

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

**FORM 6-K**

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

**FOR THE MONTH OF NOVEMBER 2022**

**COMMISSION FILE NUMBER 001-39081**

**BioNTech SE**

(Translation of registrant's name into English)

**An der Goldgrube 12**

**D-55131 Mainz**

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(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 November 7, 2022, BioNTech SE (the “Company”) issued a press release announcing its third quarter 2022 financial results and corporate update and details of a conference call to be held at 8:00 am EST on November 7, 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: November 7, 2022

**EXHIBIT INDEX**

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

## BioNTech Announces Third Quarter 2022 Financial Results and Corporate Update

- BioNTech and Pfizer continue to build on global COVID-19 vaccine leadership with first-to-market Original/Omicron BA.4/BA.5-adapted bivalent vaccine launches across multiple countries and regions worldwide
- Approximately 300 million doses of the Original/Omicron BA.1- and BA.4/BA.5-adapted bivalent vaccines invoiced as of mid-October 2022
- In infectious diseases, Phase 1 trial initiated with a combination vaccine candidate, incorporating the Pfizer-BioNTech Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine and Pfizer's quadrivalent modified RNA (modRNA) influenza vaccine candidate, both based on BioNTech's proprietary mRNA platform
- Continued oncology pipeline expansion with three new first-in-human trial starts for BNT116, BNT142, and BNT313
- Presented positive follow-up data from the Phase 1/2 trial evaluating the Company's novel CAR-T cell therapy candidate, BNT211, in patients with relapsed or refractory solid tumors at ESMO 2022
- For the nine months ended September 30, 2022, revenues of €13.0 billion<sup>1</sup> (9M 2021: €13.4 billion<sup>1</sup>), net profit of €7.2 billion (9M 2021: €7.1 billion) and fully diluted earnings per share of €27.70 or \$29.47<sup>2</sup> (9M 2021: €27.46 or \$32.85<sup>2</sup>)
- Strong liquidity of €13.4 billion cash and cash equivalents plus total trade receivables of €7.3 billion outstanding as of September 30, 2022; €3.2 billion of the €7.3 billion trade receivables were received in cash as of October 15, 2022
- BioNTech raises the lower end of its 2022 full year financial guidance to include estimated COVID-19 vaccine revenue of €16 - 17 billion

Conference call and webcast scheduled for November 7, 2022, at 8:00 am ET (2:00 pm CET)

MAINZ, Germany, November 7, 2022 (GLOBE NEWSWIRE) -- [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech" or the "Company") today reported financial results for the three and nine months ended September 30, 2022 and provided an update on its corporate progress.

"I would like to thank our growing BioNTech team for their outstanding performance in the first nine months of 2022 which allowed us to be the first Company to provide access to a BA.4/BA.5 variant adapted bivalent vaccine at an unprecedented speed. We are working to leverage this experience and apply the lessons learned from the development of Omicron-adapted vaccines to other disease areas and product candidates," said **Prof. Ugur Sahin, M.D., CEO and Co-founder of BioNTech**. "The next chapter of BioNTech's evolution is becoming tangible; we continue to expand our COVID-19 vaccine and infectious disease portfolio and advance our oncology pipeline. We reaffirm our commitment to improving the health of people worldwide by developing immunotherapies that utilize the full potential of the immune system to fight cancer, infectious and other serious diseases."

### Financial Review for the Third Quarter and First Nine Months of 2022

<i>in millions, except per share data</i>	Third Quarter 2022	Third Quarter 2021	First Nine Months 2022	First Nine Months 2021
Total Revenues <sup>1</sup>	€3,461.2	€6,087.3	€13,032.3	€13,444.2
Net Profit	€1,784.9	€3,211.0	€7,155.7	€7,126.3
Diluted Earnings per Share	€6.98	€12.35	€27.70	€27.46

**Total revenues** reported were €3,461.2 million<sup>1</sup> for the three months ended September 30, 2022 (Q3 2021: €6,087.3 million<sup>1</sup>). As expected, the course of the pandemic remains dynamic and led to fluctuations in quarterly revenues. For the nine months ended September 30, 2022, total revenues were €13,032.3 million<sup>1</sup> (9M 2021: €13,444.2 million<sup>1</sup>).

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 September 30, 2022, BioNTech's commercial revenues included €2,554.2 million<sup>1</sup> gross profit share (Q3 2021: €4,358.5 million<sup>1</sup>). For the nine months ended September 30, 2022, BioNTech's commercial revenues included €9,128.4 million<sup>1</sup> gross profit share (9M 2021: €10,202.7 million<sup>1</sup>). 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 nine months ended September 30, 2022, BioNTech recognized €564.5 million and €2,284.6 million of direct COVID-19 vaccine sales to customers in BioNTech's territory, Germany and Turkey, as well as €259.4 million and €1,470.9 million from sales of products manufactured by BioNTech for its collaboration partners. During the comparative prior year periods, €1,350.8 million and €2,586.2 million were recognized from sales to customers in BioNTech's territory as well as €312.3 million and €514.3 million from sales of products manufactured by BioNTech for its collaboration partners respectively.

