

**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 AUGUST 2022**

**COMMISSION FILE NUMBER 001-39081**

**BioNTech SE**

(Translation of registrant's name into English)

**An der Goldgrube 12  
D-55131 Mainz  
Germany  
+49 6131-9084-0**

(Address of principal executive offices)

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

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

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

**DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K**

On August 8, 2022, BioNTech SE (the “Company”) issued a press release announcing its second quarter 2022 financial results and corporate update and details of a conference call to be held at 8:00 am EST on August 8, 2022 to discuss the results. The press release and the conference call presentation are attached as Exhibits 99.1 and 99.2, respectively, and incorporated by reference herein.

The information contained in Exhibits 99.1 and 99.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly set forth by specific reference in such a filing.

**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: August 8, 2022

**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<a href="#">BioNTech Announces Second Quarter 2022 Financial Results and Corporate Update</a>
99.2	<a href="#">Second Quarter 2022: Corporate Update and Financial Results</a>

## BioNTech Announces Second Quarter Financial Results and Corporate Update

- Second quarter revenues of €3.2 billion<sup>1</sup>, net profit of €1.7 billion and fully diluted earnings per share of €6.45 (\$6.87<sup>2</sup>) as well as first half 2022 revenues of €9.6 billion, net profit of €5.4 billion and fully diluted earnings per share of €20.69 (\$18.92<sup>2</sup>)
- Reiterates BioNTech COVID-19 2022 vaccine revenue guidance of €13 billion to €17 billion
- Preparing for potential launch of two variant-adapted bivalent COVID-19 vaccines containing the original strain and Omicron BA.1 or BA.4/5 spike protein as recommended by U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and other regulators; expect to be able to begin delivering Omicron-adapted vaccines as early as October 2022, subject to regulatory approval
- Signed agreement with U.S. government to provide additional 105 million doses of COVID-19 vaccine with option for another 195 million doses
- Received U.S. Emergency Use Authorization (EUA) for COVID-19 vaccine in children six months through four years of age and for a booster dose in children five through 11 years of age
- Continued pipeline expansion with initiation of two new Phase 1 clinical trials (BNT116 and BNT142) to 18 clinical-stage oncology programs in 23 ongoing clinical trials; BNT211, first-in-class CAR-T program targeting CLDN6, receives EMA Priority Medicines (PRIME) designation
- Commenced construction of first BioNTainer mRNA vaccine manufacturing facility in Africa

Conference call and webcast scheduled for August 8, 2022, at 8:00 am ET (2:00 pm CET)

**MAINZ, Germany, August 8, 2022 (GLOBE NEWSWIRE)** -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or the "Company") today reported financial results for the three and six months ended June 30, 2022 and provided an update on its corporate progress.

"In the first half of 2022, we achieved important milestones as we have further strengthened our COVID-19 vaccine leadership and have expanded our broad pipeline and accelerated its maturation. Our COVID-19 product pipeline includes variant-adapted and next-generation vaccine candidates, aimed at prolonged and broad protection," said Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech. "In oncology, we have presented encouraging data updates for our individualized mRNA cancer vaccine candidate BNT122 in pancreatic cancer and our novel CAR-T cell therapy candidate BNT211 in solid tumors, leading to our first PRIME designation by EMA. We drive toward the preparation of registrational trials as well as the delivery of our first BioNTainers to Africa, aiming to provide access to novel medicines."

#### Key Second Quarter Financial Results

in millions, except per share data	Second Quarter 2022	Second Quarter 2021	First Half 2022	First Half 2021
Total Revenues <sup>1</sup>	€3,196.5	€5,308.5	€9,571.1	€7,356.9
Net Profit	€1,672.0	€2,787.2	€5,370.8	€3,915.3
Diluted Earnings per Share	€6.45	€10.77	€20.69	€15.14

"With our strong performance year to date, we believe to be well on track to achieve our previous financial guidance for the ongoing financial year," said Jens Holstein, CFO of BioNTech. "With our initiatives around variant adapted COVID-19 vaccine candidates, we expect an uptake in demand in our key markets in the fourth quarter of 2022, subject to regulatory approval. We will continue to invest heavily in research and development in 2022 and beyond and remain focused on furthering our oncology pipeline as well as driving our leadership in COVID-19 vaccine development. We are driving toward potential launches of multiple innovative products to address diseases with high unmet medical need in the coming three to five years."

#### Outlook for the 2022 Financial Year Reiterated

The Company reiterates its prior 2022 financial year outlook, which includes the following components:

*BioNTech COVID-19 Vaccine Revenues for the 2022 Financial Year:*

Estimated BioNTech COVID-19 vaccine revenues for the full 2022 financial year	€13 billion - €17 billion
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This revenue estimate reflects expected revenues related to BioNTech's share of gross profit from COVID-19 vaccine sales in the collaboration partners' territories, from direct COVID-19

vaccine sales to customers in BioNTech's territory and expected revenues generated from products manufactured by BioNTech and sold to collaboration partners.

*Planned 2022 Financial Year Expenses and Capex:*

R&D expenses	€1,400 million - €1,500 million
SG&A expenses	€450 million - €550 million
Capital expenditures	€450 million - €550 million

The ranges reflect current base case projections and do not include potential effects caused by or driven from additional collaborations or potential merger and acquisition transactions.

*Estimated 2022 Financial Year Tax Assumptions:*

BioNTech Group estimated annual effective income tax rate	~28%
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**Detailed Second Quarter Financial Results**

- **Revenues:** Total revenues reported were €3,196.5 million<sup>1</sup> for the three months ended June 30, 2022, compared to €5,308.5 million<sup>1</sup> for the comparative prior year period. For the six months ended June 30, 2022, total revenues were €9,571.1 million<sup>1</sup>, compared to €7,356.9 million<sup>1</sup> for the comparative prior year period. BioNTech believes the development of the pandemic remains dynamic, causing a re-phasing of orders and with this leading to fluctuations in quarterly revenues. This revenue fluctuation caused by the re-phasing of orders is expected to remain over the rest of the financial year with an uptake in demand in key markets in the fourth quarter of 2022 related to the Omicron-adapted bivalent vaccine, subject to regulatory approval.

Under the collaboration agreements, territories have been allocated between BioNTech, Pfizer Inc. ("Pfizer") and Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("Fosun Pharma") based on marketing and distribution rights. During the three months ended June 30, 2022, BioNTech's commercial revenues included €1,987.4 million<sup>1</sup> gross profit share (€3,923.7 million<sup>1</sup> gross profit share and €168.6 million<sup>1</sup> sales milestones during the comparative prior year period). For the six months ended June 30, 2022, BioNTech's commercial revenues included €6,574.2 million<sup>1</sup> gross profit share (€5,428.4 million<sup>1</sup> gross profit share and €415.8 million<sup>1</sup> sales milestones during the comparative prior year period). BioNTech's share of the collaboration partners' gross profit is based on COVID-19 vaccine sales in Pfizer's and Fosun Pharma's territories and represents a net figure.

In addition, during the three and six months ended June 30, 2022, BioNTech recognized €557.0 million and €1,720.1 million of direct COVID-19 vaccine sales to customers in BioNTech's territory, Germany and Turkey, as well as €608.3 million and €1,211.5 million from sales of products manufactured by BioNTech for its collaboration partners. During the comparative prior year periods, €1,035.6 million and €1,235.4 million were recognized from sales to customers in BioNTech's territory as well as €138.1 million and €202.0 million from sales of products manufactured by BioNTech for its collaboration partners, respectively.

- *Cost of Sales:* Cost of sales were €764.6 million for the three months ended June 30, 2022, compared to €883.8 million for the comparative prior year period. For the six months ended June 30, 2022, cost of sales were €2,058.7 million, compared to €1,116.9 million for the comparative prior year period. The change in cost of sales resulted mainly from the recognition of costs related to BioNTech's COVID-19 vaccine revenues which included the share of gross profit owed to its collaboration partner Pfizer. In addition, cost of sales was impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with contract manufacturing organizations.
- *Research and Development Expenses:* Research and development expenses were €399.6 million for the three months ended June 30, 2022, compared to €201.1 million for the comparative prior year period. For the six months ended June 30, 2022, research and development expenses were €685.4 million, compared to €417.3 million for the comparative prior year period. The increase was mainly due to recognizing costs related to the manufacturing of pre-launch Omicron vaccine candidates as research and development expenses in the period incurred and an increase in headcount.
- *General and Administrative Expenses:* General and administrative expenses were €130.0 million for the three months ended June 30, 2022, compared to €47.8 million for the comparative prior year period. For the six months ended June 30, 2022, general and administrative expenses were €220.8 million, compared to €86.7 million for the comparative prior year period. The increase was mainly due to recognizing increased expenses for purchased external services as well as an increase in headcount.
- *Income Taxes:* Income taxes were accrued with an amount of €647.3 million for the three months ended June 30, 2022, compared to €1,235.6 million for the comparative prior year period. For the six months ended June 30, 2022, income taxes were accrued in an amount of €1,966.6 million, compared to €1,749.8 million for the comparative prior year period. The derived effective income tax rate for the six months ended June 30, 2022 was 26.8%.



- *Net Profit:* Net profit was €1,672.0 million for the three months ended June 30, 2022, compared to €2,787.2 million for the comparative prior year period. For the six months ended June 30, 2022, net profit was €5,370.8 million, compared to €3,915.3 million for the comparative prior year period.
- *Cash, Cash Deposits and Trade Receivables:* As of June 30, 2022, cash and cash equivalents were €9,334.8 million. In addition, trade receivables remained outstanding as of June 30, 2022, mainly due to the contractual settlement of the gross profit share under the COVID-19 collaboration with Pfizer, which has a temporal offset of more than one calendar quarter. As Pfizer's fiscal quarter for subsidiaries outside the United States differs from BioNTech's financial reporting cycle, it creates an additional time lag between the recognition of revenues and the payment receipt. Trade receivables for example include the gross profit share for the first quarter of 2022 (as defined by the contract) for which the settlement payment was received subsequent to the end of the reporting period in July 2022. Of the total trade receivables of €10,382.9 million which were outstanding as of June 30, 2022, €5,581.1 million were received in cash as of July 15, 2022. The total cash and cash equivalents amounted to €14,884.5 million as of July 15, 2022.
- *Shares Outstanding:* Shares outstanding as of June 30, 2022, were 242,685,401.

