90.8	€38.9	€51.9	133

From the three months ended March 31, 2021 compared to the three months ended March 31, 2022, our general and administrative expenses increased by €51.9 million or 133% from €38.9 million to €90.8 million, mainly due to

increased expenses for purchased management consulting and legal services as well as an increase in wages, benefits and social security expenses resulting from an increase in headcount.

Other Operating Income / Expenses

The following table summarizes our other result, including other operating income and expenses, for the periods indicated:

<i>(in millions)</i>	Three months ended March 31,		Change	
	2022	2021	€	%
Other result				
Other operating income	€134.7	€111.3	€23.4	21
Foreign exchange differences, net	124.0	40.7	83.3	205
Gain on derivative instruments at fair value through profit or loss	2.8	—	2.8	—
Government grants	—	67.9	(67.9)	(100)
Other	7.9	2.7	5.2	193
Other operating expenses	€(71.6)	€(0.6)	€(71.0)	n.m.
Loss on derivative instruments at fair value through profit or loss	(69.3)	—	(69.3)	—
Other	(2.3)	(0.6)	(1.7)	283
Total other result	€63.1	€110.7	€(47.6)	(43)

From the three months ended March 31, 2021 compared to the three months ended March 31, 2022, our total other result decreased by €47.6 million from €110.7 million to €63.1 million, mainly due to recording changes in fair values of foreign exchange forward contracts that we entered into to manage some of our transaction exposures but were not designated as hedging instruments under IFRS. In addition, other income related to government grants recognized in the prior year period did not re-occur during the three months ended March 31, 2022. The decreasing effects were offset by recording higher other income from foreign exchange differences arising on operating items. The increase reflects the change in foreign exchange rate and relates to our U.S. dollar denominated trade receivables which were mainly incurred under our COVID-19 collaboration with Pfizer, U.S. dollar denominated trade payables as well as U.S. dollar denominated other financial liabilities which mainly relate to obligations incurred from our license agreements.

Finance Income / Expenses

The following table summarizes our finance result for the periods indicated:

<i>(in millions)</i>	Three months ended March 31,		Change	
	2022	2021	€	%
Finance result				
Finance income	€272.1	€24.8	€247.3	
Fair value adjustments of financial instruments measured at fair value	216.8	—	216.8	—
Foreign exchange differences, net	54.8	24.5	30.3	124
Interest income	0.5	0.3	0.2	67
Finance expenses	€(6.7)	€(44.7)	€38.0	(85)
Interest expenses related to financial assets	(3.2)	—	(3.2)	—
Amortization of financial instruments	(2.6)	(2.5)	(0.1)	4
Interest expenses related to lease liabilities	(0.9)	(0.7)	(0.2)	29
Fair value adjustments of financial instruments measured at fair value	—	(41.5)	41.5	(100)
Total finance result	€265.4	€(19.9)	€285.3	n.m.

From the three months ended March 31, 2021 compared to the three months ended March 31, 2022, our total financial result increased by €285.3 million from a negative financial result of €19.9 million to a positive financial result

of €265.4 million, mainly due to increased income arising from the final fair value measurement adjustments of the derivative embedded within the convertible note upon early redeeming the convertible note as of March 1, 2022, the redemption date (see Note 6 of our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report).

Income Taxes

For the three months ended March 31, 2022 and 2021, 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 plus the tax effect of any discrete items. For the three months ended March 31, 2022 and 2021, our effective income tax rate was approximately 26.3% and 31.3%, respectively, in part due to average trade tax rates in Mainz, Marburg and Idar-Oberstein decreasing from 2022 onward. During the three months ended March 31, 2022, current income taxes were recognized with respect to the German tax group. Deferred tax effects were recognized with respect to identified discrete items. In addition, the non-tax effective fair value measurement of the convertible note was considered as permanent difference. As of March 31, 2022, we continue to maintain a valuation allowance against deferred tax assets of our U.S. tax group as there is not sufficient probability in terms of IAS 12 that there will be future taxable profits available against which the unused tax losses and temporary differences can be utilized.

Related Party Transactions

Related party transactions that occurred during the three months ended March 31, 2022 and 2021 are explained in Note 11 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, 2022 have been prepared in accordance with IFRS, as issued by the IASB.