**Cost of sales** were €752.8 million for the three months ended September 30, 2022 (Q3 2021: €1,211.4 million). For the nine months ended September 30, 2022, cost of sales were €2,811.5 million (9M 2021: €2,328.3 million). 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 the Company's collaboration partner Pfizer. In addition, cost of sales were impacted by expenses arising from inventory write-offs and expenses for production capacities derived from contracts with contract manufacturing organizations.

**Research and development expenses** were €341.8 million for the three months ended September 30, 2022 (Q3 2021: €260.4 million). For the nine months ended September 30, 2022, research and development expenses were €1,027.2 million (9M 2021: €677.7 million). The increase was mainly due to increased headcount and higher expenses in the context of the share-based payments.

**General and administrative expenses** were €141.0 million for the three months ended September 30, 2022 (Q3 2021: €68.2 million). For the nine months ended September 30, 2022, general and administrative expenses were €361.8 million (9M 2021: €154.9 million), mainly due to recognizing increased expenses for purchased external services as well as an increase in headcount.

**Income taxes** were accrued with an amount of €659.2 million for the three months ended September 30, 2022 (Q3 2021: €1,456.4 million). For the nine months ended September 30, 2022, income taxes were accrued in an amount of €2,625.8 million (9M 2021: €3,206.2 million). The derived effective income tax rate for the nine months ended September 30, 2022 was 26.8%.

**Net profit** was €1,784.9 million for the three months ended September 30, 2022 (Q3 2021: €3,211.0 million). For the nine months ended September 30, 2022, net profit was €7,155.7 million (9M 2021: €7,126.3 million).

As of September 30, 2022, **cash and cash equivalents** were €13,423.7 million. Trade receivables remained outstanding as of September 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 second quarter of 2022 (as defined by the contract) for which the settlement payment was received subsequent to the end of the reporting period in October 2022. Of the total trade receivables of €7,309.4 million which were outstanding as of September 30, 2022, €3,185.9 million were received in cash as of October 15, 2022.

"Thanks to our strong execution in the third quarter of 2022, we updated our COVID-19 vaccine revenue guidance for the year 2022 to the upper end of the original range. We started shipments of our Omicron-adapted bivalent vaccines early in September and we expect to carry on with our deliveries throughout the fourth quarter of 2022," said **Jens Holstein, CFO of BioNTech**. "We believe in the potential of our COVID-19 franchise and plan to build on our leading position with ongoing innovations in this field. The power of our scientific innovation combined with our strong financial position allows us to accelerate and expand our diversified clinical pipeline and to create future growth in the interest of all stakeholders."

**Updated Outlook for the 2022 Financial Year:**

**Raised COVID-19 vaccine revenue target to upper end of original guidance. Reiterate planned expenses and capex. Updated the estimated annual effective income tax rate.**

The Company's outlook 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	€16 billion - €17 billion (previously €13 billion - €17 billion)
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BioNTech updates its 2022 financial guidance, raising its COVID-19 vaccine revenue estimate to the upper end of the original range: €16 - 17 billion (previously: €13 - 17 billion). The updated guidance reflects the shipment of the Omicron-adapted bivalent vaccine boosters, which started early in September and is expected to continue throughout the fourth quarter of 2022 as well as higher prices and a positive foreign currency effect.

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. BioNTech's COVID-19 vaccine gross profit share from Pfizer is impacted by inventory write-offs. Pfizer inventory write-offs for COVID-19 products reduce BioNTech's gross profit share and therefore, reduce BioNTech's vaccine revenues.

**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	-27% (previously -28%)
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**Operational Review of the Third Quarter 2022 and Key Post Period-End Events**

**COVID-19 Vaccine Programs – BNT162 (COMIRNATY)**

BioNTech and Pfizer continue to build on their global COVID-19 vaccine leadership with first-to-market Original/Omicron BA.4/BA.5-adapted vaccine launches. The Companies have now three commercial stage COVID-19 vaccine products on the market that include the original COVID-19 vaccine and two Omicron adapted vaccines: Original/BA.1- and BA.4/5.-adapted bivalent vaccines. BioNTech's flexible

mRNA platform and production infrastructure supported rapid development and manufacturing of variant-adapted vaccines at an unprecedented speed. BioNTech will continue to innovate to advance a diverse pipeline of follow-on and next generation product candidates. BioNTech believes its COVID-19 vaccine franchise will remain a long-term sustainable business opportunity.

#### *Commercial updates*

Following regulatory approvals, BioNTech and Pfizer immediately began shipping Original/Omicron BA.1 and BA.4/BA.5-adapted bivalent COVID-19 vaccines in September 2022 in time for fall and winter booster campaigns. Shipments in the United States began approximately two months after the U.S. Food and Drug Administration (FDA) provided its guidance for the BA.4/BA.5-adapted bivalent COVID-19 vaccine.

