# 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 NOVEMBER 2021

**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)

ndicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F $oxdot$ Form 40-F $oxdot$
ndicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):
ndicate 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 November 9, 2021, BioNTech SE (the "Company") provided a development update and reported its financial results for the three and nine months ended September 30, 2021. The interim condensed consolidated financial statements as well as the operating and financial review and prospects of the Company, for the three and nine months ended September 30, 2021, 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: November 9, 2021

# EXHIBIT INDEX

<u>Exhibit</u> <u>Description of Exhibit</u>

99.1 Quarterly Report for the Three and Nine Months Ended September 30, 2021.

# BIONTECH



BioNTech SE

Quarterly Report for the Three and Nine Months Ended September 30, 2021

# BioNTech SE

Quarterly Report for the Three and Nine Months Ended September 30, 2021 Index

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# **Interim Condensed Consolidated Financial Statements**

# Interim Condensed Consolidated Statements of Profit or Loss

			Three months ended September 30,		hs ended ber 30,
		2021	2020	2021	2020
(in millions, except per share data)	Note	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenues					
Research & development revenues	3	€47.2	€59.7	€96.1	€113.4
Commercial revenues	3	6,040.1	7.8	13,348.1	23.5
Total revenues		€6,087.3	€67.5	€13,444.2	€136.9
Cost of sales	4	(1,211.4)	(6.8)	(2,328.3)	(18.3)
Research and development expenses	5	(260.4)	(227.7)	(677.7)	(388.0)
Sales and marketing expenses		(10.5)	(4.3)	(32.5)	(7.8)
General and administrative expenses	6	(68.2)	(23.5)	(154.9)	(58.1)
Other operating expenses	7	(26.4)	(0.4)	(27.3)	(1.3)
Other operating income	7	213.1	8.8	360.6	10.0
Operating income / (loss)		€4,723.5	€(186.4)	€10,584.1	€(326.6)
Finance income	8	26.6	0.5	51.4	1.1
Finance expenses	8	(81.9)	(21.1)	(301.0)	(24.5)
Interest expenses related to lease liabilities		(0.8)	(0.5)	(2.0)	(1.4)
Profit / (loss) before tax		€4,667.4	€(207.5)	€10,332.5	€(351.4)
Income taxes	9	(1,456.4)	(2.5)	(3,206.2)	(0.3)
	9		1 1		
Profit / (loss) for the period		€3,211.0	€(210.0)	€7,126.3	€(351.7)
Earnings per share					
Basic profit / (loss) for the period per share		€13.14	€(0.88)	€29.22	€(1.51)
Diluted profit / (loss) for the period per share		€12.35	€(0.88)	€27.46	€(1.51)



# Interim Condensed Consolidated Statements of Comprehensive Income / (Loss)

	Three months ended September 30,		Nine mont Septem	
	2021	2020	2021	2020
(in millions) Note	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Profit / (loss) for the period	€3,211.0	€(210.0)	€7,126.3	€(351.7)
Other comprehensive income / (loss)				
Other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods, net of tax				
Exchange differences on translation of foreign operations	2.9	(3.7)	6.3	(7.2)
Net other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods	€2.9	€(3.7)	€6.3	€(7.2)
Other comprehensive income / (loss) for the period, net of tax	€2.9	€(3.7)	€6.3	€(7.2)
Comprehensive income / (loss) for the period, net of tax	€3,213.9	€(213.7)	€7,132.6	€(358.9)



# Interim Condensed Consolidated Statements of Financial Position

Assets	Note	(unaudited)	
Non-current assets			
Intangible assets		€162.9	€163.5
Property, plant and equipment		294.4	227.0
Right-of-use assets		147.7	99.0
Other assets		0.9	1.0
Deferred tax assets	9	75.3	161.2
Total non-current assets		€681.2	€651.7
Current assets			
Inventories	11	393.4	64.1
Trade and other receivables	10	10,603.9	165.5
Other financial assets	10	1.8	137.2
Other assets		109.3	61.0
Income tax assets		0.9	0.9
Deferred expenses		49.4	28.0
Cash and cash equivalents		2,392.7	1,210.2
Total current assets		€13,551.4	€1,666.9
Total assets		€14,232.6	€2,318.6
		32 9-3-13	
Equity and liabilities			
Equity			
Share capital		246.3	246.3
Capital reserve		1,674.4	1,514.5
Treasury shares		(3.8)	(4.8)
Retained earnings / (accumulated losses)		6,716.7	(409.6)
Other reserves	12	77.9	25.4
Total equity		€8,711.5	€1,371.8
Non-current liabilities			
Interest-bearing loans and borrowings	10	267.7	231.0
Other financial liabilities	10	324.9	31.5
Provisions		5.7	5.5
Contract liabilities		10.5	71.9
Other liabilities		9.7	0.6
Deferred tax liabilities		_	0.3
Total non-current liabilities		€618.5	€340.8
Current liabilities			
Interest-bearing loans and borrowings	10	19.0	9.1
Trade payables	10	258.9	102.3
Other financial liabilities	10	924.5	74.1
Government grants	7	3.1	92.0
Income tax liabilities	9	3,118.4	_
Provisions	14	189.7	0.9
Contract liabilities		284.2	299.6
Other liabilities		104.8	28.0
Total current liabilities		€4,902.6	€606.0
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Total liabilities		€5,521.1	€946.8



# Interim Condensed Consolidated Statements of Changes in Stockholders' Equity

(in millions)	Note	Share capital	Capital reserve	Treasury shares	Retained earnings / (accumulated losses)	Other reserves	Total equity
As of January 1, 2020		€232.3	€686.7	€(5.5)	€(424.8)	€4.8	€493.5
Loss for the period		_	_	_	(351.7)	_	(351.7)
Other comprehensive loss		_	_	_	_	(7.2)	(7.2)
Total comprehensive loss		€—	€—	€—	€(351.7)	€(7.2)	€(358.9)
Issuance of share capital	12	14.0	785.1	_	_	_	799.1
Transaction costs	12	_	(30.2)	_	_	_	(30.2)
Share-based payments	13	_	_	_	_	24.2	24.2
As of September 30, 2020		€246.3	€1,441.6	€(5.5)	€(776.5)	€21.8	€927.7
As of January 1, 2021		€246.3	€1,514.5	€(4.8)	€(409.6)	€25.4	€1,371.8
Profit for the period		_	_	_	7,126.3	_	7,126.3
Other comprehensive income		_	_	_	_	6.3	6.3
Total comprehensive income		€—	€—	€—	€7,126.3	€6.3	€7,132.6
Issuance of share capital and treasury shares	12	_	162.6	1.0	_	_	163.6
Transaction costs	12	_	(2.7)	_	_	_	(2.7)
Share-based payments	13	_	_	_	_	46.2	46.2
As of September 30, 2021		€246.3	€1,674.4	€(3.8)	€6,716.7	€77.9	€8,711.5



# Interim Condensed Consolidated Statements of Cash Flows

	Three mon Septem		Nine months ended September 30,	
	2021	2020	2021	2020
(in millions)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Operating activities				
Profit / (loss) for the period	€3,211.0	€(210.0)	€7,126.3	€(351.7)
Income taxes	1,456.4	2.5	3,206.2	0.3
Profit / (loss) before tax	€4,667.4	€(207.5)	€10,332.5	€(351.4)
Adjustments to reconcile profit / (loss) before tax to net cash flows:	€4,007.4	€(207.5)	€10,532.5	€(331.4)
Depreciation and amortization of property, plant, equipment and intangible assets	19.8	8.8	49.2	26.2
	23.1	8.1		24.8
Share-based payment expense			62.4	24.0
Net foreign exchange differences	(194.2)	0.1	(295.5)	0.7
Gain on disposal of property, plant and equipment	(0.6)	0.6	0.4	0.7
Finance income	(0.6)	(0.5)	(1.2)	(1.1)
Interest on lease liability	0.8	0.5	2.0	1.4
Finance expense	81.9	7.1	301.0	7.3
Movements in government grants	(20.8)	(8.5)	(109.6)	(8.5)
Other non-cash income	24.9	_	24.9	(0.2)
Working capital adjustments:				
Increase in trade and other receivables, contract assets and other assets	(3,343.9)	(45.1)	(10,095.4)	(54.9)
Increase in inventories	(88.0)	(3.7)	(329.3)	(0.5)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities and provisions	332.9	47.8	1,153.9	94.5
Interest received	0.4	0.2	1.0	0.8
Interest paid	(2.2)	(0.6)	(6.1)	(1.6)
Income tax received / (paid), net	(0.7)	0.2	(1.0)	(0.2)
Net cash flows from / (used in) operating activities	€1,500.8	€(192.5)	€1,089.2	€(262.7)
Townston and the				
Investing activities	(40.5)	(10.2)	(00.1)	(40.7)
Purchase of property, plant and equipment	(40.5)	(19.3)	(88.1)	(40.7)
Proceeds from sale of property, plant and equipment	0.2	- (4.0)	1.4	(5.2)
Purchase of intangibles assets and right-of-use assets	(0.8)	(1.0)	(12.5)	(5.2)
Acquisition of subsidiaries and businesses, net of cash acquired	_	_	_	0.9
Net cash flows used in investing activities	€(41.1)	€(20.3)	€(99.2)	€(45.0)
Financing activities				
Proceeds from issuance of share capital and treasury shares, net of costs		532.3	160.9	680.1
Proceeds from loans and borrowings	_	99.5	_	102.4
Repayment of loans and borrowings	(0.5)	(0.6)	(1.9)	(0.9)
Payments related to lease liabilities	(4.8)	(1.0)	(15.9)	(3.2)
Net cash flows from / (used in) financing activities	€(5.3)	€630.2	€143.1	€778.4
The cash hono from / (used iii) illiancing activities	(3.3)	6030.2	6143.1	6770.4
Net increase in cash and cash equivalents	1,454.4	417.4	1,133.1	470.7
Change in cash and cash equivalents resulting from exchange rate differences	24.2	0.1	49.4	0.7
Cash and cash equivalents at the beginning of the period	914.1	573.0	1,210.2	519.1
Cash and cash equivalents at September 30	€2,392.7	€990.5	€2,392.7	€990.5



#### Selected Explanatory Notes to the 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 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 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. Our broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. The breadth of our immunotherapy technologies and expertise enables us to develop potential therapies and vaccines to address infectious diseases and a broad range of indications beyond. We rapidly mobilized these to address the COVID-19 pandemic with our COVID-19 vaccine, referred to as COMIRNATY® in the European Union, the United States, and certain other locations where we have received marketing approval.

In March 2021, a new entity BioNTech Turkey Tibbi Ürünler Ve Klinik Araştirma Ticaret Anonim Şirketi, which translates into English as BioNTech Turkey Pharmaceutical Products and Clinical Trials Trading JSC, Istanbul, Turkey, was founded in Turkey and is a wholly owned consolidated subsidiary of BioNTech SE.