The preparation of the unaudited interim condensed consolidated financial statements in accordance with IFRS requires the use of estimates and assumptions by the management that affect the value of assets and liabilities as reported on the balance sheet date, and revenues and expenses arising during the respective reporting period. As described in Item 5 of our Annual Report on Form 20-F as of and for the year ended December 31, 2021 as well as the Note 3 to our audited consolidated financial statements included in that Annual Report, the area where our management needed to apply judgment the most relates to the recognition of revenues. This includes but is not limited to determining commercial revenues under our collaboration agreement, which is recognized based on the collaboration partners' gross profit from COVID-19 vaccine sales where we used certain information from the collaboration partner, including revenues from the sale of products, some of which is based on preliminary data shared between the partners. These estimated figures may change in future periods as we receive final data from our collaboration partner. Those changes in our share of the collaboration partner's gross profit are recognized prospectively as change in estimates.

Further areas in which assumptions, estimates and the exercising of a degree of discretion are appropriate relate to establishing the fair value of intangibles and derivatives, the formation of provisions, as well as income taxes. We base our assumptions and estimates on parameters available when the unaudited interim condensed consolidated financial statements are prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond our control. Hence, our estimates may vary from the actual values.

Our critical accounting policies and the use of estimates are discussed further in Item 5 of our Annual Report on Form 20-F as of and for the year ended December 31, 2021 as well as Note 2.3 and Note 3 to our audited consolidated financial statements included in that Annual Report and include those related to revenue recognition, research and development expenses, share-based compensation, fair value measurement of share-based awards as well as taxes. Actual results in the areas related to critical accounting estimates could differ from management's estimates.

Legal Proceedings

As of March 31, 2022, certain claims were pending or threatened against us, mainly related to purported obligations arising out of use or alleged use of third party intellectual property. Our best estimate of potential outflow of economic resources from such proceedings amounts to €232.8 million as of March 31, 2022 (€177.9 million as of December 31, 2021), which is not expected to be settled within the next twelve months and is therefore included in non-current provisions in our consolidated statements of financial position and was recognized in cost of sales in our unaudited interim condensed consolidated statements of profit or loss. This assessment is based on assumptions deemed

reasonable by management including those about future events and uncertainties. The outcome of these matters is ultimately uncertain, such that unanticipated events and circumstances might occur that might cause us to change those assumptions and give rise to a material adverse effect on our financial position in the future.

In addition to the above, from time to time, in the normal course and conduct of our business, we may be involved in discussions with third parties about considering, for example, the use and/or remuneration for use of such third party's intellectual property. As of March 31, 2022, 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 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. We do not believe it is currently practical to estimate the potential liability, if any.

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. On the R&D front, we are focused on developing next generation COVID-19 vaccines to maintain leadership and pandemic preparedness as well as broaden the label of and access to the vaccine. We also plan to invest heavily to build out our global development organization, bringing in talent with clinical and regulatory expertise needed to rapidly advance our diversified clinical pipeline. In addition, 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 of March 31, 2022, we had cash and cash equivalents of €6,164.1 million. When analyzing our liquidity, we anticipate certain significant balance sheet items that are expected to improve our cash and cash equivalents balance subsequent to the end of the reporting period. Our trade receivables remained outstanding as of March 31, 2022 mainly due to the contractual settlement of the gross profit share under our COVID-19 collaboration with Pfizer as described in Note 6 to the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report. As of March 31, 2022, our trade receivables included trade receivables which related to the gross profit share for the fourth quarter of 2021 and the first quarter of 2022. The payment settling our gross profit share for the fourth quarter of 2021 (as defined by the contract) was received from our collaboration partner in April 2022, subsequent to the end of the reporting period. From our trade receivables outstanding as of March 31, 2022, we had collected €5,243.8 million in cash by April 14, 2022.

Cash and cash equivalents are invested in accordance with our investment policy, primarily with a focus on liquidity and capital preservation, and consist primarily of cash in bank accounts and on hand and short-term deposits with an original maturity of three months or less, which are stated at fair value.