As of mid-October 2022, BioNTech and Pfizer have invoiced approximately 300 million doses of Original/Omicron-adapted bivalent vaccine.

As part of BioNTech and Pfizer's 2-billion-doses-pledge to support equitable access to medicines, the companies have delivered approximately 1.6 billion doses of the companies' COVID-19 vaccine in total to low- and middle-income countries in line with the demand.

BioNTech expects to invoice up to 2.1 billion doses of the COVID-19 vaccine in 2022. Some dose deliveries have been shifted into 2023 due to the evolving dynamics of demand.

BioNTech believes that it and Pfizer are well positioned to supply the quantities required by global market demand.

#### *Clinical development and regulatory updates*

During the third quarter of 2022, BioNTech and Pfizer's COVID-19 vaccine received multiple regulatory approvals and authorizations, including for Omicron-adapted bivalent vaccines, label expansions for pediatric vaccinations and ongoing conversions from conditional or emergency approvals to full regulatory approvals across various regions worldwide. The companies' Original/Omicron BA.4/BA.5-adapted bivalent vaccine has received approvals in more than 45 countries and regions, as of October 25, 2022.

#### **Adapted bivalent vaccine boosters**

- In August 2022, BioNTech and Pfizer started a randomized Phase 2/3 trial evaluating the safety, tolerability and immunogenicity of the Original/Omicron BA.4/BA.5-adapted bivalent vaccine in individuals aged 12 years and older. First data from this trial were reported in October 2022. A 30-µg booster dose of the vaccine demonstrated a substantial increase in the Original/Omicron BA.4/BA.5 neutralizing antibody response above pre-booster levels based on sera taken seven days after administration, with similar responses seen across individuals aged 18 to 55 years and those older than 55 years of age (40 participants in each age group). The Omicron BA.4/BA.5-adapted bivalent vaccine was well tolerated with early data indicating a favorable safety profile, similar to that of the original vaccine.
- On August 31, 2022, BioNTech and Pfizer received U.S. FDA Emergency Use Authorization (EUA) for a 30-µg booster dose of the Original/Omicron BA.4/BA.5-adapted bivalent vaccine for individuals aged 12 years and older.
- On September 1, 2022, BioNTech and Pfizer received a positive European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) opinion and subsequent EC approval for the Original/Omicron BA.1-adapted bivalent vaccine and on September 12, 2022 for a 30-µg booster dose of the Original/Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for individuals aged 12 years and older.
- In September 2022, BioNTech and Pfizer initiated a Phase 1/2/3 study to evaluate the safety, tolerability and immunogenicity of different doses and dosing regimens of the Original/Omicron BA.4/BA.5-adapted bivalent vaccine in children 6 months through 11 years of age. This



pediatric study follows a previous Phase 1/2/3 trial in these age groups that demonstrated the original vaccine is well-tolerated and offers a high level of protection against COVID-19.

- In September 2022, BioNTech and Pfizer submitted a request to the U.S. FDA for EUA for Original/Omicron BA.4/BA.5-adapted bivalent vaccine booster and also completed a submission for conditional Marketing Authorization (cMA) in the European Union for children 5 through 11 years of age.
- In October 2022, the companies received U.S. FDA EUA for a 10-µg booster dose of the Original/Omicron BA.4/BA.5-adapted bivalent vaccine in children 5 through 11 years of age.
- The Centers for Disease Control and Prevention has added COVID-19 vaccines to the agency's lists of recommended regular immunizations and recommends that people ages 5 years and older receive one updated bivalent booster if it has been at least 2 months since their last COVID-19 vaccine dose.
- In November 2022, BioNTech and Pfizer reported updated 30-day clinical data from the randomized Phase 2/3 trial evaluating the safety, tolerability and immunogenicity of the companies' Original/Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine, given as a 30-µg booster dose, which started in August 2022. The data demonstrate a robust and broadly neutralizing immune response one month after a 30-µg booster dose. Immune responses were markedly higher for those who received the bivalent vaccine compared to the original COVID-19 vaccine, with similar favorable safety and tolerability profile demonstrated between both vaccines. Clinical data demonstrated that Omicron BA.4/BA.5-neutralizing antibody titers rose 13.2-fold from pre-booster levels in adults over 55 years and 9.5-fold for adults 18 to 55 years, one month post bivalent booster compared to 2.9-fold rise in titers elicited in the same time frame by the original vaccine booster. These results reinforce the early clinical data measured seven days after a booster dose of the bivalent vaccine, as well as the pre-clinical data, and suggest that a 30-µg booster dose of the Original/Omicron BA.4/BA.5 bivalent vaccine may induce higher level of protection against the Omicron BA.4 and BA.5 subvariants than the original vaccine. BioNTech and Pfizer have shared these data with the U.S. FDA and plan to share with the EMA and other global health authorities as soon as possible.