In July 2021, BioNTech Pharmaceuticals Co. Ltd., Shanghai, China, was founded and is a wholly owned subsidiary of BioNTech Pharmaceuticals Asia Pacific Pte. Ltd., a wholly owned consolidated subsidiary of BioNTech SE.

In September 2021, BioNTech Services Marburg GmbH was founded and is a wholly owned consolidated subsidiary of BioNTech SE.

Our unaudited interim condensed consolidated financial statements as of and for the three and nine months ended September 30, 2021 were authorized for issuance in accordance with a resolution of the audit committee on November 9, 2021.

# 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 and nine months ended September 30, 2021 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, 2020.

We prepare and present our unaudited interim condensed consolidated financial statements in Euros. If not stated differently, amounts are rounded and presented in 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 and nine months ended September 30, 2021 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, 2020. 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, 2020. Certain policies have been described further below due to the activities related to and the transactions occurred during the three and nine months ended September 30, 2021.

#### Foreign Currency Translation

Foreign currency translation effects related to operating activities include foreign exchange differences arising on operating items such as trade receivables and trade payables and are either shown as other operating income or expenses on a cumulative basis and might switch between those two positions during the year-to-date reporting periods. Foreign currency translation effects presented within finance income and expenses include foreign exchange differences arising on financing items such as loans and borrowings as well as foreign exchange differences arising on cash and cash equivalents and are either shown as finance income or expenses on a cumulative basis and might switch between those two positions during the year-to-date reporting periods.

The IFRS standards applied for the first time as of January 1, 2021, as disclosed in the notes to the audited consolidated financial statements as of and for the year ended December 31, 2020, had no



impact on our unaudited interim condensed consolidated financial statements as of and for the three and nine months ended September 30, 2021.

#### **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 have started three Phase 2 clinical trials for our FixVac product candidates BNT111 and BNT113 and in our iNeST program BNT122 as well as Phase 1 clinical trials for BNT211 (CARVac), BNT221 (NEO-PTC-01, a neoantigen-based T-cell therapy), BNT151 and BNT152+153 (RiboCytokines) as well as BNT411 (TLR-agonist). 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 and nine months ended September 30, 2021. 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:

	Three mon Septem		Nine months ended September 30,	
(in millions)	2021	2020	2021	2020
Research & development revenues from collaborations	€47.2	€59.7	€96.1	€113.4
Pfizer Inc.	29.1	45.6	43.4	69.8
Genentech Inc.	13.4	12.0	39.3	38.9
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	_	1.7	7.4	2.6
Other	4.7	0.4	6.0	2.1
Commercial revenues	€6,040.1	€7.8	€13,348.1	€23.5
COVID-19 vaccine revenues	6,021.6	_	13,303.2	_
Sales to collaboration partners*	312.3	_	514.3	_
Direct product sales to customers	1,350.8	_	2,586.2	_
Share of collaboration partners' gross profit and sales milestones	4,358.5	_	10,202.7	_
Other sales	18.5	7.8	44.9	23.5
Total	€6,087.3	€67.5	€13,444.2	€136.9

<sup>\*</sup>Represents sales to our collaboration partners of products manufactured by us.



#### **Research & Development Revenues from Collaborations**

During the three and nine months ended September 30, 2021, our collaborations with Genentech Inc., or Genentech, Pfizer Inc., or Pfizer, Shanghai Fosun Pharmaceutical (Group) Co., Ltd, or Fosun Pharma, and other collaboration partners were progressed and respective research and development revenues were derived from deferred upfront payments as well as upon achieving development and regulatory milestones.

During the three and nine months ended September 30, 2021, our Influenza collaboration with Pfizer was progressed and research and development revenues of €29.1 million and €43.4 million were derived from deferred upfront payments based on progress incurred and development milestones achieved. In comparison, during the three and nine months ended September 30, 2020, research and development revenues from our collaboration with Pfizer were mainly related to our COVID-19 vaccine collaboration.

As part of our BNT162 vaccine program against COVID-19, we are additionally collaborating with Fosun Pharma to develop a COVID-19 vaccine in China. Upon receiving the authorization for emergency use and launching our COVID-19 vaccine in Hong Kong, development and regulatory milestones of €7.4 million have been achieved and recognized as research and development revenues during the three months ended March 31, 2021. No further research and development revenues were recognized during the nine months ended September 30, 2021. In comparison, during the three and nine months ended September 30, 2020, €1.7 million and €2.6 million research and development revenues were derived from a non-refundable upfront cash payment received as well as development milestones achieved under the collaboration, respectively.

#### **Commercial Revenues**

During the three and nine months ended September 30, 2021 commercial revenues increased due to rapid increases in 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 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. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal.

Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and the COVID-19 vaccine is transferred, the vaccine is sold from one partner to the other. During the three and nine months ended September 30, 2021, we recognized €312.3 million and €514.3 million of revenues, respectively, from selling drug product batches manufactured by us to our partners.

By supplying our territories during the three and nine months ended September 30, 2021, we recognized €1,350.8 million and €2,586.2 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 September 30, 2021, €4,341.5 million gross profit share and €17.0 million of sales milestones have been recognized as revenues. During the nine months ended September 30, 2021, €9,769.9 million gross profit share and €432.8 million of sales milestones have been recognized as revenues. In order to determine our share of our collaboration partners' gross



profits, we used certain information from the collaboration partners, including revenues from the sale of products, some of which is based on preliminary data shared between the partners and might vary once final data is available.

Revenues from contracts with customers were recognized as follows:

	Three months ended September 30,		Nine mont Septem	
(in millions)	2021	2020	2021	2020
Timing of revenue recognition				
Goods and services transferred at a point in time	€1,677.1	€6.1	€3,138.7	€19.9
Goods and services transferred over time	4,410.2	61.4	10,305.5	117.0
Total	€6,087.3	€67.5	€13,444.2	€136.9

## 4 Cost of Sales

The cost of sales recognized during the three and nine months ended September 30, 2021 and 2020 are shown in the following table:

	Three months ended September 30,		Nine mont Septem	
(in millions)	2021	2020	2021	2020
Cost of sales related to COVID-19 vaccine revenues	€1,194.8	€—	€2,290.1	€—
Cost related to other sales	16.6	6.8	38.2	18.3
Total	€1,211.4	€6.8	€2,328.3	€18.3

# 5 Research and Development Expenses

The research and development expenses recognized during the three and nine months ended September 30, 2021 and 2020 are shown in the following table:

	Three months ended September 30,		Nine mont Septem	
(in millions)	2021	2020	2021	2020
Purchased services	€160.8	€143.1	€402.6	€201.1
Wages, benefits and social security expense	70.0	29.2	185.7	88.7
Laboratory supplies	10.2	43.9	38.1	65.1
Depreciation and amortization	8.5	7.2	23.1	21.1
Other	10.9	4.3	28.2	12.0
Total	€260.4	€227.7	€677.7	€388.0



# 6 General and Administrative Expenses

The general and administrative expenses recognized during the three and nine months ended September 30, 2021 and 2020 are shown in the following table:

	Three months ended September 30,		Nine mont Septem	
(in millions)	2021	2020	2021	2020
Wages, benefits and social security expense	€22.5	€7.0	€53.9	€21.2
Purchased services	14.6	6.7	38.1	15.0
Insurance premiums	14.7	1.9	23.4	3.5
IT and office equipment	6.3	2.1	14.3	4.8
Depreciation and amortization	1.8	1.2	4.4	3.9
Other	8.3	4.6	20.8	9.7
Total	€68.2	€23.5	€154.9	€58.1

# 7 Other Operating Income and Expenses

The other operating income recognized during the three and nine months ended September 30, 2021 and 2020 is shown in the following table:

	Three months ended September 30,		Nine mon Septem	
(in millions)	2021	2020	2021	2020
Foreign exchange differences, net	€190.3	€—	€265.4	€—
Government grants	20.9	8.5	88.9	8.5
Other	1.9	0.3	6.3	1.5
Total	€213.1	€8.8	€360.6	€10.0

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.

The other operating income derived from government grants mainly relates to the government grant for which we became eligible during the year ended December 31, 2020 as part of an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support our COVID-19 vaccine program, BNT162.

The other operating expenses recognized during the three and nine months ended September 30, 2021 and 2020 are shown in the following table:

	Three months ended September 30,		Nine mont Septem	
(in millions)	2021	2020	2021	2020
Loss on derivative instruments at fair value through profit or loss	€24.9	€—	€24.9	€—
Other	1.5	0.4	2.4	1.3
Total	€26.4	€0.4	€27.3	€1.3



The loss on derivative instruments at fair value through profit or loss relates to foreign exchange forward contracts that did not qualify for hedge accounting (see Note 10).

# 8 Finance Income and Expenses

The finance income recognized during the three and nine months ended September 30, 2021 and 2020 is shown in the following table:

	Three mon Septem		Nine mont Septem	
(in millions)	2021	2020	2021	2020
Foreign exchange differences, net	€26.0	€—	€50.2	€—
Interest income	0.6	0.5	1.2	1.1
Total	€26.6	€0.5	€51.4	€1.1

The finance expenses recognized during the three and nine months ended September 30, 2021 and 2020 are shown in the following table:

	Three months ended September 30,		Nine mont Septem	
(in millions)	2021	2020	2021	2020
Fair value adjustments of financial instruments measured at fair value	€81.5	€6.3	€293.4	€6.3
Amortization of financial instruments	0.4	0.8	7.6	1.0
Foreign exchange differences, net	_	14.0	_	17.2
Total	€81.9	€21.1	€301.0	€24.5

During the three and nine months ended September 30, 2021, €81.5 million and €293.4 million, finance expenses were recognized, respectively, from remeasuring the derivative embedded in our convertible note (see Note 10).

The foreign exchange differences included in finance income and expenses arose from valuing our U.S. dollar bank accounts.

#### 9 Income Tax

For the nine months ended September 30, 2021, income taxes are calculated based on the best estimate of the weighted average annual income tax rates expected for the full financial year (estimated annual effective income tax rate) on ordinary income before tax plus the tax effect of any discrete items. Our effective income tax rate was approximately 31% for the nine months ended September 30, 2021. Current income taxes were recognized with respect to the German tax group. For the German entities, the estimated annual effective income tax rate anticipates the full use of the tax loss carry forwards resulting in an expense of the deferred tax assets over the fiscal year 2021. Consequently, during the three and nine months ended September 30, 2021, a proportionate amount of the deferred tax assets related to the tax loss carryforward was utilized. The change in deferred tax assets was partly compensated by deferred tax effects of identified discrete items. As of September 30, 2021, 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 and nine months ended September 30, 2021 and 2020 are shown in the following table:

	Three mon Septem		Nine mont Septem	
(in millions)	2021	2020	2021	2020
Current income taxes	€1,368.5	€0.2	€3,120.6	€0.3
Deferred taxes	87.9	2.3	85.6	_
Income taxes	€1,456.4	€2.5	€3,206.2	€0.3

## 10 Financial Assets and Financial Liabilities

Set out below is an overview of financial assets, other than cash and cash equivalents, held as of September 30, 2021 and December 31, 2020:

#### Financial assets at amortized cost

(in millions)	September 30,	December 31,
(III millions)	2021	2020
Trade and other receivables	€10,603.9	€165.5
Other financial assets	1.8	137.2
Total	€10,605.7	€302.7
Total current	10,605.7	302.7
Total non-current	_	_

Trade and other receivables significantly increased mainly due to the trade receivables from our COVID-19 collaboration with Pfizer as well as our own sales. The contractual settlement of the gross profit share has a temporal offset of more than one calendar quarter. As Pfizer's fiscal quarter for subsidiaries outside the United States differs from ours, it creates an additional time lag between the recognition of revenues and the payment receipt. Consequently, as of September 30, 2021, our trade receivables included in addition to the profit share for the third quarter of 2021, trade receivables which related to the gross profit share for the second quarter of 2021. The payment settling our gross profit share for the second quarter of 2021 (as defined by the contract) was received from our collaboration partner subsequent to the end of the reporting period in October 2021.