During the three months ended March 31, 2022, we repaid large parts of our outstanding loans (see Note 6 to the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report).

On July 27, 2020, we offered 5,500,000 American Depositary Shares, or ADSs, each representing one of our ordinary shares, in a public, underwritten offering on the Nasdaq Global Select Market at a public offering price of \$93.00 per ADS, or the Underwritten Offering. On August 27, 2020, following the Underwritten Offering, we issued 16,124 ADSs each representing one of our ordinary shares, in a rights offering at the same public offering price of \$93.00 per ADS, or the Rights Offering. The Underwritten Offering and the Rights Offering are part of a single, global offering which we refer to as the Global Offering. The gross proceeds of the Global Offering were \$513.0 million (€436.3 million).

A fund associated with Temasek Capital Management Pte. Ltd. and another accredited investor participated in a private investment which we refer to as the June 2020 Private Placement. The private placement includes an investment in a four-year mandatory convertible note and an investment in ordinary shares. The €100.0 million four-year mandatory convertible note has a coupon of 4.5% per annum and a conversion premium of 20% above the reference price. During the three months ended March 31, 2022, we redeemed the convertible note with Temasek early (see Note 6 to the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report).

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC and SVB Leerink LLC (now known as SVB Securities LLC), as sales agents, to establish an at-the-market offering program, pursuant to which we may sell, from time to time, ADSs representing ordinary shares for aggregate gross proceeds of up to \$500.0 million. During the years ended December 31, 2020 and 2021, we sold 735,490 ADS and 995,890 ADS, respectively, each representing one of our ordinary shares and previously held in treasury, under the Sales Agreement. During the years ended December 31, 2020 and 2021, the aggregate gross proceeds were \$92.9 million (€76.5 million) and \$200.0 million (€163.6 million), respectively. As of March 31, 2022, the remaining capacity under the Sales Agreement is \$207.1 million. Under the at-the-market offering program, ADSs are sold at-the-market, via the stock exchange, and therefore no shareholders' subscription rights are affected.

In January 2022, we announced a new research, development and commercialization collaboration with Pfizer to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV). In connection with this collaboration, Pfizer has agreed to make an equity investment and acquired 497,727 ordinary shares paying a total amount of €110.6 million. The issuance of 497,727 ordinary shares with the nominal amount of €0.5 million was registered with the commercial register (*Handelsregister*) on March 24, 2022 (see Note 8 to the unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report).

In March 2022, our Management Board and Supervisory Board authorized a share repurchase program of ADSs, pursuant to which we may repurchase ADSs in the amount of up to \$1.5 billion over the next two years. During the three months ended March 31, 2022, no repurchases were made. On May 2, 2022, the first tranche of our share repurchase program of ADSs, with a value of up to \$1.0 billion commenced. We expect to use all or a portion of the ADSs we repurchase and hold in treasury to satisfy upcoming settlement obligations under our share-based payment arrangements.

We will propose a special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which corresponds to an aggregate of approximately €486.0 million, based on the shares outstanding as of April 30, 2022, pending approval at our Annual General Meeting to be held in June 2022 which we expect to serve as the record date for the dividend.

Cash Flow

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

<i>(in millions)</i>	Three months ended March 31,	
	2022	2021
Net cash flows from (used in):		
Operating activities	€4,050.2	€(311.3)
Investing activities	287.4	(28.3)
Financing activities	80.3	(4.5)
Total cash inflow (outflow)	€4,417.9	€(344.1)

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 our use of cash for operating expenses and working capital to support the business. During the three months ended March 31, 2022, our cash flows from operating activities include the settlement payment of our gross profit share of the third quarter of 2021 from our collaboration partner. As described in Note 6 to the unaudited interim condensed consolidated financial statement included elsewhere in this Quarterly Report, the contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. Therefore, subsequent to the end of the reporting period, in April 2022, we further improved our cash position as we received the settlement payment of our gross profit share for the fourth quarter of 2021 (as defined by the contract).