#### **Original COVID-19 vaccine**

- In August 2022, BioNTech and Pfizer announced updated efficacy data from a Phase 2/3 trial evaluating a 3-µg dose series of the original COVID-19 vaccine in children 6 months through 4 years of age. Vaccine efficacy, a secondary endpoint in the trial, was 73.2% in children without evidence of prior COVID-19 infection, during a period of circulating Omicron BA.2. The vaccine previously received EUA from the U.S. FDA and the companies submitted for extension of the cMA in the European Union for this age group.
- In September 2022, BioNTech and Pfizer were granted approval in the European Union for COMIRNATY as a 10-µg booster (third) dose of the original vaccine given at least six months after completion of a primary series for children 5 through 11 years of age.
- In October 2022, BioNTech and Pfizer received EC approval for the conversion of the cMA to full Marketing Authorization (MA). The conversion applies to all existing and upcoming indications and formulations of the COMIRNATY product group authorized in the European Union, including Original/BA.1 and BA.4/BA.5-adapted bivalent vaccines as booster doses for individuals aged 12 years and older.
- In October 2022, BioNTech and Pfizer received EC approval for full MA for a 3-µg dose of COMIRNATY as a three-dose series for children aged 6 months through 4 years.
- In October 2022, BioNTech and Pfizer received EC approval for a fourth dose booster of COMIRNATY in individuals 12 years of age and older at an interval of at least three months between the administration of COMIRNATY and the last prior dose of a COVID-19 vaccine.

The COVID-19 vaccine continues to offer protection post booster vaccination against severe disease, hospitalization and deaths for circulating Omicron sublineages.

BioNTech and Pfizer continue to monitor protection offered by the original and Original/Omicron adapted bivalent vaccines against emerging SARS-CoV-2 variants.

Recently published data (Muik et al. Exposure to BA.4/BA.5 Spike glycoprotein drives pan-Omicron neutralization in vaccine-experienced humans and mice; bioRxiv 2022.09.21.508818) suggest that when administered as boosters, mono- and bivalent Original/Omicron BA.4/BA.5-adapted vaccines may enhance neutralization breadth against Omicron sublineages BA.1, BA.2, BA.2.12.1, and BA.4/BA.5. The preclinical data support the assumption that boosting with an Original/Omicron BA.4/5-adapted bivalent vaccine is a suitable strategy to confer a broader neutralization and address both currently circulating Omicron variants as well as potential future emerging Omicron sublineages or new variants of concern that are closer to the wild-type strain.

#### **Next generation COVID-19 vaccine**

In addition to variant adapted vaccines, BioNTech and Pfizer are identifying and investigating novel next generation vaccine approaches to maintain a broad and longer lasting immune response and high levels of protection against COVID-19 as SARS-CoV-2 evolves. The long-term strategy takes a multipronged approach devised to develop multiple engineered vaccine candidates with the aim of delivering a pan-SARS-CoV-2-type vaccine that will help to better manage future variants of concern. The companies expect that scientific data derived from those different approaches will support the selection of the vaccine candidate 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.

- In July 2022, BioNTech and Pfizer started a Phase 2 study with a first enhanced spike antigen vaccine candidate.
- The first T cell enhancing SARS-CoV-2 vaccine product candidate (BNT164b4) in combination with the Original/Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine is expected to enter the clinic in the fourth quarter of 2022.

#### *COVID-19 – Influenza Combination mRNA Vaccine Program (BNT162b2 + BNT161)*

In October 2022, BioNTech and Pfizer initiated a Phase 1 open-label, dose-finding study to evaluate the safety, tolerability and immunogenicity of a combination of the COVID-19 and influenza mRNA vaccines to help protect individuals against two severe respiratory viral diseases. The combination vaccine consists of Original/Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine and quadrivalent modRNA influenza vaccine candidate and will be tested at different dose levels in approximately 180 healthy adults 18 to 64 years of age. The companies are building on the experiences made in the BNT161 program, which pursues development of an influenza vaccine based on BioNTech's suite of mRNA platforms.

#### **Influenza Vaccine Program (BNT161)**

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

- In July 2022, positive immunogenicity data from the Phase 2 expansion study of BNT161 were reported.
- In September 2022, Pfizer announced that the first participants have been dosed in a pivotal Phase 3 clinical trial to evaluate the efficacy, safety, tolerability and immunogenicity of a quadrivalent modRNA influenza vaccine candidate in approximately 25,000 healthy U.S. adults. Upon potential approval and commercialization, BioNTech is eligible to receive milestone payments and a royalty on Pfizer's worldwide sales.

#### **Shingles Vaccine Program**

BioNTech is collaborating with Pfizer to develop the first mRNA-based shingles vaccine candidate. A clinical trial is expected to start in the fourth quarter of 2022.