Set forth below is an overview of financial liabilities, other financial liabilities and trade payables held as of September 30, 2021 and December 31, 2020:

#### Interest-bearing loans and borrowings

(in millions)	Maturity	September 30, 2021	December 31, 2020
Lease liabilities		€129.2	€84.2
Convertible note - host contract	8/28/2024	89.8	87.5
3.50% € 50,000,000 secured bank loan	12/21/2026	48.3	47.2
2.15% € 10,000,000 secured bank loan	12/30/2027	8.1	9.0
2.08% € 9,450,000 secured bank loan	9/30/2028	7.9	8.7
1.90% € 3,528,892.48 secured bank loan	5/30/2039	3.4	3.5
Total		€286.7	€240.1
Total current		19.0	9.1
Total non-current		267.7	231.0

#### Trade payables and other financial liabilities

Trade payables and other infancial nabilities		
(in millions)	September 30, 2021	December 31, 2020
Derivatives not designated as hedging instrument		
Convertible note - embedded derivative	€324.3	€30.9
Foreign exchange forward contracts	24.9	<u> </u>
Financial liabilities at fair value through profit or loss		
Contingent consideration	0.6	0.6
Total financial liabilities at fair value	€349.8	€31.5
Trade payables and other financial liabilities at amortized cost, other than interest-bearing loans and borrowings		
Trade payables	258.9	102.3
Other financial liabilities	899.6	74.1
Total trade payables and other financial liabilities at amortized cost, other than interest-bearing loans and borrowings	€1,158.5	€176.4
Total trade payables and other financial liabilities	€1,508.3	€207.9
Total current	1,183.4	176.4
Total non-current	324.9	31.5

#### **Total financial liabilities**

(in millions)	September 30, 2021	December 31, 2020
Interest-bearing loans and borrowings	€286.7	€240.1
Trade payables and other financial liabilities	1,508.3	207.9
Total	€1,795.0	€448.0
Total current	1,202.4	185.5
Total non-current	592.6	262.5

Derivatives not designated as hedging instruments reflect the change in fair value of those foreign exchange forward contracts that were entered into during the three months ended September 30, 2021



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.

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 the audited consolidated financial statements as of and for the year ended December 31, 2020.

#### 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 financial liabilities measured at amortized cost include four fixed-interest rate loans as well as our issued convertible note. As of September 30, 2021 and December 31, 2020, the carrying value approximates their fair values as there have been no significant changes in relevant interest rates since the inception of the respective loans and note.

The fair values of financial instruments measured at fair value are reassessed on a quarterly basis. Unchanged to December 31, 2020, we used the Cox-Rubinstein binomial tree model to determine the fair value of the embedded derivative as of September 30, 2021. The valuation technique 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, 2020. The fair value adjustment derived from remeasuring the embedded derivative was mainly driven by the increase in our share price, amounted to €81.5 million for the three months ended September 30, 2021 and €293.4 million for the nine months ended September 30, 2021, respectively, and was recognized as finance expenses in our interim condensed consolidated statements of profit or loss (see Note 8). The foreign exchange forward contracts are valued using valuation techniques, which employ the use of foreign exchange spot and forward rates (Level 2). The fair value adjustment derived from remeasuring the foreign exchange forward contracts amounted to €24.9 million for the three and nine months ended September 30, 2021, and was recognized as other operating expenses in our interim condensed consolidated statements of profit or loss (see Note 7).

The initial fair value of the contingent consideration determined at acquisition remains valid since no changes of the underlying performance criteria have occurred.



#### 11 Inventories

Set out below is an overview of inventories held as of September 30, 2021 and December 31, 2020:

(in millions)	September 30, 2021	December 31, 2020
Raw materials and supplies	€208.2	€44.3
Unfinished goods	74.5	19.4
Finished goods	110.7	0.4
Total	€393.4	€64.1

The inventories increased mainly due to our production ramp-up.

During the three and nine months ended September 30, 2021, inventory write-offs related to the manufacturing of our COVID-19 vaccine amounting to €88.0 million and €107.8 million were recognized in cost of sales as a result of the respective inventories not fulfilling the specification defined by our quality standards or shelf-life expiration.

## 12 Issued Capital and Reserves

At-The-Market Offering Program

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC and SVB Leerink LLC, as sales agents, to establish an at-the-market offering program, pursuant to which we may sell, from time to time, American Depositary Shares, or ADSs, representing ordinary shares for aggregate gross proceeds of up to \$500.0 million. During the nine months ended September 30, 2021, we sold 995,890 ADSs, each representing one of our ordinary shares that had previously been held in treasury, under the Sales Agreement for aggregate gross proceeds of \$200.0 million (€163.6 million). Reissuing 995,890 ordinary shares was registered as decrease of €1.0 million in treasury shares. As a result of the transaction, the capital reserve increased by €162.6 million offset by €2.7 million transaction costs, net of tax.



# 13 Share-Based Payments

#### Expense arising from share-based payment arrangements

During the three and nine months ended September 30, 2021 and 2020, the following share-based payment arrangements led to the expenses recognized for services received during the respective periods as shown in the following table:

	Three months ended September 30,		Nine mon Septem	
(in millions)	2021	2020	2021	2020
Expense arising from equity-settled share-based payment arrangements	€14.8	€7.9	€47.3	€24.2
Employee Stock Ownership Plan	4.3	4.3	15.9	12.9
Chief Executive Officer Grant	1.7	3.2	5.0	9.6
Management Board Grant*	0.7	0.4	1.6	1.7
BioNTech 2020 Employee Equity Plan for employees based in Europe	8.1	_	24.8	_
Expense arising from cash-settled share-based payment arrangements	14.6	0.2	26.5	0.6
Employee Stock Ownership Plan	4.8	_	4.8	_
Management Board Grant*	1.8	0.2	3.1	0.6
BioNTech 2020 Restricted Stock Unit Plan for North America Employees	8.0	_	18.6	_
Total	€29.4	€8.1	€73.8	€24.8
Cost of sales	1.9	0.2	5.5	0.6
Research and development expenses	17.1	6.2	48.0	19.2
Sales and marketing expenses	0.1	0.2	0.4	0.2
General and administrative expenses	10.3	1.5	19.9	4.8
Total	€29.4	€8.1	€73.8	€24.8

<sup>\*</sup> In May 2021, phantom options were granted under the Management Board Grant for the 2021 year which led to a modification from equity-settled to cash-settled share-based payment arrangement and a reclassification of €1.1 million between equity and non-current other liabilities, respectively. Expenses incurred before and after the modification date have been disclosed as equity-settled or cash-settled share-based payment arrangement, respectively.

#### Changes in share-based payment arrangements

New share-based payment arrangements and material changes to arrangements that occurred during the three and nine months ended September 30, 2021 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, 2020.

#### BioNTech 2020 Employee Equity Plan for employees based in Europe (Equity-Settled)

In December 2020, we adopted the BioNTech 2020 Employee Equity Plan for employees based in Europe, or the European Plan. Under the European Plan, Restricted Cash Units, or RSUs, are offered to our employees. As of the grant date in February 2021, with implementing the European Plan for the calendar year 2020, award agreements were entered into with all of our employees who were eligible under the European Plan, or the LTI 2020 program. In addition, further award agreements were entered into with employees who did not participate in the Employee Stock Ownership Plan, or ESOP, under the LTI-plus program. RSUs issued under the LTI 2020 program vest annually in equal



installments after four years and RSUs issued under the LTI-plus program vests annually in equal installments after two years, with both programs commencing in December 2020. Under the LTI-plus program, 50% of the RSUs awarded to the participant were awarded on commencement of the program in December 2020 and the remaining 50% were awarded to the participant shortly after the U.S. Food and Drug Administration, or the FDA, fully approved BNT162b2, our COVID-19 vaccine during the three months ended September 30, 2021 (non-vesting condition). As we have the ability to determine the method of settlement, both programs were classified as equity-settled. The cost of the awards will be recognized over the relevant 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 nine months ended September 30, 2021.

	Restricted Stock Units	Weighted average fair value (€)
Granted	627,486	89.4
Forfeited	(10,993)	88.7
As of September 30, 2021	616,493	89.4

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.

#### BioNTech 2020 Restricted Stock Unit Plan for North America Employees (Cash-Settled)

In December 2020, we adopted the BioNTech 2020 Restricted Stock Unit Plan for North America Employees, or the North American Plan. Under the North American Plan, RSUs are offered to our employees. These RSUs generally vest over four years, with 25% vesting one year after the service commencement date and the remainder vesting in equal quarterly installments thereafter. The first awards under the North American Plan were granted in February 2021. The service date for these awards is the date as of which the employee became employed by BioNTech US. As these RSUs are intended to be cash-settled upon vesting, the awards were defined as a cash-settled share-based payment arrangement. The liability related to these awards is measured, initially and at the end of each reporting period until settled, at the fair value of the award considering the price of the ADSs representing our ordinary shares. The cost of the awards will be recognized over the relevant service period, applying the graded vesting method.

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

Effective from the beginning of 2020, the first year following the completion of our IPO, until the end of the term each of the Management Board members' employment agreements, such employment agreements provide for a long-term incentive compensation in the form of yearly grants of options to purchase our ordinary shares.

With effect as of July 1, 2021, the service commencement date, the Supervisory Board appointed Jens Holstein to the Management Board as Chief Financial Officer (CFO) and approved his employment agreement. The employment agreement covers the period July 1, 2021 to June 30, 2025 and provides for a short-term and long-term incentive compensation which are in line with 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, 2020.

In May 2021, the grant date, phantom options equivalent to the number of options the Management Board members would have been entitled to receive for the 2021 year were granted under the Management Board Grant which led to a modification from equity-settled to cash-settled share-based payment arrangement and a reclassification of €1.1 million between equity and non-current other liabilities.

The phantom options allocated to our Management Board as of May 2021 allocation date are presented in the table below. The rights to receive options in 2022 remain determined as equity-settled share-based payment arrangements.