The full interim unaudited condensed consolidated financial statements can be found in BioNTech's Report on Form 6-K, filed today with the SEC and available at <https://www.sec.gov/>.

<sup>1</sup>BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in BioNTech's Annual Report on Form 20-F for the year ended December 31, 2021 as well as its Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

<sup>2</sup>Calculated applying the average foreign exchange rates for the three and six months ended June 30, 2022, respectively as published by the German Central Bank (*Deutsche Bundesbank*).

## **Second Quarter 2022 and Subsequent Program Updates**

### ***COVID-19 Vaccine Program – BNT162***

BioNTech and Pfizer continue to build on their global COVID-19 vaccine leadership with further label expansions as well as development of a diverse pipeline of follow-on and next generation vaccine candidates. Subject to regulatory approval, Omicron-adapted vaccine launches and clinical trial starts, including trials for next generation vaccines, are expected to begin in the second half of 2022.

### ***Commercial updates***

As of the beginning of July 2022, BioNTech and Pfizer have delivered in total more than 3.6 billion doses to 180 countries or territories. The companies have signed orders for approximately 2.5 billion doses for 2022, and, in the first half of the year, invoiced approximately 1.2 billion doses. The cumulative share of doses<sup>3</sup> increased in the period between January 1, 2022 to July 20, 2022 from approximately 52% to 63% in all markets<sup>4,5</sup>. In developed markets<sup>6</sup>, the share of doses for the same time period increased from approximately 59% to 68%.

As part of BioNTech and Pfizer's 2-billion-doses-pledge to support equitable access to medicines, the companies have delivered more than 1.5 billion doses of the companies' COVID-19 vaccine in total to low- and middle-income countries.

- In May 2022, BioNTech and Pfizer announced an agreement with the European Commission, or EC, to amend their originally agreed contractual delivery schedules for the COVID-19 vaccine. The amendment rephases planned deliveries to help support the EC and Member States' ongoing immunization programs and is aligned to the companies' commitment to working collaboratively to identify pragmatic solutions to address the evolving pandemic needs. Doses scheduled for delivery in June through August 2022 will now be delivered in September through to the fourth quarter of 2022. This change of delivery schedule did not impact the companies' full-year 2022 revenue guidance or the full-year commitment of doses to be delivered to EC Member States in 2022.
- In June 2022, BioNTech and Pfizer entered into a new vaccine supply agreement with the U.S. government. Under the terms of the agreement, the U.S. government will receive 105 million doses, including 30 µg, 10 µg and 3 µg doses, potentially including the Omicron-adapted adult vaccine, subject to granting of U.S. FDA Emergency Use Authorization, or EUA. The U.S. government also has the option to purchase up to an additional 195 million doses, bringing the potential total to 300 million vaccine doses. Delivery of the vaccine doses is scheduled to begin in late summer 2022 and will continue into the fourth quarter of this year. The U.S. government will pay the two companies \$3.2 billion after receiving the first 105 million doses of vaccine.

<sup>3</sup> Market share data includes only those markets in which Pfizer operates and that report market share data

<sup>4</sup> Incl. all markets in Developed Markets (5) plus Emerging Markets (Argentina, Chile, Ecuador, Hong Kong, Nepal, Peru, South Africa, Uruguay)

<sup>5</sup> Includes the U.S., EU/EEA, other Int'l Developed markets (Japan, South Korea, Switzerland, Ukraine)

<sup>6</sup> Starting date of January 1, 2022 for this data set is from Q1 2022 earnings presentation

### *Manufacturing updates*

BioNTech and Pfizer's global COVID-19 vaccine supply chain and manufacturing network includes 20 manufacturing facilities spanning four continents.

- BioNTech and Pfizer have started to manufacture bivalent Omicron BA.1- and BA.4/5-adapted vaccines. Pending regulatory approval, the companies expect to deliver the updated vaccines as soon as October 2022 and plan to supply both vaccines in time for fall booster campaigns.

*Clinical development and regulatory updates*

BioNTech and Pfizer's COVID-19 vaccine has received multiple regulatory approvals including expansions of authorizations for booster and pediatric vaccinations.

- In May 2022, the U.S. FDA expanded the EUA to include a booster dose in children five through 11 years of age. The EUA was granted based on data from the Phase 2/3 clinical trial demonstrating a high immune response following a booster dose after completion of the primary series of BNT162b2 in this age group. Data demonstrated that a booster dose given approximately six months after the second dose of the 10 µg primary series increased neutralizing antibodies by six-fold against the SARS-CoV-2 wild-type strain compared to levels observed after two doses. The vaccine was well tolerated with no new safety signals observed.

The data were also submitted to the EMA for a variation of the Conditional Marketing Authorization (CMA) in the European Union to include a booster dose in this age group and are being filed with other regulatory authorities worldwide.

- In June 2022, the U.S. FDA amended the EUA to include children six months of age through four years of age. The EUA was granted based on safety, immunogenicity and vaccine efficacy topline data from a Phase 2/3 study evaluating a third 3 µg dose in 1,678 children in this age group. Following a third dose in this age group, the vaccine elicited a strong immune response with a favorable safety profile similar to placebo. The vaccine met all immunobridging criteria required for an EUA, based on an immunogenicity analysis conducted on a subset of study participants one month following the third dose in this age group, compared to the second dose in the 16- to 25-year-old population. Further data on this age group will be shared in the coming weeks.

The data were also submitted to the EMA for a line extension of the CMA in the European Union in this age group and are expected to be filed with other regulatory authorities in the coming weeks.

- In July 2022, the U.S. FDA also approved the supplemental Biologics License Application, or sBLA, to include individuals 12 through 15 years of age in the

approved indication, expanding licensure of the vaccine to this age group, which was previously included under U.S. EUA.

BNT162b2 has demonstrated a high level of protection against several variants of concern, including Alpha, Beta, and Delta and continues to offer protection against severe disease, hospitalization and death for circulating Omicron-variants. BioNTech and Pfizer continue to monitor protection offered by BNT162b2 against emerging SARS-CoV-2 variants.

The companies are currently evaluating variant-adapted COVID-19 vaccines, including monovalent and bivalent vaccines directed against Omicron subvariants and other strains of SARS-CoV-2. Data from these studies were presented to regulatory agencies in June and July 2022, which supported the regulators' discussions for the development of Omicron-adapted vaccines and definition of the most appropriate regulatory pathways. BioNTech and Pfizer will continue to submit available data to regulatory authorities worldwide. In June 2022, the U.S. FDA advised vaccine manufacturers to develop modified vaccines that add an Omicron BA.4/5 spike protein encoding component to the current vaccine composition to create a bivalent booster vaccine.

- In June 2022, BioNTech and Pfizer announced positive safety, tolerability and immunogenicity data for two Omicron BA.1-adapted vaccine candidates, including data on a monovalent and a bivalent vaccine candidate combining the existing vaccine and a vaccine candidate targeting the Omicron variant BA.1 spike protein.

Results from this Phase 2/3 trial in 1,234 subjects aged 56 years or older show that booster doses of 30 µg and 60 µg of both Omicron BA.1-adapted monovalent and bivalent vaccine candidates elicit significantly higher neutralizing antibody responses against Omicron BA.1 compared to BNT162b2, consistent with the regulatory requirements for superiority. The monovalent Omicron-adapted vaccine 30 µg and 60 µg achieved the regulatory requirement of super superiority.

One month after administration, a booster dose of the Omicron BA.1-adapted monovalent candidates increased neutralizing geometric mean titers, or GMTs, against Omicron BA.1 13.5- and 19.6-fold above pre-booster dose levels. Booster vaccination with the bivalent Omicron BA.1-adapted vaccine candidates resulted in a 9.1- and 10.9-fold increase in neutralizing GMTs against Omicron BA.1, respectively. Both vaccine candidates demonstrated a favorable safety and tolerability profile similar to BNT162b2.

In preclinical studies in mice, both monovalent and bivalent Omicron BA.4/5-adapted vaccine candidates were observed to substantially increase Omicron neutralization responses against all Omicron sublineages, including BA.1, BA.4/5 and the wild-type strain.

Given the FDA guidance, BioNTech and Pfizer plan to distribute a bivalent vaccine encoding for the spike protein of the original strain as well as of the BA.4/BA.5 Omicron sublineage to be used as a booster, subject to regulatory authorizations. In addition, BioNTech and Pfizer plan to initiate a clinical trial in August 2022 to generate immunogenicity and safety data for an Omicron BA.4/5-adapted bivalent vaccine.

- In July 2022, BioNTech and Pfizer completed the submission to the EMA for an Omicron-adapted bivalent COVID-19 vaccine, based on the BA.1 sublineage, for individuals 12 years of age and older. This application follows guidance from the EMA to move forward with introducing an Omicron-adapted bivalent vaccine candidate to address the continued evolution of the SARS-CoV-2 virus. The companies are preparing to initiate the submission of pre-clinical and Chemistry, Manufacturing and Controls (CMC) data for a bivalent vaccine candidate encoding Omicron BA.4/5 spike protein to EMA beginning in August 2022.
- In a recent preprint publication (bioRxiv. Omicron BA.2 breakthrough infection enhances cross-neutralization of BA.2.12.1 and BA.4/BA.5; August 2022) BioNTech reported data demonstrating that sera from triple mRNA-vaccinated individuals who experienced Omicron sublineage BA.2 breakthrough infection demonstrated broad neutralizing activity against variants of concern, including Omicron BA.2 derived variants BA.2.12.1, BA.4/BA.5. In addition, the data showed that neutralization of BA.2 and BA.4/BA.5 sublineages by BA.2 convalescent sera is driven to a large extent by antibodies targeting the N-terminal domain, or NTD, of the spike glycoprotein. In comparison, neutralization by Omicron BA.1 convalescent sera depends on antibodies targeting the receptor binding domain. These findings suggest that Omicron BA.2 triggers significant NTD specific recall responses in vaccinated individuals, which enhances the neutralization of BA.4/BA.5 sublineages. Given the current epidemiology with a predominance of BA.2 derived sublineages like BA.4/BA.5 and rapidly ongoing evolution, these findings will increase current understanding on Omicron immune escape mechanisms and the effects of immunization on variant cross-neutralization, and thus will help guide further vaccine development.