Net cash generated from operating activities for the three months ended March 31, 2022 was €4,050.2 million, comprising a profit before tax of €5,018.1 million, negative non-cash adjustments of €169.4 million, and a net positive change in assets and liabilities of €497.2 million. Non-cash items primarily included finance income related to our convertible bond fair value update. The net positive change in assets and liabilities was primarily due to an increase in other financial liabilities mainly including obligations incurred from our license agreements.

Net cash used in operating activities for the three months ended March 31, 2021 was €311.3 million, comprising a profit before tax of €1,642.3 million, negative non-cash adjustments of €24.2 million, and a net negative change in

assets and liabilities of €1,927.8 million. The net negative change in assets and liabilities was primarily due to an increase in trade and other receivables related to our COVID-19 collaboration with Pfizer as discussed elsewhere in this Quarterly Report.

Investing Activities

Net cash generated from investing activities for the three months ended March 31, 2022 was €287.4 million, mainly derived from €375.2 million proceeds from cash deposit which returned to cash upon maturity of their original investments' term.

Net cash used in investing activities for the three months ended March 31, 2021 was €28.3 million, of which €21.7 million was attributable to the purchase of property, plant and equipment.

Financing Activities

During the three months ended March 31, 2022, we generated cash from financing activities of €80.3 million, primarily with respect to an equity investment in our shares made by Pfizer alongside our new research, development and commercialization collaboration to develop a potential first mRNA-based vaccine for the prevention of shingles (herpes zoster virus, or HZV).

During the three months ended March 31, 2021, we used cash from financing activities of €4.5 million.

Operation and Funding Requirements

Prior to December 2020, we incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. As of December 31, 2020, our accumulated losses amounted to €409.6 million. Those have been offset by the profit generated during the year ended December 31, 2021 and the three months ended March 31, 2022 and our retained earnings as of March 31, 2022 amounted to €13,581.7 million.

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 expansion of sites in Germany and new sites in the United States, and potentially others globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;
- develop our sales, marketing, and distribution infrastructure for our COVID-19 vaccine and any other products for which we may obtain marketing approval or emergency use authorization;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- acquire other companies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above

We are a party to license and research and development agreements with universities and other third parties, as well as patent assignment agreements, under which we have obtained rights to patents, patent applications and know-

how. We enter into contracts in the normal course of business with CROs for clinical trials, clinical and commercial supply manufacturing, with vendors for preclinical research studies and for other services and products for operating purposes. We work together with CMOs, who manufacture our product candidates and products and enter into lease agreements to lease laboratory, GMP manufacturing, storage and office spaces. Purchase obligations under our agreements to the extent that they are quantifiable and not cancelable have been considered when defining our guidance for future cash commitments. Most of the committed cash outflow within the remaining months in 2022 is related to CMO purchase obligations amounting to €556.6 million and lease payments amounting to €25.5 million. Further, we have CMO purchase obligations with an amount of €271.3 million and lease payment obligations of €186.5 million for the years 2023 and beyond.

We are subject to all of the risks related to the development and commercialization of pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

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

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement, misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs;
- 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. You should carefully consider the risks and uncertainties described under the heading “Risk Factors” in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 30, 2022. If any of those risks in our Annual Report 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.

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 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; our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments; 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 rate and degree of market acceptance of our COVID-19 vaccine and, if approved, our investigational medicines; the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; the timing of and our ability to obtain and maintain regulatory approval for our product candidates; our collaboration with Pfizer to develop and market a COVID-19 vaccine (including a potential booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; 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 the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us; our ability to progress our Malaria, Tuberculosis and HIV programs, including timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature and duration of support from the World Health Organization, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent and the nature and feasibility of these solutions; our estimates of research and development revenues, commercial revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, shares outstanding; our ability and that of our collaborators to commercialize and market our product candidates, if approved, including our COVID-19 vaccine; our ability to manage our development and expansion; regulatory developments in the United States and foreign countries; our ability to effectively scale our production capabilities and manufacture our products, including our target COVID-19 vaccine production levels, and our product candidates; and other factors not known to us at this time. 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 neither promises nor guarantees, and 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 from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading “Risk Factors” in this quarterly report for the three months ended March 31, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC’s website at <https://www.sec.gov/>. 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. These forward-looking statements are based on BioNTech’s current expectations and speak only as of the date hereof.