Phantom options outstanding	Allocation date May 2021
Prof. Ugur Sahin, M.D.	17,780
Sean Marett	7,112
Dr. Sierk Poetting	7,112
Dr. Özlem Türeci, M.D.	7,112
Ryan Richardson	6,163
Jens Holstein*	6,463

<sup>\*</sup> With effect as of July 1, 2021, Jens Holstein was appointed to the Management Board as Chief Financial Officer (CFO).

#### Measurement of Fair Values

Under this cash-settled share-based payment arrangement, the fair values of the liabilities will be remeasured until the settlement date continuously using a Monte-Carlo simulation model which incorporates the impact of the performance criteria regarding share price and index development as described 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, 2020. Continuously, the fair values are recognized over the award's vesting period beginning as of the service commencement date (January 1, 2020) until four years commencing on the first anniversary of the allocation date have lapsed.

#### 14 Provisions

From time to time, we may be involved in legal proceedings arising out of the normal course and conduct of our business. As of September 30, 2021, certain proceedings were pending or threatened against us or our subsidiaries, mainly related to purported obligations arising out of use or alleged use of third party intellectual property. Our best estimate of potential outflow of economic resources from such proceedings amounts to €188.2 million, which is included in current provisions in our unaudited interim condensed consolidated statements of financial position as of September 30, 2021. 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.



# 15 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 was as follows for the periods indicated:

	Three months ended September 30,			Nine months ended September 30,	
(in millions)	2021	2020	2021	2020	
Purchases of various goods and services from entities controlled by ATHOS KG	€0.3	€0.3	€0.7	€1.8	
Purchases of property and other assets from entities controlled by ATHOS KG	_	_	_	2.3	
Total	€0.3	€0.3	€0.7	€4.1	

The outstanding balances of transactions with ATHOS KG or entities controlled by them were as follows as of the dates indicated:

(in millions)	September 30, 2021	December 31, 2020
ATHOS KG	€0.3	€0.5
Total	€0.3	€0.5

None of the balances are secured and no bad debt expense has been recognized in respect of amounts owed by related parties.

# 16 Events after the Reporting Period

In October 2021, BioNTech Real Estate An der Goldgrube 12 GmbH & Co. KG. was founded. The partnership is wholly owned by its limited partner BioNTech Real Estate Holding GmbH, a wholly owned subsidiary of BioNTech SE.

In October 2021, we expanded our infectious disease portfolio capabilities by acquiring PhagoMed Biopharma GmbH (subsequently renamed as BioNTech R&D (Austria) GmbH), an Austrian biotechnology company, specialized in the development of a new class of antibacterials. The total consideration can reach up to €150.0 million, consisting of upfront consideration of €50.0 million (less acquired debt) with the possibility of the selling shareholders earning up to an additional €100.0 million through the achievement of certain clinical development milestones. As the closing of the transaction occurred only recently, we have not yet determined the final consideration transferred and what elements of the consideration are part of the business combination. We also have not performed the detailed purchase price allocation analysis necessary to derive the required estimates of the fair value of the acquired assets and liabilities assumed.



#### **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 extent to which initial or booster doses of a COVID-19 vaccine continue to be necessary in the future; competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, 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; the collaboration between BioNTech and Pfizer to develop 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 of the collaboration with the African Union and the Africa CDC; the nature and duration of support from WHO, 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 and nine months ended September 30, 2021 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.



### **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 and nine months ended September 30, 2021.

#### **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 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. Our broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. The breadth of our immunotherapy technologies and expertise enables us to develop potential therapies and vaccines to address infectious diseases and a broad range of indications beyond. We rapidly mobilized these to address the COVID-19 pandemic with our COVID-19 vaccine, referred to as COMIRNATY® in the European Union, the United States, and other locations where we have received marketing approval.

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 intend to invest the proceeds we generate from sales of our COVID-19 vaccine to accelerate the maturation of our oncology and infectious disease pipeline and the expansion into additional therapeutic areas, such as autoimmunity, allergy, regenerative medicine and inflammatory diseases.

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 significantly improve clinical outcomes for patients.

We have assembled an exceptional team of over 2,800 employees and have established relationships with eight pharmaceutical collaborators, including Bayer AG, or Bayer, Genentech, Inc., or Genentech, Genevant Sciences GmbH, or Genevant, Genmab A/S, or Genmab, Pfizer Inc., or Pfizer, Regeneron Pharmaceuticals, Inc., or Regeneron, Sanofi S.A., or Sanofi and Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma.



#### **Corporate Development**

- With effect as of July 1, 2021, the Supervisory Board appointed Jens Holstein to the Management Board as Chief Financial Officer (CFO). Jens Holstein joined the Management Board to help strengthen our growth trajectory as a global, fully integrated immunotherapy company with an approved or authorized product. He previously served as CFO for MorphoSys AG and in various CFO and general management roles within the Fresenius SE Group. Jens Holstein takes over the CFO role from Dr. Sierk Poetting who will fully focus on his tasks as Chief Operating Officer going forward.
- With effect as of August 4, 2021, we entered into a purchase agreement with Kite Pharma Inc., Santa Monica, California, United States to acquire their clinical manufacturing facility in Gaithersburg, Maryland, United States and their T Cell Receptor (TCR) R&D platform. The acquired Gaithersburg facility and employees are expected to provide production capacity to support clinical trials in the United States and to complement our existing cell therapy manufacturing facility in Idar-Oberstein, Germany. We expect that the facility will support the development of our expanding pipeline of novel cell therapies, including cancer product candidates based on our CAR-T Cell amplifying mRNA vaccine (CARVac) and NEOSTIM platforms as well as the newly acquired individualized neoantigen TCR program. Under the terms of the agreement, Kite received a one-time upfront payment from us. The asset acquisition is an important step in our goal to build a global biotechnology company for individualized cancer medicine by further strengthening our footprint in the United States.
- In October 2021, we expanded our infectious disease portfolio capabilities by acquiring PhagoMed Biopharma GmbH (subsequently renamed as BioNTech R&D (Austria) GmbH), an Austrian biotechnology company, specialized in the development of a new class of antibacterials.

#### **Key Pipeline Updates**

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

#### **Infectious Disease**

Infectious disease is a growth pillar for us and we are developing vaccine candidates to address multiple pathogens that pose significant global public health challenges.

#### COVID-19 Vaccine Program - BNT162b2

BNT162b2 Clinical Development Updates

Multiple clinical trials are ongoing to expand COVID-19 vaccine reach and explore booster doses to address waning immunity. Clinical data to date support a third dose booster of the vaccine in adults to augment vaccine protection over time. A third dose booster of BNT162b2 confers high neutralizing antibody titers against SARS-CoV-2 ancestral virus and the Beta and Delta variants that are higher than the levels observed after the two-dose primary series.

Additionally, studies are underway evaluating variant-specific versions of the vaccine to generate data to inform our strategy to address emerging SARS-CoV-2 variants. While to date, there is no clinical data suggesting the need for a variant-specific version of the vaccine, we are establishing a preemptive prototype approach to the development, manufacturing and regulatory processes for variant specific vaccines. This prototype approach is aimed to be substantiated by broad clinical data that are being prepared for submission to regulatory authorities.

• In August 2021, we and Pfizer started a clinical trial to evaluate the safety and immunogenicity of variant-encoding vaccine candidates, including a multivalent vaccine



against two variants of concern. The study will enroll approximately 1,200 adults 18 to 85 years of age. Participants will receive a third 30 µg dose of a multivalent Delta and Alpha version of the vaccine, or monovalent Delta or Alpha versions administered six months after the second dose of the two-dose primary series of BNT162b2. Vaccine- and SARS-CoV-2-naïve participants in the study will receive two doses of the multivalent Delta and Alpha vaccine administered 21 days apart. First data from this study are anticipated in the fourth quarter of 2021.

- On September 6, 2021, we and Pfizer announced data from a Phase 3 clinical trial of 306 participants 18-55 years of age who received a booster dose approximately six months after completing the two-dose primary regimen, with a median follow-up time of 2.6 months post-third dose. The booster dose elicited significantly higher SARS-CoV-2 neutralizing antibody titers against the ancestral strain compared to the levels observed after the two-dose primary series with titers against ancestral virus more than 5 times as high at 1 month after the third dose compared to 1 month after the two-dose primary series. The safety profile was favorable and similar to after dose two of the primary series and generally consistent with other clinical data for BNT162b2. Previously reported Phase 1 data showed a similar pattern of third dose responses against the ancestral strain, Beta and Delta variants. Based on these data a third dose booster of BNT162b2 for emergency use in certain population groups was authorized by the U.S. Food and Drug Administration (FDA) and the Conditional Marketing Authorization (CMA) in the European Union was updated upon approval from the European Commission (EC) following a positive opinion from the European Medicines Agency (EMA) for a third dose of BNT162b2. The data are also being submitted to other regulatory authorities worldwide.
- On September 20, 2021, we and Pfizer announced positive topline results from a Phase 2/3 trial in children demonstrating strong immune response one month after the second dose in 2,268 children aged 5 to under 12 years. The vaccine showed a favorable safety profile and robust neutralizing antibody responses in this cohort using a two-dose regimen of 10 µg administered 21 days apart. Antibody responses were comparable to those in a previous study in people 16 to 25 years of age immunized with 30 µg doses. One month after the second dose, the geometric mean ratio of SARS-CoV-2 neutralizing titers in the children aged 5 to under 12 years to those in people 16 to 25 years of age was 1.04, meeting the predefined immunobridging success criteria. These data were recently submitted for publication.
- Subsequently, on October 26, 2021, the companies reported further results from the Phase 2/3 trial in children that included an additional 2,379 children from the supplemental safety group, bringing the total to approximately 4,500. In this analysis, BNT162b2 showed a favorable safety profile, robust immune responses as well as a vaccine efficacy rate of 90.7% in participants without prior SARS-CoV-2 infection, measured 7 days after the second dose, during a period when Delta was the prevalent strain. Topline readouts for the other two age cohorts from the trial children 2-5 years of age and children 6 months to 2 years of age are expected as soon as the fourth quarter of 2021 or early first quarter 2022.
- On October 21, 2021, we and Pfizer announced topline results from a Phase 3 clinical trial to evaluate the safety, tolerability and efficacy of a 30 µg booster dose versus placebo in more than 10,000 participants aged 16 years and older who previously received two doses of BNT162b2 at least six months prior to randomization. These first results from a randomized, controlled COVID-19 vaccine booster dose trial demonstrated that a booster dose restored vaccine protection to the high levels achieved after the second dose, showing a relative vaccine efficacy of 95.6% compared to those who did not receive a booster dose. Multiple subgroup analyses showed efficacy was consistent irrespective of age, sex, race, ethnicity and co-morbidities. The adverse event profile was consistent with previous clinical safety data. The companies plan to share these data with the FDA, EMA, and other regulatory agencies and submit detailed results for publication.



• A global Phase 2/3 trial to evaluate the safety, tolerability and immunogenicity of BNT162b2 in preventing COVID-19 in healthy pregnant women 18 years of age and older is ongoing. The study will also assess safety in infants of vaccinated pregnant women and the transfer of potentially protective antibodies to their infants.