BioNTech and Pfizer are investigating and identifying novel next-generation vaccine approaches to maintain a broad and longer lasting immune response and high levels of protection against SARS-CoV-2 as it evolves. The long-term strategy takes a multipronged approach devised to develop and test multiple engineered vaccine candidates to achieve the goal of delivering a pan-SARS-CoV-2-type vaccine that will ultimately help to better manage upcoming variants of concern. The companies expect that scientific data derived from those

different approaches will support the vaccine candidate selected for evaluation in a pivotal trial.

BioNTech and Pfizer plan to test several novel vaccine constructs that have been engineered to engage multiple arms of the immune system, including antibodies and T cells. These next-generation vaccine approaches the companies plan to evaluate include an enhanced SARS-CoV-2 spike antigen and a T cell enhancing vaccine candidate.

- In July 2022, as a first step of BioNTech and Pfizer's long-term strategy of developing a next-generation COVID-19 vaccine, a randomized, active-controlled, observer-blind, Phase 2 study was initiated to evaluate the safety, tolerability, and immunogenicity of a 30 µg dose of an enhanced spike antigen vaccine candidate. This first of multiple candidates with an engineered design, BNT162b5, consists of RNAs encoding for a sequence-modified spike protein of the SARS-CoV-2 ancestral strain and the Omicron BA.2 variant. The enhanced prefusion spike protein in BNT162b5 has been modified with the aim to increase the magnitude and breadth of antibody neutralization response to better protect against COVID-19.
- Additionally, in the second half of 2022, BioNTech and Pfizer anticipate progressing T cell enhancing and pan-SARS-CoV-2 vaccine candidates into the clinic.

#### ***Additional Infectious Disease Programs***

BioNTech is on track to initiate two first-in-human clinical trials in the second half of 2022 that include mRNA-based product candidates designed to address shingles (in collaboration with Pfizer), and herpes simplex virus type 2 (HSV 2; BNT163).

First-in-human clinical trials for tuberculosis (BNT164) and malaria (BNT165) are now expected to start in the second half of 2022 or early 2023.

#### ***Influenza Vaccine Program***

BNT161 - BioNTech is collaborating with Pfizer to develop an influenza vaccine based on BioNTech's suite of mRNA platforms.

- A Phase 1/2 trial to evaluate BNT161, a quadrivalent nucleoside-modified RNA (modRNA) vaccine candidate, is ongoing and a dose-finding study for a self-amplifying RNA (saRNA) vaccine candidate has started.
- In July 2022, data were reported from the Phase 2 expansion study of BNT161 in subjects 65 years of age and older showing first evidence of substantial induction of strain specific CD4+ and CD8+ responses. At day seven after vaccination with BNT161, the geometric mean fold rise, or GMFR, for CD4+ T cells was more than two-fold for all four encoded strains. For strain specific CD8+ T cells, the GMFR was

more than two-fold for the Victoria B subtype and influenza B subtype (H3N2). The GMFR was higher compared to the control quadrivalent influenza vaccine for both CD4+ and CD8+ strain specific T cell responses. Based on these encouraging T cell responses and observed seroconversion, a Phase 3 study of the quadrivalent modified mRNA influenza vaccine is planned to initiate in the second half of 2022.

### **Oncology**

BioNTech's immuno-oncology strategy is based on pioneering approaches that harness the immune response to treat cancer. The Company has multiple clinical stage assets across different therapeutic classes which may have the potential to tackle tumors using complementary strategies, either by targeting tumor cells directly or by modulating the immune response against the tumor. The Company's oncology pillars include mRNA therapeutic vaccines, cell therapies (CAR-, TCR-, and neoantigen-specific T cell therapies), mRNA-encoded effector molecules (RiboMabs and RiboCytokines), next-generation immune checkpoint inhibitors and agonists, anti-tumor antibodies and immune-modulatory small molecules. Many product candidates have the potential to be combined with other pipeline assets or already approved therapies.

BioNTech's clinical stage oncology pipeline includes a total of 18 product candidates in 23 ongoing clinical trials including five in randomized Phase 2 clinical trials: two FixVac programs (BNT111 and BNT113), two indications for the iNeST product candidate autogene cevumeran (BNT122/RO7198457), and the bispecific antibody immune checkpoint modulator BNT311 (GEN1046). BNT116, a FixVac program for non-small cell lung cancer (NSCLC) and BNT142, a RiboMab program targeting CD3 on T cells and Claudin-6 (CLDN6) in solid tumors, have recently entered first-in-human clinical testing.

BioNTech expects continued pipeline advancement and expansion, as well as further data readouts from the ongoing trials, for the remainder of 2022.

### **mRNA programs**

#### *FixVac*

BioNTech's off-the-shelf cancer immunotherapy approach, FixVac, leverages the Company's proprietary uridine mRNA (uRNA) backbone for full actualization of the intrinsic adjuvanticity of RNA that encodes cancer-specific shared antigens for intravenous administration using the proprietary RNA-LPX formulation and aiming for induction of strong antigen-specific immune responses. FixVac product candidates may be of clinical utility in combination with anti-PD1 in patients with lower mutational burden tumors, including those who have already experienced checkpoint inhibitor (CPI) therapy.

Two FixVac programs are in ongoing Phase 2 trials: BNT111 in PD1 inhibitor refractory/relapsed melanoma (in collaboration with Regeneron Pharmaceuticals, Inc., "Regeneron") and BNT113 in HPV16+ PDL1+ head and neck cancer.

BNT116 is being evaluated in a Phase 1 clinical trial. It is designed to elicit an immune response to six tumor-associated antigens that cover up to 100% of patients in all major histologic subtypes of non-small cell lung cancer.

- In July 2022, the first participant was dosed in a first-in-human clinical trial evaluating the safety, tolerability and preliminary efficacy of BNT116 alone and in combination in patients with advanced or metastasized NSCLC. The trial will comprise several cohorts and is intended to establish a safe dose for BNT116 monotherapy as well as for BNT116 in combination with cemiplimab (Regeneron's Libtayo®) in patients who have progressed on prior PD-1 inhibitor treatment or are not eligible for chemotherapy, and in combination with docetaxel in patients who have received prior platinum-based chemotherapy.

#### *Individualized neoantigen specific immunotherapy (iNeST)*

BioNTech's individualized cancer immunotherapy approach (iNeST) is also based on a pharmacologically optimized uridine mRNA (uRNA) backbone delivered in the Company's proprietary RNA-LPX formulation.

BioNTech's lead iNeST product candidate, autogene cevumeran (BNT122), is being developed together with Genentech, Inc. ("Genentech") as part of a co-development and co-commercialization collaboration.

Each patient is treated with a vaccine informed by the mutation profile of their personal cancer and manufactured on-demand. The RNA encodes a unique composition of the patient's own tumor mutations and results in generation of neoantigen specific CD4+ and CD8+ T cell responses. BioNTech believes this modality is well-suited for use in early-stage cancers and the adjuvant setting.

- A randomized Phase 2 trial of autogene cevumeran in the adjuvant treatment of circulating tumor DNA (ctDNA) positive, surgically resected Stage II (high-risk)/Stage III colorectal cancer is ongoing.
- A data update from the ongoing randomized Phase 2 trial of autogene cevumeran combined with pembrolizumab in patients with first-line metastatic melanoma is now expected in the first half of 2023.
- In June 2022, initial data from an investigator-initiated Phase 1 clinical trial of autogene cevumeran evaluating safety and tolerability in combination with the anti-PD-L1 immune checkpoint inhibitor atezolizumab and chemotherapy in patients with



surgically removed pancreatic ductal adenocarcinoma, or PDAC, was presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. 16 patients had their tumor surgically removed, were subsequently treated with a single dose of atezolizumab and received autogene cevumeran. Preliminary data from these 16 treated patients showed that autogene cevumeran was well tolerated. *De novo* neoantigen-specific T cell responses of high magnitude were induced in 50% (eight out of 16) of patients. After an early median follow-up of 18 months, patients with this type of immune response had a significantly longer recurrence-free survival, or RFS, than those without a high magnitude vaccine-induced immune response. Based on these data, BioNTech and Genentech are planning a randomized study to further evaluate the efficacy and safety of autogene cevumeran in combination with atezolizumab and chemotherapy in patients with resected PDAC.

#### *RiboMabs*

BioNTech's RiboMab product candidates, BNT141 and BNT142, are based on mRNA and designed to encode cancer cell targeting antibodies. These product candidates leverage the Company's proprietary optimized mRNA technology combining nucleoside modifications to minimize immunogenicity with modifications in the mRNA backbone with the aim of maximizing protein expression. RiboMabs may address the limitations of recombinant antibodies, including avoidance of protein manufacturing challenges and short plasma half-life.

BNT141 encodes an antibody targeting Claudin-18.2, expressed in high unmet medical need tumors, including multiple epithelial solid tumors, such as gastric, biliary and pancreatic cancers.

BNT142 encodes a bispecific T cell engaging antibody that targets CD3, a T cell receptor component, and CLDN6, an oncofetal cell surface antigen found in solid tumors such as testicular and ovarian cancers.