#### **Further Infectious Disease Programs**

BioNTech is applying its validated mRNA vaccine platform across multiple high-need infectious diseases.

BioNTech is on track to initiate a first-in-human clinical trial in the fourth quarter of 2022 for mRNA-based product candidate BNT163, designed to address herpes simplex virus type 2 (HSV 2). A first-in-human clinical trial of an mRNA vaccine to protect against malaria (BNT165) is expected to start in the fourth quarter of 2022 or early 2023. A first-in-human clinical trial of an mRNA vaccine to protect against tuberculosis (BNT164) is expected to start early 2023.

In 2023, BioNTech expects to start up to five vaccine clinical trials in infectious diseases.

### **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. These drug classes 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 19 product candidates in 24 ongoing clinical trials including five randomized Phase 2 clinical trials: two FixVac programs (BNT111 and BNT113), two indications for the iNeST product candidate autogene cevumeran (BNT122/RO7198457) and the bispecific antibody immune checkpoint modulator BNT311 (GEN1046).

In the third quarter of 2022, BioNTech started three first-in-human clinical trials: BNT116, a FixVac program for non-small cell lung cancer (NSCLC), BNT142, a bispecific RiboMab targeting CD3 on T cells and Claudin-6 (CLDN6) in solid tumors and, most recently, BNT313, a HexaBody targeting CD27, a new product candidate from BioNTech's collaboration with Genmab A/S being evaluated in solid tumors.

BioNTech expects continued pipeline advancement and expansion as well as one more data readout from an ongoing trial for the remainder of 2022. In 2023, BioNTech expects to provide up to ten clinical trial updates in oncology.

### **Third Quarter 2022 Clinical Oncology Pipeline Update**

**BNT116**, BioNTech's FixVac product candidate for the treatment of advanced or metastatic non-small cell lung cancer (NSCLC), encodes for six tumor-associated antigens that cover up to 100% of patients in all major histologic subtypes of NSCLC and aims to elicit a tumor-antigen-specific immune response. FixVac is an off-the-shelf cancer immunotherapy approach based on BioNTech's uridine mRNA lipoplex technology targeting shared non-mutated antigens.

- 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 with cemiplimab (anti-PD-1, Regeneron's Libtayo) in patients with advanced or metastasized NSCLC. The trial is intended to establish a safe dose for BNT116 monotherapy as well as for BNT116 in combination with cemiplimab 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.
- A second trial evaluates BNT116 alone and in combination with cemiplimab as first-line treatment of patients with advanced NSCLC whose tumors express programmed cell death ligand-1 (PD-L1) in ≥ 50% of tumor cells. The primary objective of the Phase 1/2 trial is to

assess the safety and tolerability as well as the overall response rate (ORR) and tumor burden reduction. The trial is expected to dose the first patient in the fourth quarter of 2022 and is sponsored by Regeneron Pharmaceuticals, Inc.

**BNT142**, BioNTech's second RiboMab product candidate, is an mRNA that 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.

- In July 2022, the first patient 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.

**BNT211** is a CAR directing T cells against the novel target CLDN6 that is tested alone and in combination with a CAR-T cell-amplifying RNA vaccine, or CARVac, encoding CLDN6. CARVac drives *in vivo* expansion of transferred CAR-T cells, aiming to increase their persistence and efficacy. BNT211 aims to overcome CAR-T cell therapy limitations in patients with solid tumors.

- In September 2022, BioNTech presented follow-up data from its ongoing Phase 1/2 trial evaluating the safety and preliminary efficacy of BNT211 in patients with relapsed or refractory solid tumors at the European Society for Medical Oncology (ESMO) Congress 2022. Signs of anti-tumor activity were observed and the safety profile remained manageable for the two tested dose levels. Efficacy assessment of the 21 evaluable patients showed a best ORR of 33% and a DCR of 67% with one complete response, six partial responses and seven patients with stable disease. In line with the earlier data presented, encouraging clinical responses were seen in patients with testicular cancer treated with dose level 2 after lymphodepletion (n=7), where one complete response, three partial responses and two stable diseases were observed, representing an ORR of 57% and a disease control rate (DCR) of 85%.

**BNT312/GEN1042**, is a first-in-class bispecific antibody designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells. BNT312 is partnered with Genmab as part of a 50/50 collaboration in which development costs and future profit are shared.

- A Phase 1/2 trial in patients with solid tumors is ongoing. Expansion cohorts in melanoma, NSCLC, pancreatic and head and neck carcinoma are recruiting for combination regimens of BNT312 in these indications. Safety and preliminary efficacy data of BNT312 combination therapy in patients with advanced solid tumors are planned to be presented at the ESMO-Immuno-Oncology annual congress in December 2022.