#### Regulatory Updates

We and Pfizer have made progress on the regulatory front, including Biologics License Application (BLA) approval in the United States, as well as U.S. Emergency Use Authorization (EUA) for booster doses for many populations at high risk of severe COVID-19-disease. The EMA issued a positive opinion on the administration of BNT162b2 as a booster dose in adults and as a third dose in immunocompromised people.

- In August 2021, the U.S. FDA and the EMA authorized the extension of the shelf-life of the COVID-19 vaccine from six to nine months when stored at -90 to -60 degrees C.
- On August 23, 2021, the U.S. FDA approved the BLA for BNT162b2 to prevent COVID-19 in individuals 16 years of age and older based on a comprehensive data package that included longer-term follow-up data from the Phase 3 trial. BNT162b2 is the first COVID-19 vaccine to be granted full approval by the FDA.
- On September 22, 2021, the FDA authorized a third dose booster for emergency use in individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications from COVID-19 including severe COVID-19. The booster dose, which is the same formulation and dose strength as used in the primary series, is to be administered at least six months after completion of the primary series. A third dose was authorized on August 12, 2021, under the EUA for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.
- On October 5, 2021, the EC granted a variation to the CMA for the administration of a third dose booster of BNT162b2 at least six months after the second dose in individuals 18 years of age and older. This followed a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the EMA. The positive opinion follows the companies' submission of a variation to the EMA requesting to update the CMA with data supporting a booster dose to prevent COVID-19 in individuals 16 years of age and older. The CHMP also recommended that people with severely weakened immune systems should be given a third dose of the vaccine at least 28 days after their second dose.
- In October, 2021, we and Pfizer announced the submission of data supporting the vaccination of children 5 to under 12 years of age to the EMA for a variation of the CMA in the European Union. The variation request includes data from the Phase 2/3 study, which is enrolling children 6 months to under 12 years of age. The data will also be filed with other regulatory authorities in the coming weeks.
- On October 29, 2021, we and Pfizer received the first U.S FDA EUA of a COVID-19 vaccine in children ages 5 through 11 years of age based on data from a Phase 2/3 randomized, controlled trial. This EUA follows the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) vote on October 26, 2021, recommending that the FDA grant EUA in this population.
- In November 2021, the EC authorized a new formulation of BNT162b2, that further simplifies vaccine handling. This decision followed a positive opinion from the EMA CHMP. The new formulation also allows for longer storage, as vials can be stored for 10 weeks at



refrigerator temperatures from 2°C to 8°C, and after first puncture, can be stored and transported at 2°C to 30°C and used within 12 hours.

#### Commercial Updates

We and Pfizer have delivered an aggregate of over two billion doses of BNT162b2 vaccine to more than 152 countries and territories around the world as of November 2, 2021.

Further discussions for additional dose commitments are ongoing for 2022 and beyond.

- On September 22, 2021, we and Pfizer announced plans to expand the existing agreement with the U.S. government by providing an additional 500 million doses at a not-for-profit price for donation to low- and lower-middle-income countries and the organizations that support them. This expanded agreement brings the total number of doses to be supplied to the U.S. government for donation to one billion. The companies are committed to working toward equitable and affordable access to COVID-19 vaccines for all people around the world, actively working with governments and health partners worldwide, and have pledged to provide two billion doses to low- and middle-income countries in 2021 and 2022.
- In October 2021, the Japanese government agreed to purchase another 120 million doses, starting in January 2022, bringing the total number of doses purchased to 314 million.
- On October 28, 2021, we and Pfizer announced that the U.S. government purchased an additional 50 million doses to continue to support preparedness for pediatric vaccinations, including securing vaccines for children under 5 years of age. With this purchase, the U.S. government has exercised its final purchase option under the existing supply agreement, bringing the total number of doses secured under the agreement to 600 million, excluding the one billion doses to be supplied at a not-for-profit price for donation.

#### Manufacturing Updates

- We and Pfizer expect to manufacture 2.7 billion to three billion doses by the end of 2021 and anticipate capacity to manufacture up to four billion doses in 2022. The companies have developed a global COVID-19 vaccine supply chain and manufacturing network, which now spans four continents and includes more than 20 manufacturing facilities.
- On July 21, 2021, we and Pfizer announced the signing of a letter of intent with the Biovac Institute (Pty) Ltd., a Cape Town-based, South African biopharmaceutical company, for the manufacture of vaccine for distribution within the African Union. Biovac's Cape Town facility is expected to be incorporated into the vaccine supply chain by the end of 2021, and at full operational capacity, the annual production will exceed 100 million finished doses annually.
- On August 26, 2021, we and Pfizer announced the signing of a letter of intent with Eurofarma Laboratórios SA, a Brazilian biopharmaceutical company, to manufacture vaccine for distribution within Latin America. Eurofarma will obtain drug product from facilities in the United States, and manufacturing of finished doses is expected to commence in 2022. At full operational capacity, annual production is expected to exceed 100 million finished COVID-19 doses.

#### Influenza Vaccine Program – BNT161

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

• On September 27, 2021, the first participants were dosed in a Phase 1 clinical trial to evaluate the safety, tolerability and immunogenicity of a single dose quadrivalent mRNA vaccine (BNT161) against influenza in healthy adults 65-85 years of age, with an FDA-approved



standard quadrivalent influenza vaccine as a control. BNT161 encodes World Health Organization recommended strains. Data from the trial is expected in the first half of 2022.

#### **Other Infectious Diseases**

We are committed to developing vaccines and sustainable end-to-end vaccine production on the African continent and to provide affordable access to low- and lower-middle-income countries. We have continued our efforts to establish the necessary infrastructure and to grow our infectious disease pipeline.

- 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.
- On July 26, 2021, we announced plans to develop sustainable solutions to address infectious diseases on the African continent. We aim to develop an mRNA-based malaria vaccine and the initiation of a clinical trial is expected by end of 2022. On October 26, 2021, we announced that construction of the first mRNA manufacturing facility in Africa is expected to begin in mid-2022, following the signing of a Memorandum of Understanding with the Rwandan government and the Institut Pasteur de Dakar (Senegal). We believe this facility could become the first node in a decentralized and robust African end-to-end manufacturing network with an expected annual manufacturing capacity of several hundreds of million mRNA vaccine doses to provide sustainable vaccine supply on the African continent.
- We also announced that clinical trials for our first tuberculosis vaccine candidate are planned to begin by end of 2022, just two years after the program was initiated. We have collaborated with the Bill and Melinda Gates Foundation since 2019 to develop preclinical vaccine and immunotherapy candidates to prevent HIV and tuberculosis infection.
- There are an additional five undisclosed programs.

#### Oncology

We are advancing the development of a broad oncology pipeline, which spans multiple anti-tumor and immune-modulating approaches. Our clinical pipeline now includes randomized Phase 2 clinical trials for FixVac programs, BNT111 and BNT113, and for iNeST product candidate autogene cevumeran (BNT122, RO7198457), bringing our clinical programs to a total of 15 product candidates in 19 ongoing clinical trials, including four Phase 2 randomized clinical trials.

We expect to further advance our oncology pipeline in the fourth quarter of 2021 with one preclinical program expected to move into a first-in-human Phase 1 trial.

Seven updates with positive clinical and preclinical data supporting our oncology pipeline will be presented at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting which takes place on November 10–14, 2021. The information below regarding the SITC presentations reflects data in submitted abstracts and supplemental data may be presented at the conference.

#### FixVac

Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancerspecific shared antigens. FixVac product candidates also feature our proprietary immunogenic mRNA backbone and proprietary RNA-LPX delivery formulation, which



are designed to enhance stability and translation as well as trigger both innate and adaptive immune responses.

- BNT111 in advanced melanoma.
  - BNT111 is in an ongoing Phase 1 trial for the treatment of advanced melanoma.
  - BNT111 is in an ongoing randomized Phase 2 trial for the treatment of patients with advanced melanoma. The trial is being conducted in collaboration with Regeneron.

The trial is a global, three-arm Phase 2 trial evaluating BNT111 in combination with cemiplimab (Regeneron and Sanofi's Libtayo®), versus both agents as monotherapy, in 120 patients with anti-PD1-refractory/relapsed unresectable Stage III or IV melanoma. Libtayo is being co-developed by Regeneron and Sanofi.

On September 15, 2021, the U.S. FDA granted Orphan Drug Designation to BNT111 for the treatment of Stage IIB through IV melanoma.

At SITC, we intend to present additional data from the ongoing Phase 1 trial evaluating the safety and tolerability of BNT111 in patients with advanced melanoma. Data demonstrated that the immunogenicity and safety profile of BNT111 as a monotherapy were comparable in patients grouped as having evidence of disease (ED) and in patients with no evidence of disease (NED). As of May 24, 2021, 14 of 22 (64%) patients with ED and 19 of 28 (68%) patients with NED demonstrated BNT111-induced T-cell responses against at least one tumor-associated antigen (TAA). In NED patients, clinical efficacy was encouraging with median disease-free survival of 34.8 months.

- **BNT112** is in an ongoing Phase 1/2 trial for the treatment of prostate cancer.
  - At SITC, we intend to present data from the ongoing Phase 1/2 trial of BNT112 as a monotherapy and in combination with cemiplimab in patients with metastatic castration-resistant prostate cancer (mCRPC) and newly diagnosed high risk localized prostate cancer (LPC). Overall, as of June 22, 2021, the data suggest that BNT112 as monotherapy and in combination with a PD-1 inhibitor (cemiplimab) is well-tolerated in mCRPC. Additionally, data suggest that BNT112 induces robust immune responses, as de novo induction and expansion of pre-existing antigen-specific T-cell responses was observed in all patients with available Post-IVS-ELISpot.
- BNT113 is in an ongoing Phase 1/2 basket trial for the treatment of HPV16+ head and neck cancer.
  - The trial is 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 (HNSCC) expressing PD-L1 is ongoing.
- BNT115 is in an ongoing investigator-initiated Phase 1 trial for the treatment of ovarian cancer.
- **BNT116** is in preclinical development for the treatment of non-small cell lung cancer.

*Individualized Neoantigen Specific Immunotherapies (iNeST)* 

iNeSTs are individualized cancer immunotherapies that target specific neoantigens that are present on a patient's tumor. Our iNeST immunotherapies contain pharmacologically optimized uridine mRNA



encoding up to 20 patient-specific neoantigens, delivered in our proprietary RNA-LPX formulation. We are developing our iNeST autogene cevumeran in collaboration with Genentech.

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

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

#### 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/PD-L1 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. BNT151 encodes an IL-2 variant, BNT152 encodes IL-7 and BNT153 encodes IL-2.

- **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 the respective standard of care.
- **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 dose of each compound. Part 2 will be the dose escalation of BNT152 and BNT153 in combination.