- BNT142 – In July 2022, the first participant was dosed in an open-label, multi-center, Phase 1/2 dose escalation, safety, and pharmacokinetic trial of BNT142 followed by expansion cohorts in patients with CLDN6-positive advanced solid tumors. The trial is evaluating BNT142 as monotherapy in patients that have exhausted therapy or are not eligible for standard of care therapy. After dose escalation, BNT142 will be evaluated in expansion cohorts in testicular cancer, ovarian cancer, and non-squamous NSCLC.

#### **Cell therapies**

##### *CAR-T cell immunotherapy*

BNT211, BioNTech's first chimeric antigen receptor, or CAR-T cell product candidate, targets CLDN6-positive solid tumors in combination with a CAR-T cell-amplifying RNA vaccine, or CARVac, encoding CLDN6. CARVac is also based on a pharmacologically optimized uridine mRNA (uRNA) backbone delivered in the Company's proprietary RNA-LPX formulation. CLDN-6 CAR-T cells are equipped with a second-generation CAR of high sensitivity and specificity for the tumor-specific carcino-embryonic antigen CLDN6. CARVac drives *in vivo* expansion of transferred CAR-T cells, aiming to increase their persistence and efficacy. BNT211 is designed to overcome CAR-T cell therapy limitations in patients with solid tumors.

- BNT211 – A Phase 1/2 open-label dose escalation and dose expansion trial evaluating BNT211 in patients with CLDN6-positive solid tumors is ongoing.

Data from the ongoing trial were presented at the American Association for Cancer Research (AACR) Conference in April 2022 and at the annual meeting of the Association for Cancer Immunotherapy (CIMI) in May 2022. The preliminary efficacy data showed encouraging signs of clinical activity with a disease control rate of 86% and an overall response rate of 43%. The results also demonstrated an encouraging safety profile as adverse events and dose limiting toxicities were manageable.

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

- In June 2022, the EMA granted Priority Medicines (PRIME) designation to BNT211 for the third- or later-line treatment of testicular germ cell tumors. The PRIME status is granted to drug candidates that may offer a major therapeutic advantage over existing treatments and provides early and proactive EMA support to developers of medicines that target an unmet medical need. BNT211 will benefit from this interaction with the EMA through the next development phase.

## **Antibodies**

### *Next generation immunomodulators*

In August 2022, BioNTech announced the expansion of its global strategic collaboration with Genmab A/S ("Genmab") for the joint development of BNT313 (GEN1053), a CD27 antibody, applying Genmab's proprietary HexaBody® technology. Under this 50/50 collaboration, the development costs and potential future profits for BNT313 will be shared equally.

- BNT313 (GEN1053) – A Phase 1 trial to evaluate the safety, tolerability, and preliminary efficacy of BNT313 on malignant solid tumors as monotherapy is expected to be initiated in the second half of 2022. The trial will consist of two parts. The dose escalation part will explore the safety of escalating doses of BNT313 as monotherapy. The expansion part is planned to provide additional safety and initial antitumor activity information on the selected dose regimen for BNT313 monotherapy

in selected tumor indications, as well as more detailed data related to the mode of action.

#### **Corporate Updates**

A key component of BioNTech's corporate strategy is strengthening the Company's technology platforms, digital capabilities and infrastructure through select strategic partnerships and acquisitions. In April 2022, BioNTech was granted a pandemic preparedness contract by the Federal Republic of Germany and the Company entered into an exclusive research collaboration with Matinas BioPharma Holdings, Inc. ("Matinas BioPharma").

- In June 2022, BioNTech began construction of its first Africa-based mRNA vaccine manufacturing facility in Kigali, Rwanda, with a target for the first set of manufacturing BioNTainers to be delivered to the site by the end of 2022. The facility will initially include two BioNTainers equipped to manufacture a range of mRNA-based vaccines targeted to the needs of the African Union member states, including potentially the COVID-19 vaccine and investigational malaria and tuberculosis vaccine candidates if approved or authorized by regulatory authorities. The Company believes the estimated initial annual capacity of, for example, the COVID-19 vaccine may be as high as approximately 50 million doses and manufacturing in the BioNTainers could commence as soon as approximately 12 to 18 months after their installation.

BioNTech also provides an update on key Supervisory Board developments and the status of the return of capital to shareholders.

- In June 2022, at the Annual General Meeting (AGM) the Company's shareholders voted to reappoint Helmut Jeggler as a member of the Supervisory Board and appointed two additional Supervisory Board members, Prof. Dr. Anja Morawietz and Prof. Dr. Rudolf Staudigl. In a meeting following the AGM, the Supervisory Board re-elected Helmut Jeggler as its Chairman. All three members will serve in their roles until the 2026 AGM.
- In June 2022, at the Annual General Meeting, the Company's shareholders approved the proposed special cash dividend of €2.00 per ordinary share (including those held in the form of ADSs), which led to an aggregate payment of €484.3 million.
- During the three months ended June 30, 2022, 2,078,207 American Depositary Shares (ADSs) were repurchased under the Company's share repurchase program

at an average price of \$145.65, for total consideration of \$302.7 million (€286.9 million).

In light of the potential energy supply issues in Europe, BioNTech is evaluating its ongoing mitigation efforts to ensure business continuity.

- BioNTech monitors the natural gas supply situation as part of its regular business continuity management and is evaluating possible additional energy supply measures. BioNTech's commercial production of its COVID-19 vaccine is currently run on natural gas, but the Company expects that it could be powered by alternative fuel sources without interruption, if needed. According to the Company's most recent information and analyses, commercial mRNA manufacturing in BioNTech's facilities is not expected to be impacted by a natural gas shortage, such as the current one. Nonetheless, the Company cannot predict with certainty the impact that a continuing or more severe natural gas shortage would have on its operations. BioNTech's R&D and clinical development activities are currently dependent on gas, and the Company is putting measures in place to mitigate related risks. BioNTech is also currently evaluating the impact to its partners, including Pfizer, suppliers and other service providers. BioNTech is proactively engaging with collaboration partners and governmental authorities to mitigate adverse impacts from any potential energy shortage.

#### **Environmental, Social, and Governance (ESG)**

The rating agency ISS ESG, part of the Institutional Shareholder Services group (ISS) reiterated BioNTech's "Prime" ESG rating. BioNTech improved its rating from "C+" to "B-" compared to the previous year and remains in the top 10% of the biopharmaceutical industry, according to the ISS ESG Rating.

#### **Conference Call and Webcast Information**

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts on the same day at 8.00 a.m. EDT (2.00 p.m. CEST) to report its financial results and provide a corporate update for the second quarter of 2022.

To access the live conference call via telephone, please register via this [link](#). Once registered, dial-in numbers and a pin number will be provided. It is recommended to register at least a day in advance.

The slide presentation and audio of the webcast will be available via this [link](#).

Participants may also access the slides and the webcast of the conference call via the "Events & Presentations" page of the Investor Relations section of the Company's website at

<https://biontech.de/>. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for 30 days following the call.

#### **About BioNTech**

Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bispecific immune checkpoint modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

For more information, please visit [www.BioNTech.de](http://www.BioNTech.de)

#### **Forward-Looking Statements**

This press release 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: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY<sup>®</sup> where approved for use under full or conditional marketing authorization, in territories controlled by BioNTech's collaboration partners, particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; BioNTech's pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after BioNTech's initial sales to national governments; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; competition from other COVID-19 vaccines or related to BioNTech's 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 BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including those relating to additional formulations of BioNTech's COVID-19 vaccine, and BioNTech's 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 BioNTech's research and development programs; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; the impact of the COVID-19 pandemic on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by us; BioNTech's ability to progress BioNTech's 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 development of sustainable vaccine production and supply solutions on the African continent, including its BioNTainers, and the nature and feasibility of these solutions; BioNTech's estimates of vaccine revenues, and projections of estimated research and development expenses, selling, general and administrative expenses, capital expenditures, and income taxes; BioNTech's ability and that of BioNTech's collaborators to commercialize and market BioNTech's product candidates, if approved, including BioNTech's COVID-19 vaccine; BioNTech's ability to manage BioNTech's development and expansion; regulatory developments in the United States and foreign countries; BioNTech's ability to effectively scale BioNTech's production capabilities and manufacture BioNTech's products, including BioNTech's target COVID-19 vaccine production levels, and BioNTech's product candidates; and other factors not known to BioNTech 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 press release 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 BioNTech's quarterly report on Form 6-K for the quarter ended June 30, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at <https://www.sec.gov/>. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking

statements contained in this press release 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.

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### Interim Condensed Consolidated Statements of Profit or Loss

<i>(in millions, except per share data)</i>	Three months ended June 30,		Six months ended June 30,	
	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>
<b>Revenues</b>				
Commercial revenues	€3,166.3	€5,280.5	€9,528.5	€7,308.0
Research & development revenues	30.2	28.0	42.6	48.9
<b>Total revenues</b>	<b>€3,196.5</b>	<b>€5,308.5</b>	<b>€9,571.1</b>	<b>€7,356.9</b>
<b>Cost of sales</b>	<b>(764.6)</b>	<b>(883.8)</b>	<b>(2,058.7)</b>	<b>(1,116.9)</b>
Research and development expenses	(399.6)	(201.1)	(685.4)	(417.3)
Sales and marketing expenses	(17.8)	(13.3)	(32.1)	(22.0)
General and administrative expenses	(130.0)	(47.8)	(220.8)	(86.7)
Other operating expenses	(240.7)	(0.3)	(309.5)	(0.9)
Other operating income	565.8	36.2	697.7	147.5
<b>Operating income</b>	<b>€2,209.6</b>	<b>€4,198.4</b>	<b>€6,962.3</b>	<b>€5,860.6</b>
Finance income	115.5	0.3	387.6	24.8
Finance expenses	(5.8)	(175.9)	(12.5)	(220.3)
<b>Profit before tax</b>	<b>€2,319.3</b>	<b>€4,022.8</b>	<b>€7,337.4</b>	<b>€5,665.1</b>
Income taxes	(647.3)	(1,235.6)	(1,966.6)	(1,749.8)
<b>Profit for the period</b>	<b>€1,672.0</b>	<b>€2,787.2</b>	<b>€5,370.8</b>	<b>€3,915.3</b>
<b>Earnings per share</b>				
Basic profit for the period per share	€6.86	€11.42	€22.00	€16.07
Diluted profit for the period per share	€6.45	€10.77	€20.69	€15.14