**BNT313/GEN1053** is a monospecific antibody candidate targeting CD27 to address malignant solid tumors. It is based on Genmab's HexaBody technology and is engineered to induce clustering of CD27 on the plasma membrane of T cells with the aim to enhance T cell activation, proliferation and differentiation without depleting T cells. BNT313 is partnered with Genmab as part of a 50/50 collaboration in which development costs and potential future profits for BNT313 will be shared equally.

- In November 2022, a Phase 1 trial was initiated to evaluate the safety, tolerability and preliminary efficacy of BNT313 as a monotherapy for the treatment of malignant solid tumors. The dose escalation part will explore the safety of escalating doses of BNT313. The expansion part is planned to provide additional safety and initial antitumor activity information on the selected dose regimen in selected tumor indications, as well as more detailed data related to the mode of action.
- At the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November 2022, BioNTech intends to present preclinical data that characterize the mechanism of action of HexaBody-CD27. In the *in vitro* experiments, HexaBody-CD27 exhibited CD27 agonist activity independently of Fc gamma receptor-mediated crosslinking. HexaBody-CD27

enhanced activation, proliferation, and proinflammatory cytokine secretion of human CD4+ and CD8+ T cells as well as CD8+ T -cell mediated cytotoxic activity towards tumor cells *in vitro*. In mice expressing human CD27 protein, it enhanced expansion and IFN- $\gamma$  secretion of antigen-specific CD8+ T cells *in vivo*. Overall, the data demonstrated a unique potential mechanism of action that distinguishes HexaBody-CD27 from benchmark monoclonal antibodies targeting CD27.

#### Corporate Updates

- BioNTech continues to facilitate equitable access to its medicines. As part of this commitment, construction of BioNTech's first Africa-based mRNA vaccine manufacturing facility in Kigali, Rwanda is progressing with the first BioNTainer being ready for shipment by the end of 2022. The facility is planned to be able to manufacture a range of mRNA-based vaccines targeted to the needs of the African Union member states, such as the COVID-19 vaccine and investigational malaria and tuberculosis vaccine candidates pending authorization by respective regulatory authorities. Implementation of a Rwandan manufacturing team is also advancing with first senior team members already onboarded.
- In October 2022, BioNTech signed a Letter of Intent with the State of Victoria in Australia for a strategic partnership to collaborate on the research and development of potential mRNA-based vaccines and therapies. The parties will establish a research and innovation center in Melbourne where BioNTech plans to set up a clinical scale end-to-end mRNA manufacturing facility based on its BioNTainer solution to support the design, manufacture and clinical testing of product candidates.
- BioNTech values and respects valid and enforceable intellectual property rights of others and remains confident in its intellectual property. During the course of the third quarter of 2022, CureVac AG and ModernaTX, Inc. filed patent infringement lawsuits against BioNTech and its partner, Pfizer. BioNTech is evaluating these lawsuits and intends to determine the appropriate action in response to these lawsuits.
- BioNTech continues to monitor the natural gas supply situation as part of its regular business continuity management and continues to evaluate possible additional energy supply measures. BioNTech has evaluated its ongoing mitigation efforts to ensure business continuity in light of potential energy supply issues in Europe and elsewhere. BioNTech's manufacturing supply chain remains stable, and the Company does not anticipate energy-related disruptions. BioNTech's commercial production of its COVID-19 vaccine continues to 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 continue to be dependent on gas, and the Company is putting measures in place to mitigate related risks. BioNTech continues to evaluate the impact to its partners, including Pfizer, suppliers and other service providers.
- The first tranche of BioNTech's share repurchase program of ADSs, with a value of up to \$1.0 billion, was executed from May 2, 2022 to October 10, 2022. In the first tranche of the share repurchase program, BioNTech repurchased 6,945,513 ADSs at an average price of \$143.98. In November 2022, BioNTech's Management Board and Supervisory Board authorized the second tranche of the Company's share repurchase program of ADSs, with a value of up to \$0.5 billion, commencing on December 7, 2022.

The full unaudited interim 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/>.

#### Endnotes

<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 nine months ended September 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K filed on

November 7, 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 nine months ended September 30, 2021 and 2022, respectively, as published by the German Central Bank (Deutsche Bundesbank).

### Conference Call and Webcast Information

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts on November 7, 2022 at 8.00 a.m. EDT (2.00 p.m. CEST) to report its financial results and provide a corporate update for the third 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. 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.com](http://www.BioNTech.com)