#### RiboMabs

Our RiboMab product candidates, BNT141 and BNT142, are designed to encode secreted antibodies. These product candidates leverage our proprietary nucleoside-modified mRNA which is designed to minimize the immunomodulatory activity of the mRNA. RiboMab product candidates are formulated using liver-targeting LNPs for intravenous delivery. BNT141 encodes an IgG antibody which upon injection is secreted into the bloodstream. BNT142 is designed to encode a secreted bispecific antibody that targets CD3 and CLDN6.

- BNT141 We plan to start a Phase 1 clinical trial for BNT141 in the fourth quarter of 2021.
- BNT142 We now plan to start a Phase 1 clinical trial for BNT142 in the first half of 2022.

### CAR-T Cell Immunotherapy

**BNT211** is our CAR-T cell therapy for the treatment of CLDN6+ solid tumors. BNT211 targets CLDN6 and will initially be evaluated in combination with a CARVac that encodes CLDN6.

A first-in-human Phase 1/2 open-label dose escalation and dose expansion trial evaluating BNT211 in patients with Claudin-6-positive solid tumors is ongoing. The trial evaluates Claudin-6 CAR-T cells dosed as monotherapy and in combination with Claudin-6 CARVac.

At SITC, we intend to present data from this trial. Overall, as of July 23, 2021, Claudin-6 CAR-T cells dosed as monotherapy and in combination with Claudin-6 CARVac showed a favorable safety profile at doses tested with encouraging signs of efficacy. At the first tumor assessment six weeks after adoptive T-cell transfer for the five evaluable patients, four patients showed stable disease (SD) and one patient showed progressive disease (PD). Three patients showed initial tumor shrinkage per RECIST1.1.

#### *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.

At SITC, we intend to present preclinical data demonstrating NEO-STIM's ability to induce CD8+ and CD4+ T-cell responses using peripheral blood mononuclear cells from patients with ovarian cancer. These responses were polyfunctional, specific and have the capacity to degranulate.

### **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 thought to induce beneficial co-stimulation, promoting specific T cell activation, survival, proliferation and T cell effector functions. 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 1/2 dose escalation trial with multiple expansion cohorts in patients with solid tumors is ongoing.
  - At SITC, we intend to present exploratory pharmacodynamic analyses and potential biomarkers of response in an expansion cohort of patients with metastatic or unresectable NSCLC who had multiple lines of prior systemic therapy, including a checkpoint inhibitor. As of May 2021, 40 patients were enrolled and BNT311 elicited pharmacodynamic effects consistent with its proposed mechanism of action. In addition, relationships between disease control and PD-L1 tumoral expression, as well as time from last prior anti-PD-1 therapy were observed.
- A Phase 2 trial of BNT311 as monotherapy and in combination with pembrolizumab in patients with recurrent/refractory metastatic non-small cell lung cancer is planned to start in the fourth quarter of 2022.
- BNT312 (GEN1042) A Phase 1/2 trial with multiple expansion cohorts in patients with solid tumors is ongoing.

At SITC, we intend to report, in a mini-oral presentation, clinical data from the dose escalation part of the ongoing Phase 1/2 trial. Overall, the data demonstrated a favorable safety profile in patients with advanced solid tumors, as well as biologic and early antitumor activity. As of June 11, 2021, disease control was achieved in 25 of 49 (51%) patients, including two confirmed partial responses per RECIST1.1 in melanoma and neuroendocrine lung 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 (ES-SCLC) is ongoing.
  - At SITC we intend to present preliminary clinical data from the Phase 1/2 trial. Overall, as of July 1, 2021, BNT411 demonstrated an acceptable safety profile at all doses tested as a monotherapy and in combination with atezolizumab, carboplatin and etoposide. Pharmacodynamic signals were encouraging and showed a strong induction of type 1 interferon-dominated cytokines in line with the proposed mechanism-of-action. BNT411 has shown early signal of prolonging stable disease even in heavily pre-treated patients including post-anti-PD-1. Both pharmacodynamics and anti-tumor responses warrant further expansion in various indications either as a monotherapy or in combination with other standard-of-care treatments.

## **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. The first product candidate under the Genevant collaboration, BNT171, is being developed for Ornithine Transcarbamylase (OTC) Deficiency. Our mRNA replacement product candidate is associated with a favorable tolerability profile and good protein expression (in mice) and demonstrated phenotype rescue in a mouse disease model. Currently, we have placed the programs on hold in order to focus on other disease areas.

### **Financial Operations Overview**

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
(in millions, except per share data)	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenues				
Research & development revenues	€47.2	€59.7	€96.1	€113.4
Commercial revenues	6,040.1	7.8	13,348.1	23.5
Total revenues	€6,087.3	€67.5	€13,444.2	€136.9
Cost of sales	(1,211.4)	(6.8)	(2,328.3)	(18.3)
Research and development expenses	(260.4)	(227.7)	(677.7)	(388.0)
Sales and marketing expenses	(10.5)	(4.3)	(32.5)	(7.8)
General and administrative expenses	(68.2)	(23.5)	(154.9)	(58.1)
Other operating expenses	(26.4)	(0.4)	(27.3)	(1.3)
Other operating income	213.1	8.8	360.6	10.0
Operating income / (loss)	€4,723.5	€(186.4)	€10,584.1	€(326.6)
Finance income	26.6	0.5	51.4	1.1
Finance expenses	(81.9)	(21.1)	(301.0)	(24.5)
Interest expenses related to lease liabilities	(0.8)	(0.5)	(2.0)	(1.4)
Profit / (loss) before tax	€4,667.4	€(207.5)	€10,332.5	€(351.4)
	(4.450.4)	(2.5)	(D. DOG D)	(0.8)
Income taxes	(1,456.4)	(2.5)	(3,206.2)	(0.3)
Profit / (loss) for the period	€3,211.0	€(210.0)	€7,126.3	€(351.7)
Earnings per share				
Basic profit / (loss) for the period per share	€13.14	€(0.88)	€29.22	€(1.51)
Diluted profit / (loss) for the period per share	€12.35	€(0.88)	€27.46	€(1.51)

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, 2020.

# **Operational Impacts of COVID-19**

The impact of COVID-19 during the three and nine months ended September 30, 2021 and 2020 is explained in Note 2 to the unaudited interim condensed consolidated financial statements.



### **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 (worldwide collaboration outside of China) and Fosun Pharma (China).

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, 2020 as well as the notes to our audited consolidated financial statements included in that Annual Report.

### Comparison of the three and nine months ended September 30, 2021 and 2020

### Revenues

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

	Three mor Septem		Char	Change	
(in millions)	2021	2020	€ Chan	ige %	
Revenues					
Research & development revenues from collaborations	€47.2	€59.7	€(12.5)	(21)	
Pfizer Inc.	29.1	45.6	(16.5)	(36)	
Genentech Inc.	13.4	12.0	1.4	12	
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	_	1.7	(1.7)	(100)	
Other	4.7	0.4	4.3	n.m.	
Commercial revenues	€6,040.1	€7.8	€6,032.3	n.m.**	
COVID-19 vaccine revenues	6,021.6	_	6,021.6	_	
Sales to collaboration partners*	312.3	_	312.3	_	
Direct product sales to customers	1,350.8	_	1,350.8	_	
Share of collaboration partners' gross profit and sales milestones	4,358.5	_	4,358.5	_	
Other sales	18.5	7.8	10.7	137	
Total revenues	€6,087.3	€67.5	€6,019.8	n.m.	

<sup>\*</sup>Represents sales to our collaboration partners of products manufactured by us.

<sup>\*\*</sup> n.m. – not meaningful



	Nine mon	ths ended		
	Septem	September 30,		ıge
(in millions)	2021	2020	€	%
Revenues				
Research & development revenues from collaborations	€96.1	€113.4	€(17.3)	(15)
Pfizer Inc.	43.4	69.8	(26.4)	(38)
Genentech Inc.	39.3	38.9	0.4	1
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	7.4	2.6	4.8	185
Other	6.0	2.1	3.9	186
Commercial revenues	€13,348.1	€23.5	€13,324.6	n.m.
COVID-19 vaccine revenues	13,303.2	_	13,303.2	_
Sales to collaboration partners*	514.3	_	514.3	_
Direct product sales to customers	2,586.2	_	2,586.2	_
Share of collaboration partners' gross profit and sales milestones	10,202.7	_	10,202.7	_
Other sales	44.9	23.5	21.4	91
Total revenues	€13,444.2	€136.9	€13,307.3	n.m.

<sup>\*</sup>Represents sales to our collaboration partners of products manufactured by us.

For the three months ended September 30, 2021 compared to the three months ended September 30, 2020, our total revenues from contracts with customers increased by €6,019.8 million from €67.5 million to €6,087.3 million as well as by €13,307.3 million from €136.9 million during the nine months ended September 30, 2020 to €13,444.2 million during the nine months ended September 30, 2021. Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 80 countries worldwide, which resulted in a recognition of revenues from the sale of pharmaceutical products for the first time.

# Research & Development Revenues from Collaborations

For the three months ended September 30, 2021 compared to the three months ended September 30, 2020, research and development revenues from collaborations decreased by €12.5 million or 21% from €59.7 million to €47.2 million as well as by €17.3 million or 15% from €113.4 million in the nine months ended September 30, 2020 to €96.1 million in the nine months ended September 30, 2021. This was mainly due to a decrease in revenues from our COVID-19 vaccine collaboration with Pfizer which led to significant revenues during the three and nine months ended September 30, 2020 and progressed into the commercial phase leading to less research and development revenues during the three and nine months ended September 30, 2021. The decrease was partially offset by recognizing €29.1 million and €43.4 million research and development revenues, respectively during the three and nine months ended September 30, 2021 from deferred upfront payments based on progress incurred and development milestones achieved under our influenza collaboration with Pfizer. Additionally, upon receiving the authorization for emergency use and launching our COVID-19 vaccine in Hong Kong, development and regulatory milestones of €7.4 million have been achieved and recognized as research and development revenues from our collaboration with Fosun Pharma during the three months ended March 31, 2021. In comparison, during the three and nine months ended September 30, 2020, €1.7 million and €2.6 million research and development revenues were derived from a non-refundable upfront cash payment received as well as development milestones achieved under the collaboration, respectively.



#### Commercial Revenues

For the three months ended September 30, 2021 compared to the three months ended September 30, 2020, commercial revenues increased by €6,032.3 million from €7.8 million to €6,040.1 million as well as by €13,324.6 million from €23.5 million in the nine months ended September 30, 2020 to €13,348.1 million in the nine months ended September 30, 2021, mainly due to rapid increases in 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 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. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal.

Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and the COVID-19 vaccine is transferred, the vaccine is sold from one partner to the other. During the three and nine months ended September 30, 2021, we recognized €312.3 million and €514.3 million of revenues, respectively, from selling drug product batches manufactured by us to our partners.

By supplying our territories during the three and nine months ended September 30, 2021, we recognized €1,350.8 million and €2,586.2 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 September 30, 2021, €4,341.5 million gross profit share and €17.0 million of sales milestones have been recognized as revenues. During the nine months ended September 30, 2021, €9,769.9 million gross profit share and €432.8 million of sales milestones have been recognized as revenues. In order to determine our share of our collaboration partners' gross profits, we used certain information from the collaboration partners, including revenues from the sale of products, some of which is based on preliminary data shared between the partners and might vary once final data is available.