## Interim Condensed Consolidated Statements of Financial Position

<i>(in millions)</i>	June 30, 2022 <i>(unaudited)</i>	December 31, 2021
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	€221.4	€202.4
Property, plant and equipment	420.4	322.5
Right-of-use assets	243.7	197.9
Other financial assets	51.5	21.3
Other assets	0.9	0.8
Deferred expenses	9.4	13.6
<b>Total non-current assets</b>	<b>€947.3</b>	<b>€758.5</b>
<b>Current assets</b>		
Inventories	367.7	502.5
Trade and other receivables	10,382.9	12,381.7
Other financial assets	0.1	381.6
Other assets	46.6	64.9
Income tax assets	0.4	0.4
Deferred expenses	75.6	48.5
Cash and cash equivalents	9,334.8	1,692.7
<b>Total current assets</b>	<b>€20,208.1</b>	<b>€15,072.3</b>
<b>Total assets</b>	<b>€21,155.4</b>	<b>€15,830.8</b>
<b>Equity and liabilities</b>		
<b>Equity</b>		
Share capital	248.6	246.3
Capital reserve	1,689.8	1,674.4
Treasury shares	(5.9)	(3.8)
Retained earnings	14,769.4	9,882.9
Other reserves	128.8	93.9
<b>Total equity</b>	<b>€16,830.7</b>	<b>€11,893.7</b>
<b>Non-current liabilities</b>		
Loans and borrowings	206.6	171.6
Other financial liabilities	6.1	6.1
Income tax liabilities	6.8	4.4
Provisions	7.3	184.9
Contract liabilities	55.9	9.0
Other liabilities	17.9	12.8
Deferred tax liabilities	100.4	66.7
<b>Total non-current liabilities</b>	<b>€401.0</b>	<b>€455.5</b>
<b>Current liabilities</b>		
Loans and borrowings	32.3	129.9
Trade payables	291.1	160.0
Other financial liabilities	807.3	1,190.4
Government grants	3.0	3.0
Refund liabilities	—	90.0
Income tax liabilities	1,417.9	1,568.9
Provisions	596.2	110.2
Contract liabilities	656.3	186.1
Other liabilities	119.6	43.1
<b>Total current liabilities</b>	<b>€3,923.7</b>	<b>€3,481.6</b>
<b>Total liabilities</b>	<b>€4,324.7</b>	<b>€3,937.1</b>
<b>Total equity and liabilities</b>	<b>€21,155.4</b>	<b>€15,830.8</b>

## Interim Condensed Consolidated Statements of Cash Flows

<i>(in millions)</i>	Three months ended June 30,		Six months ended June, 30	
	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>
<b>Operating activities</b>				
Profit for the period	€1,672.0	€2,787.2	€5,370.8	€3,915.3
Income taxes	647.3	1,235.6	1,966.6	1,749.8
<b>Profit before tax</b>	<b>€2,319.3</b>	<b>€4,022.8</b>	<b>€7,337.4</b>	<b>€5,665.1</b>
Adjustments to reconcile profit before tax to net cash flows:				
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	33.2	16.4	60.8	29.4
Share-based payment expense	12.6	22.0	22.0	39.3
Net foreign exchange differences	(344.6)	(70.1)	(338.5)	(101.3)
Gain on disposal of property, plant and equipment	0.2	0.2	0.2	0.4
Finance income	(1.5)	(0.3)	(218.8)	(0.6)
Finance expense	5.8	175.6	12.5	220.3
Movements in government grants	—	(20.9)	—	(88.8)
Net loss on derivative instruments at fair value through profit or loss	86.5	—	84.6	—
Working capital adjustments:				
Decrease / (increase) in trade and other receivables, contract assets and other assets	3,174.8	(4,651.0)	2,771.3	(6,751.5)
Decrease / (increase) in inventories	91.6	(158.5)	134.8	(241.3)
(Decrease) / increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	(663.1)	565.5	194.4	821.0
Interest received	1.5	0.3	2.2	0.6
Interest paid	(5.8)	(2.1)	(12.2)	(3.9)
Income tax paid	(791.4)	(0.2)	(2,081.4)	(0.3)
<b>Net cash flows from / (used in) operating activities</b>	<b>€3,919.1</b>	<b>€(100.3)</b>	<b>€7,969.3</b>	<b>€(411.6)</b>
<b>Investing activities</b>				
Purchase of property, plant and equipment	(70.6)	(25.9)	(114.7)	(47.6)
Proceeds from sale of property, plant and equipment	—	0.3	—	1.2
Purchase of intangible assets and right-of-use assets	(4.8)	(4.2)	(21.5)	(11.7)
Purchase of financial instruments	(3.0)	—	(30.0)	—
Proceeds from maturity of other financial assets	—	—	375.2	—
<b>Net cash flows from / (used in) investing activities</b>	<b>€(78.4)</b>	<b>€(29.8)</b>	<b>€209.0</b>	<b>€(58.1)</b>
<b>Financing activities</b>				
Proceeds from issuance of share capital and treasury shares, net of costs	—	160.9	110.5	160.9
Proceeds from loans and borrowings	0.2	—	0.2	—
Repayment of loans and borrowings	—	(0.7)	(18.8)	(1.4)
Payments related to lease liabilities	(10.5)	(7.3)	(21.9)	(11.1)
Share repurchase program	(286.9)	—	(286.9)	—
Dividends	(484.3)	—	(484.3)	—
<b>Net cash flows from / (used in) financing activities</b>	<b>€(781.5)</b>	<b>€152.9</b>	<b>€(701.2)</b>	<b>€148.4</b>
Net increase / (decrease) in cash and cash equivalents	3,059.2	22.8	7,477.1	(321.3)
Change in cash and cash equivalents resulting from exchange rate differences	111.5	(0.2)	165.0	25.2
Cash and cash equivalents at the beginning of the period	6,164.1	891.5	1,692.7	1,210.2
<b>Cash and cash equivalents at June 30</b>	<b>€9,334.8</b>	<b>€914.1</b>	<b>€9,334.8</b>	<b>€914.1</b>



# 2<sup>nd</sup> Quarter 2022 Financial Results & Corporate Update

August 8, 2022

Exhibit 99.2



## This Slide Presentation Includes Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: our expected revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY® where approved for use under full or conditional marketing authorization, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners; our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the rate and degree of market acceptance of our COVID-19 vaccine and, if approved, our investigational medicines; the initiation, timing, progress, results, and cost of our research and development programs, including those relating to additional formulations of our COVID-19 vaccine, 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 ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; our and our counterparties' ability to manage and source necessary energy resources; our ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines; the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance; unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us; our ability to progress our Malaria, Tuberculosis and HIV programs, including timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature and duration of support from the World Health Organization, the European Commission and other organizations with establishing infrastructure; the development of sustainable vaccine production and supply solutions on the African continent, including our BioNTainers, 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 presentation 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 our quarterly report for the three months ended June 30, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at <https://www.sec.gov/>. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this presentation 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.

## Safety Information

COMIRNATY® ▼ (the Pfizer-BioNTech COVID-19 vaccine) has been granted conditional marketing authorization (CMA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people from 5 yrs of age. The vaccine is administered as a 2-dose series, 3 weeks apart. In addition, the CMA has been expanded to include a booster dose (third dose) at least 6 months after the second dose in individuals 18 yrs of age and older. For immunocompromised individuals, the third dose may be given at least 28 days after the second dose. The European Medicines Agency's (EMA's) human medicines committee (CHMP) has completed its rigorous evaluation of COMIRNATY®, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available.

### IMPORTANT SAFETY INFORMATION:

- Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.
- Very rare cases of myocarditis and pericarditis have been observed following vaccination with Comirnaty. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, tingling sensations and sweating) may occur in association with the vaccination process itself. Stress-related reactions are temporary and resolve on their own. Individuals should be advised to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting.
- The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY® may be lower in immunosuppressed individuals.
- As with any vaccine, vaccination with COMIRNATY® may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of vaccine.
- In clinical studies, adverse reactions in participants 16 yrs of age and older were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia and chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.
- The overall safety profile of COMIRNATY® in participants 5 to 15 yrs of age was similar to that seen in participants 16 yrs of age and older.
- The most frequent adverse reactions in children 5 to 11 yrs of age were injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%).
- The most frequent adverse reactions in clinical trial participants 12 to 15 yrs of age were injection site pain (> 90%), fatigue and headache (> 70%), myalgia and chills (> 40%), arthralgia and pyrexia (> 20%).
- There is limited experience with use of COMIRNATY® in pregnant women. Administration of COMIRNATY® in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.
- It is unknown whether COMIRNATY® is excreted in human milk.
- Interactions with other medicinal products or concomitant administration of COMIRNATY® with other vaccines has not been studied.
- For complete information on the safety of COMIRNATY® always make reference to the approved Summary of Product Characteristics and Package Leaflet available in all the languages of the European Union on the EMA website.

The black equilateral triangle ▼ denotes that additional monitoring is required to capture any adverse reactions. This will allow quick identification of new safety information. Individuals can help by reporting any side effects they may get. Side effects can be reported to [EudraVigilance](#) or directly to BioNTech using email [medinfo@biontech.de](mailto:medinfo@biontech.de), telephone +49 6131 9084 0, or via the website [www.biontech.de](http://www.biontech.de)

## Safety Information

### AUTHORIZED USE IN THE U.S.

- COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 yrs of age and older. It is also authorized under EUA to provide a 3-dose primary series to individuals 6 months through 4 yrs of age, 2-dose primary series to individuals 5 yrs of age and older, a third primary series dose to individuals 5 yrs of age and older who have been determined to have certain kinds of immunocompromise, a single booster dose to individuals 5 through 11 yrs of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®, a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise, a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY®, a first booster dose to individuals 18 yrs of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine, a second booster dose to individuals 50 yrs of age and older who have received a first booster dose of any authorized COVID-19 vaccine; and a second booster dose to individuals 12 yrs of age and older who have been determined to have certain kinds of immunocompromise and who have received a first booster dose of any authorized COVID-19 vaccine.