### 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® 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 BioNTech's COVID-19 vaccine 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 potential personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; 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 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, and shares outstanding; 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 three and nine months ended September 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 September 30,		Nine months ended September 30,	
	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>	2022 <i>(unaudited)</i>	2021 <i>(unaudited)</i>
<b>Revenues</b>				
Commercial revenues	€3,394.8	€6,040.1	€12,923.3	€13,348.1
Research & development revenues	66.4	47.2	109.0	96.1
<b>Total revenues</b>	<b>€3,461.2</b>	<b>€6,087.3</b>	<b>€13,032.3</b>	<b>€13,444.2</b>
<b>Cost of sales</b>	<b>(752.8)</b>	<b>(1,211.4)</b>	<b>(2,811.5)</b>	<b>(2,328.3)</b>
Research and development expenses	(341.8)	(260.4)	(1,027.2)	(677.7)
Sales and marketing expenses	(12.8)	(10.5)	(44.9)	(32.5)
General and administrative expenses	(141.0)	(68.2)	(361.8)	(154.9)
Other operating expenses	(285.1)	(26.4)	(594.6)	(27.3)
Other operating income	459.8	213.1	1,157.5	360.6
<b>Operating income</b>	<b>€2,387.5</b>	<b>€4,723.5</b>	<b>€9,349.8</b>	<b>€10,584.1</b>
Finance income	60.9	26.6	448.5	51.4
Finance expenses	(4.3)	(82.7)	(16.8)	(303.0)
<b>Profit before tax</b>	<b>€2,444.1</b>	<b>€4,667.4</b>	<b>€9,781.5</b>	<b>€10,332.5</b>
Income taxes	(659.2)	(1,456.4)	(2,625.8)	(3,206.2)
<b>Profit for the period</b>	<b>€1,784.9</b>	<b>€3,211.0</b>	<b>€7,155.7</b>	<b>€7,126.3</b>
<b>Earnings per share</b>				
Basic profit for the period per share	€7.43	€13.14	€29.47	€29.22
Diluted profit for the period per share	€6.98	€12.35	€27.70	€27.46



## Interim Condensed Consolidated Statements of Financial Position

<i>(in millions)</i>	September 30, 2022 <i>(unaudited)</i>	December 31, 2021
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	€226.2	€202.4
Property, plant and equipment	488.5	322.5
Right-of-use assets	272.0	197.9
Other financial assets	52.8	21.3
Other assets	1.1	0.8
Deferred expenses	7.5	13.6
Deferred tax assets	343.7	—
<b>Total non-current assets</b>	<b>€1,391.8</b>	<b>€758.5</b>
<b>Current assets</b>		
Inventories	294.8	502.5
Trade and other receivables	7,309.4	12,381.7
Other financial assets	4.8	381.6
Other assets	162.7	64.9
Income tax assets	0.4	0.4
Deferred expenses	73.0	48.5
Cash and cash equivalents	13,423.7	1,692.7
<b>Total current assets</b>	<b>€21,268.8</b>	<b>€15,072.3</b>
<b>Total assets</b>	<b>€22,660.6</b>	<b>€15,830.8</b>
<b>Equity and liabilities</b>		
<b>Equity</b>		
Share capital	248.6	246.3
Capital reserve	1,050.4	1,674.4
Treasury shares	(10.3)	(3.8)
Retained earnings	16,554.3	9,882.9
Other reserves	523.3	93.9
<b>Total equity</b>	<b>€18,366.3</b>	<b>€11,893.7</b>
<b>Non-current liabilities</b>		
Loans and borrowings	237.0	171.6
Other financial liabilities	6.1	6.1
Income tax liabilities	8.0	4.4
Provisions	7.3	184.9
Contract liabilities	53.8	9.0
Other liabilities	17.4	12.8
Deferred tax liabilities	7.0	66.7
<b>Total non-current liabilities</b>	<b>€336.6</b>	<b>€455.5</b>
<b>Current liabilities</b>		
Loans and borrowings	37.0	129.9
Trade payables	296.5	160.0
Other financial liabilities	686.9	1,190.4
Government grants	3.0	3.0
Refund liabilities	—	90.0
Income tax liabilities	1,387.5	1,568.9
Provisions	768.1	110.2
Contract liabilities	673.9	186.1
Other liabilities	104.8	43.1
<b>Total current liabilities</b>	<b>€3,957.7</b>	<b>€3,481.6</b>
<b>Total liabilities</b>	<b>€4,294.3</b>	<b>€3,937.1</b>
<b>Total equity and liabilities</b>	<b>€22,660.6</b>	<b>€15,830.8</b>