#### Cost of Sales

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

	Three mon Septem		Change	
(in millions)	2021	2020	€	%
Cost of sales				_
Cost of sales related to COVID-19 vaccine revenues	€1,194.8	_	€1,194.8	_
Cost related to other sales	16.6	6.8	9.8	144
Total cost of sales	€1,211.4	€6.8	€1,204.6	n.m.



	Nine mon Septem		Change	
(in millions)	2021	2020	€	%
Cost of sales				
Cost of sales related to COVID-19 vaccine revenues	€2,290.1	€—	€2,290.1	_
Cost related to other sales	38.2	18.3	19.9	109
Total cost of sales	€2,328.3	€18.3	€2,310.0	n.m.

For the three months ended September 30, 2021 to the three months ended September 30, 2020, our cost of sales increased by €1,204.6 million from €6.8 million to €1,211.4 million as well as by €2,310.0 million from €18.3 million for the nine months ended September 30, 2020 compared to €2,328.3 million during the nine months ended September 30, 2021, mainly due to recognizing cost of sales from our COVID-19 vaccine sales which included the share of gross profit that we owe our collaboration partner Pfizer based on our sales.

## Research and Development Expenses

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

	Three mon	ths ended			
	September 30,		Chan	Change	
(in millions)	2021	2020	€	%	
Research and development expenses					
Purchased services	€160.8	€143.1	€17.7	12	
Wages, benefits and social security expense	70.0	29.2	40.8	140	
Laboratory supplies	10.2	43.9	(33.7)	(77)	
Depreciation and amortization	8.5	7.2	1.3	18	
Other	10.9	4.3	6.6	153	
Total research and development expenses	€260.4	€227.7	€32.7	14	

Nine mont	hs ended		
Septem	ber 30,	Chang	e
2021	2020	€	%
€402.6	€201.1	€201.5	100
185.7	88.7	97.0	109
38.1	65.1	(27.0)	(41)
23.1	21.1	2.0	9
28.2	12.0	16.2	135
€677.7	€388.0	€289.7	75
	Septem 2021 €402.6 185.7 38.1 23.1 28.2	€402.6 €201.1 185.7 88.7 38.1 65.1 23.1 21.1 28.2 12.0	September 30,       Chang         2021       2020       €         €402.6       €201.1       €201.5         185.7       88.7       97.0         38.1       65.1       (27.0)         23.1       21.1       2.0         28.2       12.0       16.2

For the three months ended September 30, 2021 compared to the three months ended September 30, 2020, our research and development expenses increased by €32.7 million or 14% from €227.7 million to €260.4 million as well as by €289.7 million or 75% from €388.0 million during the nine months ended September 30, 2020 compared to €677.7 million during the nine months ended September 30, 2021, mainly due to an increase in research and development expenses from the BNT162 program, recorded as purchased services with respect to those expenses, which are initially incurred by Pfizer and subsequently charged to us under the collaboration agreement. The increase was further driven by an increase in wages, benefits and social security expenses following an increase in headcount, the



recognition of inventor compensation expenses as well as expenses incurred under share-based-payment arrangements.

### General and Administrative Expenses

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

	Three mon	ths ended		
	Septem	ber 30,	Chan	ge
(in millions)	2021	2020	€	%
General and administrative expenses				
Wages, benefits and social security expense	€22.5	€7.0	€15.5	221
Purchased services	14.6	6.7	7.9	118
Insurance premiums	14.7	1.9	12.8	674
IT and office equipment	6.3	2.1	4.2	200
Depreciation and amortization	1.8	1.2	0.6	50
Other	8.3	4.6	3.7	80
Total general and administrative expenses	€68.2	€23.5	€44.7	190

	Nine mon Septem		Chan	Change	
(in millions)	2021	2020	€	%	
General and administrative expenses					
Wages, benefits and social security expense	€53.9	€21.2	€32.7	154	
Purchased services	38.1	15.0	23.1	154	
Insurance premiums	23.4	3.5	19.9	569	
IT and office equipment	14.3	4.8	9.5	198	
Depreciation and amortization	4.4	3.9	0.5	13	
Other	20.8	9.7	11.1	114	
Total general and administrative expenses	€154.9	€58.1	€96.8	167	

For the three months ended September 30, 2021 compared to the three months ended September 30, 2020, our general and administrative expenses increased by €44.7 million or 190% from €23.5 million to €68.2 million as well as by €96.8 million or 167% from €58.1 million during the nine months ended September 30, 2020 compared to €154.9 million during the nine months ended September 30, 2021, mainly due to an increase in wages, benefits and social security expenses following an increase in headcount and expenses incurred under the share-based-payment arrangements, increased expenses



for purchased management consulting and legal services as well as higher insurance premiums caused by the increased business volume.

### **Other Operating Income and Expenses**

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

	Three mon	ths ended			
	Septem	September 30,		Change	
(in millions)	2021	2020	€	%	
Other result					
Other operating income	€213.1	€8.8	€204.3	n.m.	
Foreign exchange differences, net	190.3	_	190.3	_	
Government grants	20.9	8.5	12.4	146	
Other	1.9	0.3	1.6	533	
Other operating expenses	€(26.4)	€(0.4)	€(26.0)	n.m.	
Loss on derivative instruments at fair value through profit or loss	(24.9)	_	(24.9)	_	
Other	(1.5)	(0.4)	(1.1)	275	
Total other result	€186.7	€8.4	€178.3	n.m.	

Nine months ended					
	September 30,		Chan	Change	
(in millions)	2021	2020	€	%	
Other result					
Other operating income	€360.6	€10.0	€350.6	n.m.	
Foreign exchange differences, net	265.4	_	265.4	_	
Government grants	88.9	8.5	80.4	946	
Other	6.3	1.5	4.8	320	
Other operating expenses	€(27.3)	€(1.3)	€(26.0)	n.m.	
Loss on derivative instruments at fair value through profit or loss	(24.9)	_	(24.9)	_	
Other	(2.4)	(1.3)	(1.1)	85	
Total other result	€333.3	€8.7	€324.6	n.m.	

For the three months ended September 30, 2021 compared to the three months ended September 30, 2020, our total other result increased by €178.3 million from €8.4 to €186.7 million as well as by €324.6 million from €8.7 million during the nine months ended September 30, 2021 to €333.3 million during the nine months ended September 30, 2021, mainly due recording higher foreign exchange differences arising on operating items during the three and nine months ended September 30, 2021, respectively. The increase reflects the change in foreign exchange rate and relates to our U.S. dollar denominated trade receivables which specifically increased under our COVID-19 collaboration with Pfizer, U.S. dollar denominated trade payables as well as U.S. dollar denominated other financial liabilities which mainly relate to obligations incurred from our license agreements. The amounts were partly offset by recording the change in fair value of foreign exchange forward contracts that were entered into during the three months ended September 30, 2021 to manage some of our transaction exposures but were not designated as hedging instruments. Further, other operating income increased from government grants for which we became eligible during the year ended December 31, 2020 as



part of an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support our COVID-19 vaccine program.

### Finance Income / Expenses

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

	Three mon	ths ended		
	Septem	ber 30,	Cha	nge
(in millions)	2021	2020	€	%
Finance result				
Finance income	€26.6	€0.5	€26.1	n.m.
Foreign exchange differences, net	26.0	_	26.0	_
Interest income	0.6	0.5	0.1	20
Finance expenses	€(81.9)	€(21.1)	€(60.8)	288
Fair value adjustments of financial instruments measured at fair value	(81.5)	(6.3)	(75.2)	n.m.
Amortization of financial instruments	(0.4)	(8.0)	0.4	(50)
Foreign exchange differences, net	_	(14.0)	14.0	(100)
Interest expenses related to lease liabilities	€(0.8)	€(0.5)	€(0.3)	60
Total finance result	€(56.1)	€(21.1)	€(35.0)	166

	Nine months ended September 30,		Chan	Change	
(in millions)	2021	2020	1	%	
Finance result					
Finance income	€51.4	€1.1	€50.3	n.m.	
Foreign exchange differences, net	50.2	_	50.2	_	
Interest income	1.2	1.1	0.1	9	
Finance expenses	€(301.0)	€(24.5)	€(276.5)	n.m.	
Fair value adjustments of financial instruments measured at fair value	(293.4)	(6.3)	(287.1)	n.m.	
Amortization of financial instruments	(7.6)	(1.0)	(6.6)	660	
Foreign exchange differences, net	_	(17.2)	17.2	(100)	
Interest expenses related to lease liabilities	€(2.0)	€(1.4)	€(0.6)	43	
Total finance result	€(251.6)	€(24.8)	€(226.8)	915	

For the three months ended September 30, 2021 compared to the three months ended September 30, 2020, our total financial result decreased by €35.0 million from a negative financial result of €56.1 million as well as by €226.8 million from a negative financial result of €56.1 million as well as by €226.8 million from a negative financial result of €24.8 million during the nine months ended September 30, 2020 compared to a negative financial result of €251.6 million during the nine months ended September 30, 2021, mainly due to increased expenses arising from fair value measurement adjustments of the derivative embedded within the convertible note. The change in fair value was mainly driven by the increase in our share price and was recognized as finance expenses in our interim condensed consolidated statements of profit or loss. The effect was offset by recording positive foreign exchange differences



during the three and nine months ended September 30, 2021 compared to negative foreign exchange differences recorded during the three and nine months ended September 30, 2020.

#### **Income Taxes**

For the nine months ended September 30, 2021, income taxes are calculated based on the best estimate of the weighted average annual income tax rates expected for the full financial year (estimated annual effective income tax rate) on ordinary income before tax plus the tax effect of any discrete items. Our effective income tax rate was approximately 31% for the nine months ended September 30, 2021. Current income taxes were recognized with respect to the German tax group. For the German entities, the estimated annual effective income tax rate anticipates the full use of the tax loss carry forwards resulting in an expense of the deferred tax assets over the fiscal year 2021. Consequently, during the three and nine months ended September 30, 2021, a proportionate amount of the deferred tax assets related to the tax loss carryforward was utilized. The change in deferred tax assets was partly compensated by deferred tax effects of identified discrete items. As of September 30, 2021, 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.

During the three and nine months ended September 30, 2020, we had accumulated tax losses with respect to corporate tax and trade tax. Deferred tax assets on tax losses had not been recognized as there was not sufficient probability in terms of IAS 12 that there would be future taxable profits available against which the unused tax losses could be utilized. The accumulated tax losses related to Germany and the United States. There was no expiration date for any of the accumulated tax losses under German or U.S. tax law.

### **Related Party Transactions**

Related party transactions that occurred during the three and nine months ended September 30, 2021 and 2020 are explained in Note 15 to the unaudited interim condensed consolidated financial statements.