The booster schedule is based on the labeling information of the vaccine used for the primary series.

### IMPORTANT SAFETY INFORMATION

Individuals should not get the vaccine if they:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

Individuals should tell the vaccination provider about all of their medical conditions, including if they:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects the immune system
- are pregnant, plan to become pregnant, or are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

The vaccine may not protect everyone. Side effects reported with the vaccine include:

- There is a remote chance that the vaccine could cause a severe allergic reaction
  - A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, vaccination providers may ask individuals to stay at the place where they received the vaccine for monitoring after vaccination
  - Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
  - If an individual experiences a severe allergic reaction, they should call 9-1-1 or go to the nearest hospital

## Safety Information

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine, more commonly in males under 40 yrs of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. Individuals should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart
- Additional side effects that have been reported with the vaccine include:
  - severe allergic reactions; non-severe allergic reactions such as injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); decreased appetite; diarrhea; vomiting; arm pain; and fainting in association with injection of the vaccine
- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away

Data on administration of this vaccine at the same time as other vaccines have not yet been submitted to FDA. Individuals considering receiving this vaccine with other vaccines should discuss their options with their healthcare provider.

Patients should always ask their healthcare providers for medical advice about adverse events. Individuals are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit <https://www.vaers.hhs.gov> or call 1-800- 822-7967. In addition, side effects can be reported to Pfizer Inc. at [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling 1-800-438-1985.

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Ryan Richardson, Chief Strategy Officer

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## Advancing Toward Our Vision



Immunotherapy powerhouse expanding into multiple therapeutic areas

## Highlights in Q2: Corporate & Oncology Pipeline



### Corporate Updates

- Reported Q2 total revenues of €3.2 bn<sup>1</sup> and year-to-date revenues of €9.6 bn<sup>1</sup>
- Began construction of first BioNTainer mRNA vaccine manufacturing facility in Africa
- Signed new equal share cost/profit collaboration agreement with Genmab for joint development of an antibody targeting CD27






### Oncology: Pipeline Advancement

- BNT122 (iNeST): Positive data from Phase 1 trial in patients with resected pancreatic cancer showing favorable safety profile and encouraging signs of clinical activity<sup>2</sup>
- BNT116 (FixVac): FPD in Phase 1 trial in advanced NSCLC
- BNT142 (RiboMab): FPD in Phase 1/2 trial in CLDN6 positive solid tumors
- BNT211 (CLDN6 CAR-T cell therapy): EMA Priority Medicines (PRIME) designation for 3<sup>rd</sup> or later-line treatment of testicular cancer

<sup>1</sup> BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2021 as well as the Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

<sup>2</sup> Investigator-initiated trial

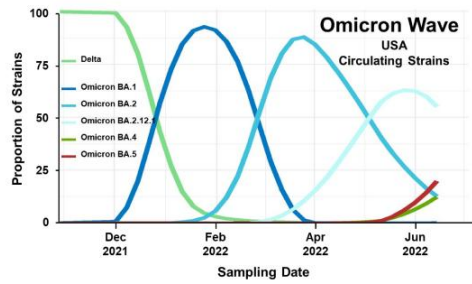
## Highlights in Q2: COVID-19 Vaccine / COMIRNATY

 <p>Broad label across age groups</p>	<ul style="list-style-type: none"><li>FDA granted EUA for primary series in children 6 months through 4 yrs of age and for booster dose in children 5 through 11 yrs of age</li></ul> <p>Pediatric label now includes<sup>1</sup>:</p> <ul style="list-style-type: none"><li>6 mo. to &lt;5 yrs (3 µg)</li><li>5 yrs to &lt;12 yrs (10 µg)</li><li>12 yrs+ (30 µg)</li></ul>
 <p>Strong global distribution</p>	<ul style="list-style-type: none"><li>More than 3.6 bn doses delivered to 180 countries and territories since launch Dec. 2020<sup>2</sup></li><li>Order book 2022: ~2.5 bn doses<sup>2</sup><ul style="list-style-type: none"><li>New agreement with U.S. government to provide additional 105m doses of COVID-19 vaccine with option for another 195m doses</li></ul></li><li>Fostering global health equity: On track to deliver a total of 2 bn doses to low- and middle-income countries by end of 2022</li></ul>
 <p>Variant adapted &amp; next-gen vaccines</p>	<p>Variant adapted vaccines:</p> <ul style="list-style-type: none"><li>Omicron BA.1 adapted vaccine candidates demonstrated high immunogenicity and tolerable safety profile</li><li>Regulatory submissions of Omicron BA.1- and BA.4/5-adapted bivalent vaccines are ongoing worldwide</li></ul> <p>Next-gen vaccines:</p> <ul style="list-style-type: none"><li>Initiated Phase 2 trial of BNT162b5: bivalent vaccine candidate based on enhanced versions of SARS-CoV-2 ancestral strain and Omicron BA.2 variant spike proteins engineered for broader immunity</li></ul>

<sup>1</sup> Approved as a 2-dose series for prevention of COVID-19 in individuals 12 yrs of age and older; 2-dose series under Emergency Use Authorization for individuals 5–11 yrs old, and 3-dose series under emergency use authorization for children 6 months through 4 yrs of age

<sup>2</sup> As of beginning of July 2022

## SARS-CoV-2 Epidemiology Changes Quickly: Vaccine Updates Need Timely Adaptation With the Pace of Virus



SARS-CoV-2 virus continues to evolve:  
Currently seeing new variant waves every ~3 months

### Variant vaccine adaptation timelines

Clinical (current) ~8 months

Pre-clinical/CMC (proposed) ~3 months

<sup>10</sup> CMC, chemistry, manufacturing and controls  
GISAIID Initiative database: <https://www.gisaid.org/> (accessed June 20, 2022).

## Preparing for Launch of Omicron-Adapted Bivalent Vaccines in Early October 2022



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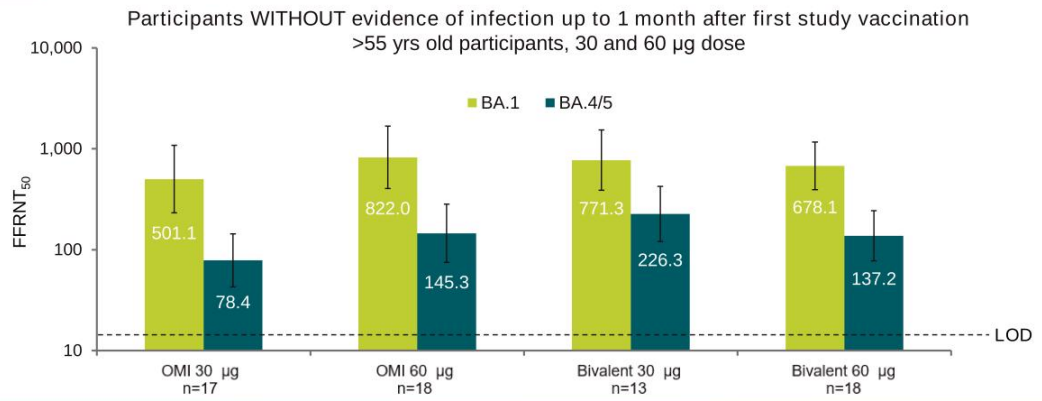
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## Omicron-BA.1 Adapted Vaccines as 4<sup>th</sup> Dose Elicit Improved Omicron Neutralization Response



Superiority<sup>1</sup> for GMR and non-inferiority<sup>2</sup> for seroresponses (monovalent and bivalent vaccines)  
**“Super” superiority<sup>3</sup>** for GMR (monovalent vaccines); Neutralization activity against BA.4/5 reduced

Internal data.

FFRNT, fluorescent foci reduction neutralization test; LOD, limit of detection; GMR, geometric mean ratio

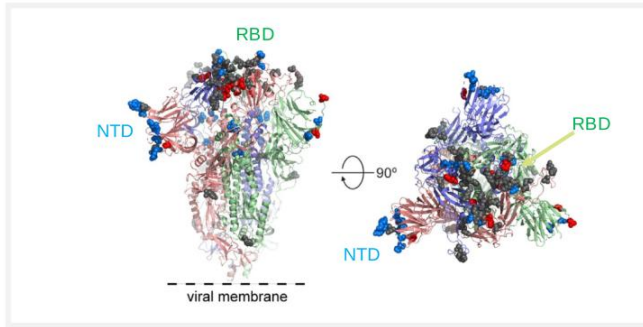
1 GMR superiority criterion: the lower bound of 95% confidence interval for GMR is >1.0

2 Non-inferiority criterion: the lower bound of 95% confidence interval for the percentage difference is >-5.

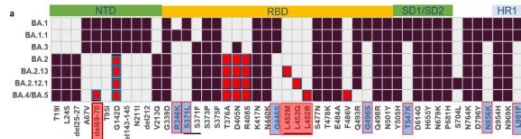
3 GMR “super” superiority criterion: the lower bound of 95% confidence interval for GMR is >1.5.

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# Omicron BA.4/5 RBD and NTD Sequences are distinct From BA.1 and BA.2



- Omicron-BA.2 unique mutations
- Omicron-BA.2 common mutations
- Omicron-BA.1 unique mutations

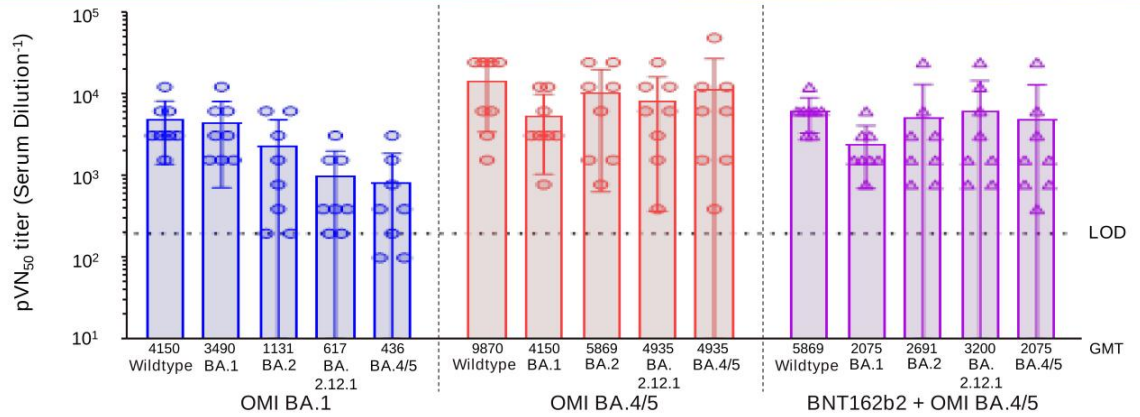


RBD, receptor binding domain; NTD, N-terminal domain  
 14 Stalls et al., Cryo-EM structures of SARS-CoV-2 Omicron BA.2 spike. Cell reports, 2022



# Omicron BA.4/5 Monovalent and Bivalent Boosters in Mice Substantially Increase Omicron Neutralization Responses to All Tested Omicron Variants

Compared to Monovalent OMI BA.1, BA.4/5 neutralizing titers increase by ~11.3 fold (mono BA.4/5) or ~4.8 fold (bivalent BA.4/5)



15 N=8 mice Balb/c mice. Mice preimmunized with 2 doses of BNT162b2; boosters given at day 104  
Pseudovirus neutralization assay; LOD, Limit of Detection; GMT, geometric mean titers

# Pursuing Multiple Novel COVID-19 Vaccine Approaches to Provide Durable and High-Level Protection against Evolving Variants

## Long-term: Next-Generation Vaccine Approaches

### Next generation SARS-CoV-2 spike antigen

Engineered for optimized immunogenicity

- Increase prefusion stability
- Expose more neutralizing-sensitive epitopes

### BNT162b5: bivalent vaccine candidate

Enhanced SARS-CoV-2 spike protein of ancestral strain and Omicron BA.2 sublineage



Phase 2:  
FPD in July

### T cell enhancing vaccine candidate

Designed to stimulate and enhance T cell immunity



Clinical trial start  
expected 2H 2022

### Pan-SARS-CoV-2 vaccine candidate

Potential for greater, more durable protection to manage future variants of concern



Proof-of-concept trial  
expected 2H 2022

Long-term strategy comprises multipronged approach designing and testing multiple constructs with the aim to engage different arms of the immune system including antibodies and T cells

## Oncology Pipeline: Significant Progress and Expansion in 2022

Drug class	Platform	Product candidate	Indication (targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Milestones
mRNA	FixVac	BNT111	Advanced and R/R melanoma					
		BNT112	Prostate cancer					
		BNT113	HPV16+ head and neck cancer					
		BNT115 <sup>1</sup>	Ovarian cancer					
		BNT116	NSCLC					FPD in July 2022 ✓ Data update: 1H 2023
	iNeST	Autogene cevumeran (BNT122) <sup>2</sup>	1L melanoma					
			Adjuvant colorectal cancer					
			Solid tumors					
	Intratumoral immunotherapy	SAR441000 (BNT131) <sup>3</sup>	Adjuvant pancreatic ductal adenocarcinoma <sup>1</sup>					
	RiboMabs	BNT141	Solid tumors (IL-12sc, IL15-sushi, GM-CSF, IFNα)					
Multiple solid tumors (CLDN18.2)								FPD in Jan. 2022 ✓
RiboCytokines	BNT142	Multiple solid tumors (CD3×CLDN6)						FPD in July 2022 ✓
		BNT151	Multiple solid tumors (optimized IL-2)					
		BNT152, BNT153	Multiple solid tumors (IL-7, IL-2)					
Cell therapies	CAR T cells + CARVac	BNT211	Multiple solid tumors (CLDN6)					Data update: 2H 2022
		BNT212	Pancreatic, other cancers (CLDN18.2)					
	Neoantigen-based T cells	BNT221 (NEO-PTC-01)	Multiple solid tumors					
	TCR engineered T cells	To be selected	All tumors					
Antibodies	Next-gen immune checkpoint modulators	GEN1046 (BNT311) <sup>4</sup>	Metastatic NSCLC (PD-L1×4-1BB)					
		GEN1042 (BNT312) <sup>4</sup>	Multiple solid tumors (PD-L1×4-1BB)					
		GEN1053 (BNT313) <sup>4</sup>	Multiple solid tumors (CD40×4-1BB)					
	Targeted cancer antibodies	GEN1053 (BNT313) <sup>4</sup>	Malignant solid tumors (CD27)					
BNT321 (MVT-5873)		Pancreatic cancer (sLea)						
SMIM	Toll-like receptor binding	BNT411	Solid tumors (TLR7)					

17 SMIM, small molecule immunomodulators.  
1 Investigator-initiated Phase 1 trial; 2 Collaboration with Genentech; 3 Collaboration with Sanofi; 4 Collaboration with Genmab.

## FixVac I BNT116: Phase 1 Trial in Patients with Advanced NSCLC



Key endpoints	Status
Primary: Safety and tolerability Secondary: Clinical activity	FPD in July 2022

18 NSCLC, non-small-cell lung cancer; TPS, tumor proportion score  
 \*Regeneron's Libtayo®  
 Clinicaltrials.gov: NCT05142189.

# RiboMabs: Nucleoside-modified mRNA Encoding Variable Antibody Formats for in vivo Translation

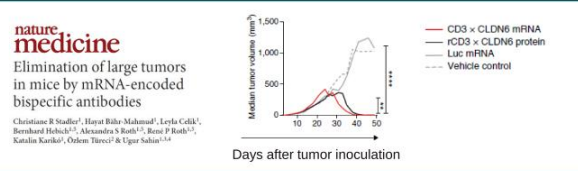
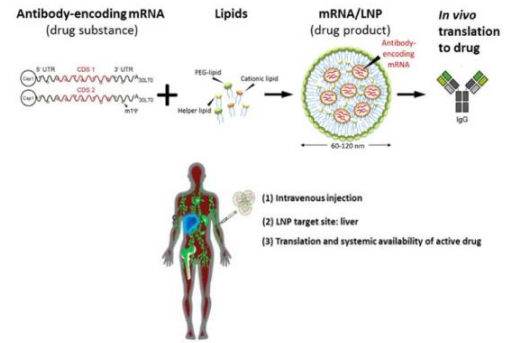
In vivo translation and systemic availability of active drug at therapeutically relevant plasma concentrations

- mRNA backbone designed for minimal immunogenicity
- Encoded antibodies target tumor-associated antigens
- Sustained in vivo production may result in prolonged serum half-life

Shared LNP formulation across platform candidates

- Liver-targeting LNP formulation for intravenous delivery

Encouraging preclinical data<sup>1</sup>



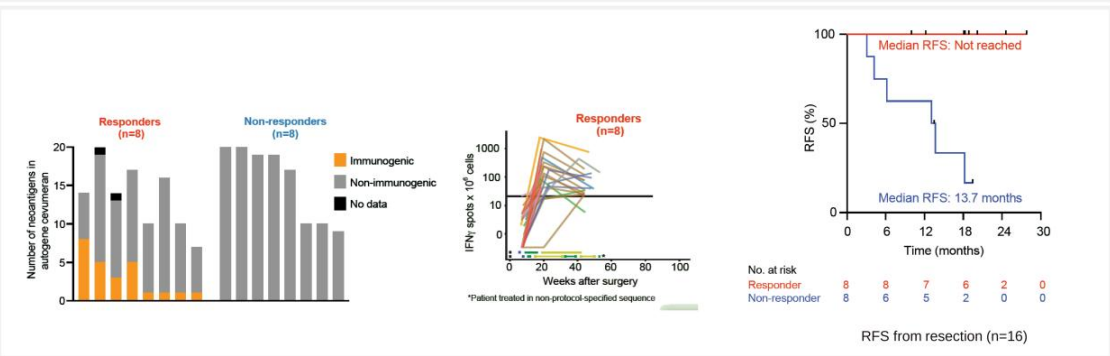
Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2
BNT141	Solid Tumors (CLDN18.2)	Progressing	Completed	Completed
BNT142	Solid Tumors (CD3+CLDN6)	Progressing	Completed	Completed

IgG, immunoglobulin G; LNP, lipid nanoparticles; TAA; CLDN18.2, Claudin-18.2; CD3 cluster of differentiation 3 (protein complex); CLDN, Claudin  
 1 Stadler, C.R. et al. Nature Medicine 2017 <https://www.nature.com/articles/nm.4356>

# iNeST | Autogene Cevumeran (BNT122) Phase 1 for Adjuvant Treatment of Pancreatic Cancer

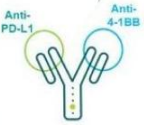
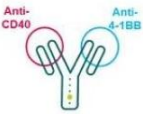

Vaccine-induced Neoantigen-specific immune responses of high magnitude against at least one of the neoantigens by ex vivo IFN $\gamma$  ELISPOT in half of the patients.