## **Critical Accounting Policies and Use of Estimates**

Our unaudited interim condensed consolidated financial statements for the three and nine months ended September 30, 2021 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, 2020 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 the determination of the useful lives of non-current assets, 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 are discussed further in Item 5 of our Annual Report on Form 20-F as of and for the year ended December 31, 2020 as well as Note 2.3 to our audited consolidated financial statements included in that Annual Report 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**

From time to time, we may be involved in legal proceedings arising out of the normal course and conduct of our business. As of September 30, 2021, certain proceedings were pending or threatened against us or our subsidiaries, mainly related to purported obligations arising out of use or alleged use of third party intellectual property. Our best estimate of potential outflow of economic resources from such proceedings amounts to €188.2 million, which is included in current provisions in our unaudited interim condensed consolidated statements of financial position as of September 30, 2021. 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.

# Liquidity and Capital Resources

#### Overview

Historically we have funded our operations primarily from private placements of our ordinary shares, issuance of ordinary shares (including in the form of American Depositary Shares, or ADSs) in connection with our initial public offering in 2019 and our global offering in 2020, generation of proceeds under our collaboration agreements, secured bank loans and issuance of a convertible note. Since December 2020, our COVID-19 vaccine has been fully approved, granted conditional marketing authorization, or approved or authorized for emergency or temporary use in over 80 countries worldwide. Consequently, we have progressed from recognizing revenues primarily from research and development activities to recognizing revenues and profits from sales of our first commercial product. These will now be used to finance our operations including research and development activities and further expansions. We intend to invest the proceeds we generate from sales of our COVID-19 vaccine to accelerate the maturation of our technologies as well as of our oncology and infectious disease pipeline including the expansion into additional therapeutic areas, such as autoimmunity, allergy, regenerative medicine and inflammatory diseases. As of September 30, 2021, we had cash and cash equivalents of €2,392.7 million. In addition, trade receivables remained outstanding mainly due to the contractual settlement of the gross profit share under our COVID-19 collaboration with Pfizer as described in Note 10 to the unaudited interim condensed consolidated financial statements. Those trade receivables include the gross profit share for the second quarter of 2021 (as defined by the contract) for which the settlement payment was received from our collaboration partner subsequent to the end of the reporting period in October 2021 and further improved our cash position.

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



We maintain two secured loans with Deutsche Bank AG, or Deutsche Bank, to finance the buildouts of our JPT Peptide Technologies GmbH facility and Innovative Manufacturing Services GmbH facility. Our €10.0 million secured credit facility, entered into with Deutsche Bank by our subsidiary BioNTech Innovative Manufacturing Services GmbH, bears interest at a rate of 2.15% and matures on December 30, 2027. The loan is repayable in equal quarterly installments of €0.3 million commencing on June 30, 2020. As of September 30, 2021, the full amount under this facility is drawn down and is already subject to repayments. Our €9.5 million secured credit facility, entered into with Deutsche Bank by our subsidiary JPT Peptide Technologies GmbH, bears interest at a rate of 2.08% and matures on September 30, 2028. The loan is repayable by quarterly installments of €0.3 million commencing on September 30, 2020. As of September 30, 2021, the full amount under this facility is drawn down and as well already subject to repayments. Each of these facilities is secured by liens over our property.

In December 2019, we signed a financing arrangement with the European Investment Bank, or the EIB, to partially support the implementation of certain technical aspects of our investment in the development of patient-tailored therapeutic vaccines for cancer in Germany, or the Investment. Under this arrangement, the EIB has agreed to provide us with a credit in an amount of up to €50.0 million to partially finance the Investment, provided that the amount of credit does not exceed 50% of the cost of the Investment. The credit consists of (i) a term loan in the amount of €25.0 million that may be drawn in a single tranche upon the achievement of certain milestone events, not all of which have been achieved (Credit A), and (ii) a term loan in the amount of €25.0 million that may be drawn in a maximum of four tranches each of which must be for a minimum of €5.0 million or the balance of the remaining facility (Credit B). Tranches under Credit B may only be drawn after Credit A has been drawn down and upon the achievement of certain milestone events. Each tranche under Credit A and Credit B must be repaid within six years from the date on which the tranche is disbursed to us. The financing arrangement is to be secured by way of liens over certain of our property. As of September 30, 2021, there has been no draw down.

In June 2020, we entered into an agreement with the EIB for a €100.0 million credit facility to partially support the development of BNT162 and fund expansion of our manufacturing capacity to provide worldwide supply of BNT162 in response to the COVID-19 pandemic. Under this arrangement, outstanding as of September 30, 2021, we have drawn down €50.0 million (Credit A). The additional €50.0 million (Credit B) will not be drawn down. The financing arrangement was secured by way of liens over certain of our property. Interest is payable on the outstanding balance of Credit A at the cash interest fixed rate of 1% per annum quarterly in arrears, plus deferred interest at fixed rate of 2.5% per annum. The nominal amount must be repaid on December 21, 2026.

On July 27, 2020, we offered 5,500,000 ADSs each representing one of our ordinary shares, in a public, underwritten offering on the Nasdaq Global Select Market at a public offering price of \$93.00 per ADS, or the Underwritten Offering. 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.

In September 2020, we became eligible to receive up to €375.0 million in funding from an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the



BMBF) to support our COVID-19 vaccine program, BNT162, of which €326.9 million have been received already. The BMBF funding was granted to accelerate our vaccine development and to upscale manufacturing capabilities in Germany. The funding will also compensate further costs that incur since the COVID-19 vaccine continues to be tested in clinical trials and because study participants will continue to be followed for two years to continue evaluating safety and efficacy.

In November 2020, we entered into a sales agreement, or the Sales Agreement, with Jefferies LLC and SVB Leerink LLC, as sales agents, to establish an at-the-market offering program, pursuant to which we may sell, from time to time, ADSs representing ordinary shares for aggregate gross proceeds of up to \$500.0 million. During the year ended December 31, 2020, we sold 735,490 ADSs, each representing one of our ordinary shares and previously held in treasury, under the Sales Agreement for aggregate gross proceeds of \$92.9 million (€76.5 million). In addition, during the nine months ended September 30, 2021, we sold 995,890 ADSs, each representing one of our ordinary shares that had previously been held in treasury, under the Sales Agreement for aggregate gross proceeds of \$200.0 million (€163.6 million). As of September 30, 2021, the remaining capacity under the Sales Agreement is \$207.1 million.

### **Cash Flow**

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

	Three months ended September 30,			Nine months ended September 30,	
(in millions)	2021	2020	2021	2020	
Net cash flows from (used in):					
Operating activities	€1,500.8	€(192.5)	€1,089.2	€(262.7)	
Investing activities	(41.1)	(20.3)	(99.2)	(45.0)	
Financing activities	(5.3)	630.2	143.1	778.4	
Total cash inflow	€1,454.4	€417.4	€1,133.1	€470.7	

### **Operating Activities**

We derive cash flows from operations primarily from collaborations, the sale of products and services rendered. Our cash flows from operating activities are significantly influenced by our use of cash for operating expenses and working capital to support the business. Historically we have experienced negative cash flows from operating activities as we have invested in the development of our technologies and manufacturing capabilities, as well as in our clinical and preclinical development of our product candidates. During the three and nine months ended September 30, 2021, our cash flows from operating activities became positive, as we received the settlement payment of our gross profit share of the first quarter of 2021 from our collaboration partner. As described in Note 10 to the unaudited interim condensed consolidated financial statement, 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 October 2021, we further improved our cash position as we received the settlement payment of our gross profit share for the second quarter of 2021 (as defined by the contract).

Net cash from operating activities for the three months ended September 30, 2021 was €1,500.8 million, comprising a profit before tax of €4,667.4 million, negative non-cash adjustments of €65.1 million, and a net negative change in assets and liabilities of €3,099.0 million. The net negative change in assets and liabilities was primarily due to an increase in trade receivables related to our COVID-19 collaboration with Pfizer, as previously discussed in this Quarterly Report.



Net cash used in operating activities for the three months ended September 30, 2020 was €192.5 million, comprising a loss before tax of €207.5 million, positive non-cash adjustments of €16.2 million, and a net negative change in assets and liabilities of €1.0 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net positive change in assets and liabilities was primarily based on the upfront payment received from our COVID-19 collaboration with Pfizer, which was recorded as contract liability and subsequently started to be recognized as revenue.

Net cash from operating activities for the nine months ended September 30, 2021 was €1,089.2 million, comprising a profit before tax of €10,332.5 million, positive non-cash adjustments of €33.6 million, and a net negative change in assets and liabilities of €9,270.8 million. Non-cash items primarily included finance expenses related to our convertible bond fair value update which were offset by net foreign exchange differences and movements in government grants. The net negative change in assets and liabilities was primarily due to an increase in trade receivables related to our COVID-19 collaboration with Pfizer, as previously discussed in this Quarterly Report.

Net cash used in operating activities for the nine months ended September 30, 2020 was €262.7 million, comprising a loss before tax of €351.4 million, positive non-cash adjustments of €50.6 million, and a net positive change in assets and liabilities of €39.1 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. Also on a year-to-date basis, the net positive change in assets and liabilities was primarily based on the increase in contract liabilities and trade payables.

### **Investing Activities**

Net cash used in investing activities for the three months ended September 30, 2021 was €41.1 million, of which €40.5 million was attributable to the purchase of property, plant and equipment with respect to our production as well as research and development facilities.

Net cash used in investing activities for the three months ended September 30, 2020 was €20.3 million, of which €19.3 million were attributable to the purchase of property, plant and equipment.

Net cash used in investing activities for the nine months ended September 30, 2021 was €99.2 million, of which €88.1 million was attributable to the purchase of property, plant and equipment.

Net cash used in investing activities for the nine months ended September 30, 2020 was €45.0 million, of which €40.7 million was attributable to the purchase of property, plant and equipment.

# Financing Activities

Our primary financing activities consist of issuances of share capital, proceeds from bank loans and payments of lease liabilities.

During the nine months ended September 30, 2021, we generated cash from financing activities of €143.1 million, primarily from the sale of treasury shares under the at-the-market offering program net of transaction cost, as previously discussed in this Quarterly Report.

During the three and nine months ended September 30, 2020, we generated cash from financing activities of €630.2 million and €778.4 million, respectively, primarily from proceeds from the issuance of shares received from Fosun Pharma via Fosun Industrial Co., Limited, Hong Kong and Pfizer, our Global Offering as well as the June 2020 Private Placement as previously described in this Quarterly Report, net of transaction costs.



### **Operation and Funding Requirements**

Historically, we have incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. As of December 31, 2020, our accumulated losses amounted to €409.6 million. Those have been compensated by the profit generated during the nine months ended September 30, 2021 and our retained earnings as of September 30, 2021 amounted to €6,716.7 million.

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

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our existing or additional 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 2021 is related to CMO purchase obligations amounting to €230.8 million and



lease payments amounting to €10.1 million. Further, we have purchase obligations with an amount of €160.1 million and lease payment obligations of €146.5 million for the years 2022 and beyond.

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

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

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

# 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, 2021. 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.