Prolonged Relapse free survival in patients who have high magnitude Immune responses.



iNeST is being developed in collaboration with Genentech.  
 RFS, recurrence-free survival  
 Balachandran VP, et al. ASCO Annual Meeting 2022; Poster presentation 2516.  
 Investor-initiated single-center study sponsored by Memorial Sloan Kettering Cancer Center

## Expanding Strategic Collaboration With Genmab

GEN1046 / BNT311 <sup>1</sup>	GEN1042 / BNT312 <sup>1</sup>	GEN1053 / BNT313 <sup>1</sup>
		
<p>Phase 2: R/R NSCLC Phase 1/2: Advanced solid tumors</p> <p>Bispecific antibody: Conditional 4-1BB co-stimulation while blocking PD-(L)1 axis</p>	<p>Phase 1/2: Advanced solid tumors</p> <p>Bispecific antibody: Combines targeting and conditional activation of CD40 and 4-1BB on immune cells</p>	<p>Phase 1/2: Solid tumors FPD expected in 2H 2022</p> <p>Monospecific HexaBody<sup>2</sup> targeting CD27 on naïve and activated T cells</p>

Next-generation immunomodulators designed to prime and activate anti-tumor T cell and Natural Killer cell function

<sup>21</sup> 1 Collaboration with Genmab based on 50/50 sharing of costs and profits  
2 HexaBody<sup>®</sup> technology owned by Genmab

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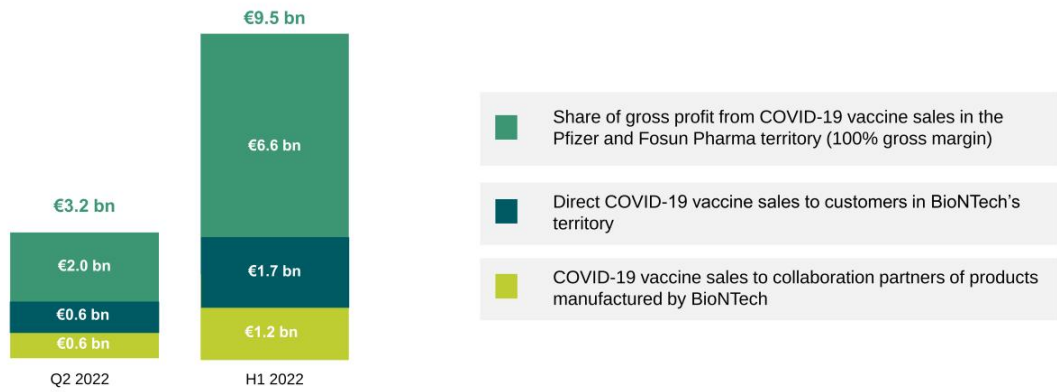
## Key Highlights for Q2 2022

<b>Total Revenues<sup>1</sup></b>	<b>Operating Result</b>
 <b>€3.2 bn</b>	 <b>€2.2 bn</b>
<b>Diluted EPS</b>	<b>Cash and Trade Receivables</b>
 <b>€6.45</b>	 <b>€9.3 bn + €10.4 bn</b>

1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2021 as well as the Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 6, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

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## Q2 and H1 2022 COVID-19 Vaccine Revenues



Q2 2022 revenues in line with our expectations

<sup>24</sup> 1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2021, as well as the Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

## Q2 and H1 2022 Financial Results – Profit or Loss

(in millions, except per share data) <sup>1</sup>	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Commercial revenues <sup>2</sup>	€3,166.3	€5,280.5	€9,528.5	€7,308.0
Research & development revenues	30.2	28.0	42.6	48.9
<b>Total revenues</b>	<b>€3,196.5</b>	<b>€5,308.5</b>	<b>€9,571.1</b>	<b>€7,356.9</b>
Cost of sales	(764.6)	(883.8)	(2,058.7)	(1,116.9)
Research and development expenses	(399.6)	(201.1)	(685.4)	(417.3)
Sales and marketing expenses	(17.8)	(13.3)	(32.1)	(22.0)
General and administrative expenses	(130.0)	(47.8)	(220.8)	(86.7)
Other operating income less expenses	325.1	35.9	388.2	146.6
<b>Operating income</b>	<b>€2,209.6</b>	<b>€4,198.4</b>	<b>€6,962.3</b>	<b>€5,860.6</b>
Finance income less expenses	109.7	(175.6)	375.1	(195.5)
Income taxes	(647.3)	(1,235.6)	(1,966.6)	(1,749.8)
<b>Profit for the period</b>	<b>€1,672.0</b>	<b>€2,787.2</b>	<b>€5,370.8</b>	<b>€3,915.3</b>
<b>Earnings per share</b>				
Basic profit for the period per share	€6.86	€11.42	€22.00	€16.07
Diluted profit for the period per share	€6.45	€10.77	€20.69	€15.14

<sup>1</sup> Numbers have been rounded, numbers presented may not add up precisely to the totals and may have been adjusted in the table context. Presentation of the consolidated statements of profit or loss has been condensed.

<sup>2</sup> BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2021 as well as the Quarterly Report as of and for the three and six months ended June 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on August 8, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

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## 2022 Financial Year Guidance Reiterated

### COVID-19 Vaccine Revenues for FY 2022<sup>1</sup>

Estimated BioNTech COVID-19 vaccine revenues	€ 13 – 17 bn
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### Planned FY 2022 Expenses and Capex<sup>1</sup>

R&D expenses	€ 1,400 - 1,500 m
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SG&A expenses	€ 450 - 550 m
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Capital expenditure	€ 450 - 550 m
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### Estimated FY 2022 Tax Assumptions

BioNTech Group estimated annual effective income tax rate	-28% <sup>2</sup>
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<sup>26</sup> 1 Ranges reflect current base case projections and do not include potential effects caused by or driven from additional collaborations or potential M&A transactions.  
2 BioNTech Group estimated annual effective income tax rate decreased from 31.6% (FY 2021) to -28% (FY 2022) due to decreasing average trade tax rates.

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## Strong Position and Outlook for Global COVID-19 Vaccine Franchise

>3.6 bn doses shipped to 180 countries or territories since product launch<sup>1</sup>

Increasing market share since January 2022<sup>2</sup>

- All markets<sup>3</sup>: increase from 52% to 63%
- Developed markets<sup>4</sup>: increase from 59% to 68%

2022 order book: ~2.5 bn doses

- U.S. government ordered additional 105 m doses with value of \$3.2 bn
  - Option for another 195 m doses
- EC order of 650 m doses for delivery in 2022
  - Amended contract for rephasing deliveries toward Q4 2022

Shipment volumes expected to increase with planned launch of  
Omicron variant-adapted vaccines in the late fall<sup>5</sup>

<sup>1</sup> As of beginning of July 2022

<sup>2</sup> Cumulative Share of Doses from January 1, 2022 to July 20, 2022 in markets in which Pfizer and BioNTech operate and that report market share data

<sup>3</sup> Incl. all markets in Developed Markets(4) plus Emerging Markets (Argentina, Chile, Ecuador, Hong Kong, Nepal, Peru, South Africa, Uruguay)

<sup>4</sup> Includes the U.S., EU/EEA, other Int'l Developed markets (Japan, South Korea, Switzerland, Ukraine)

<sup>5</sup> Starting date of January 1, 2022 for this data set is from Q1 2022 earnings presentation

<sup>28</sup> Pending regulatory approval  
Distribution of COVID-10 vaccine in collaboration with Pfizer

## Delivering on Commitment to Provide Equitable Access to Medicines

>1.5 bn COVID-19 vaccine doses shipped to low-and-middle income countries of 2 bn doses pledged<sup>1</sup>

### BioNTainer Launch in Africa

- End-to-end mRNA production units with capacity of up to >50 million doses/year
- First manufacturing facility to become a node in decentralized and robust African end-to-end manufacturing network
- Construction of facility underway following groundbreaking in Rwanda
- Potential additional sites for Senegal and South Africa



## Selected 2022 Pipeline Milestones

	Milestones	Anticipated Timing
COVID-19 vaccine: Follow on and Next Gen Vaccines	Omicron BA.4/5-adapted bivalent vaccine trial start	August 2022
	BNT162b5: Next-generation bivalent vaccine, enhanced SARS-CoV-2 encoding ancestral and BA.2 spike antigen	✓ Phase 2: FPD in July 2022
	T cell enhancing vaccine trial start	2H 2022
	Additional next-generation vaccine trial starts, including pan-SARS-CoV-2 vaccine	2H 2022
	Multiple data updates	2H 2022
4 Infectious Disease First-In-Human Trial Starts	Shingles vaccine <sup>1</sup>	2H 2022
	BNT163 HSV2 vaccine	2H 2022
	BNT164 tuberculosis vaccine <sup>2</sup>	2H 2022 / early 2023
	BNT165 malaria vaccine	2H 2022 / early 2023
4 Oncology First-in- Human Trial Starts	BNT141 RiboMab in solid tumors (CLDN18.2)	✓ FPD in Jan. 2022
	BNT142 RiboMab in solid tumors (CD3×CLDN6)	✓ FPD in July 2022
	BNT116 FixVac in combo with Cemiplimab in NSCLC	✓ FPD in July 2022
	BNT313 (GEN1053) in solid tumors <sup>3</sup>	2H 2022
3 Data Updates	BNT161 influenza mRNA vaccine <sup>1</sup>	✓ July 2022
	BNT122 <sup>4</sup> Phase 2 iNeST in combo with Pembro in frontline melanoma	now in 1H 2023
	BNT211 Phase 1/2 CAR-T/CLDN6+ in multiple solid tumors	2H 2022

<sup>30</sup> HSV 2, Herpes simplex virus type 2; FPD, first patient dosed; CLDN, Claudin; NSCLC, non-small cell lung cancer  
<sup>1</sup> Partnered with Pfizer; <sup>2</sup> Collaboration with BMGF; <sup>3</sup> Collaboration with Genmab <sup>4</sup> Partnered with Genentech



**Once in a generation opportunity to transform medicine**



Further development of COVID-19 vaccine



Accelerate late-stage oncology programs



Advance infectious disease portfolio



Pursue complementary acquisitions



Transform & expand global organization

Bring long-term value to patients, shareholders and society

**THANK  
YOU**

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