## Interim Condensed Consolidated Statements of Cash Flows

<i>(in millions)</i>	Three months ended September 30,		NineSix months ended September, 30	
	2022 <i>(unaudited)</i>	2021 <i>(unaudited, restated)</i>	2022 <i>(unaudited)</i>	2021 <i>(unaudited, restated)</i>
<b>Operating activities</b>				
Profit for the period	€1,784.9	€3,211.0	€7,155.7	€7,126.3
Income taxes	659.2	1,456.4	2,625.8	3,206.2
<b>Profit before tax</b>	<b>€2,444.1</b>	<b>€4,667.4</b>	<b>€9,781.5</b>	<b>€10,332.5</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	33.5	19.8	94.3	49.2
Share-based payment expense	59.7	23.1	81.7	62.4
Net foreign exchange differences	116.2	(194.2)	(222.3)	(295.5)
Loss on disposal of property, plant and equipment	0.2	—	0.4	0.4
Finance income	(7.7)	(0.6)	(226.5)	(1.2)
Finance expense	4.3	82.7	16.8	303.0
Movements in government grants	—	(20.8)	—	(109.6)
Net (gain) / loss on derivative instruments at fair value through profit or loss	(2.3)	24.9	82.3	24.9
Working capital adjustments:				
Decrease / (increase) in trade and other receivables, contract assets and other assets	2,245.4	(3,343.9)	5,016.7	(10,095.4)
Decrease / (increase) in inventories	72.9	(88.0)	207.7	(329.3)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	565.9	332.9	760.3	1,153.9
Interest received	4.3	0.4	6.5	1.0
Interest paid	(4.3)	(2.2)	(16.5)	(6.1)
Income tax paid	(753.3)	(0.7)	(2,834.7)	(1.0)
<b>Net cash flows from operating activities</b>	<b>€4,778.9</b>	<b>€1,500.8</b>	<b>€12,748.2</b>	<b>€1,089.2</b>
<b>Investing activities</b>				
Purchase of property, plant and equipment	(77.9)	(40.5)	(192.6)	(88.1)
Proceeds from sale of property, plant and equipment	0.4	0.2	0.4	1.4
Purchase of intangible assets and right-of-use assets	(4.7)	(0.8)	(26.2)	(12.5)
Purchase of financial instruments	(1.1)	—	(31.1)	—
(Investment) / proceeds from maturity of other financial assets	—	(367.0)	375.2	(367.0)
<b>Net cash flows from / (used in) investing activities</b>	<b>€(83.3)</b>	<b>€(408.1)</b>	<b>€125.7</b>	<b>€(466.2)</b>
<b>Financing activities</b>				
Proceeds from issuance of share capital and treasury shares, net of costs	—	—	110.5	160.9
Proceeds from loans and borrowings	0.4	—	0.6	—
Repayment of loans and borrowings	—	(0.5)	(18.8)	(1.9)
Payments related to lease liabilities	(10.0)	(4.8)	(31.9)	(15.9)
Share repurchase program	(643.8)	—	(930.7)	—
Dividends	—	—	(484.3)	—
<b>Net cash flows from / (used in) financing activities</b>	<b>€(653.4)</b>	<b>€(5.3)</b>	<b>€(1,354.6)</b>	<b>€143.1</b>
Net increase in cash and cash equivalents	4,042.2	1,087.4	11,519.3	766.1
Change in cash and cash equivalents resulting from exchange rate differences	46.7	24.2	211.7	49.4
Cash and cash equivalents at the beginning of the period	9,334.8	914.1	1,692.7	1,210.2
<b>Cash and cash equivalents at September 30</b>	<b>€13,423.7</b>	<b>€2,025.7</b>	<b>€13,423.7</b>	<b>€2,025.7</b>

BIONTECH

3<sup>rd</sup> Quarter 2022  
Financial Results  
& Corporate Update

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November 07, 2022

Exhibit 99.2



BIONTECH

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## 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: BioNTech's expected revenues and net profit related to sales of BioNTech's COVID-19 vaccine, referred to as COMIRNATY® 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 BioNTech's COVID-19 vaccine 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 potential personal injury or death arising from the use of BioNTech's COVID-19 vaccine and other products and product candidates developed or manufactured by BioNTech; 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 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, and shares outstanding; 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 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 BioNTech's quarterly report on Form 6-K for the three and nine months ended September 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 standard marketing authorization (MA) by the European Commission to prevent coronavirus disease 2019 (COVID-19) in people aged 5 years and older. The vaccine is administered as a 2-dose series, 3 weeks apart. Adults and adolescents from the age of 12 are given 30 micrograms per dose, children aged 5 to 11 years are given 10 micrograms per dose. In addition, the MA has been expanded to include a booster dose (third dose) at least 3 months after the second dose in individuals 12 years of age and older. A third primary course dose may be administered at least 28 days after the second dose to people aged 5 years and older with a severely weakened immune system. The European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has completed rigorous evaluation of COMIRNATY, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available.

In addition, COMIRNATY has also been granted standard MA for two adapted vaccines: COMIRNATY Original/Omicron BA.1, which contains mRNA encoding for the spike protein of the wild-type and of the Omicron BA.1 subvariant of SARS-CoV-2; and COMIRNATY Original/Omicron BA.4-5, which contains mRNA encoding for the spike protein of the wild-type and of the Omicron BA.4/BA.5 subvariant of SARS-CoV-2. COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may be administered as a booster in people aged 12 years and older who have received at least a primary vaccination course against COVID-19. There should be an interval of at least 3 months between administration of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 and the last prior dose of a COVID-19 vaccine.

## 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.
- There is an increased, but very rare risk (<1/10,000 cases) of myocarditis and pericarditis following vaccination with COMIRNATY. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. The risk of myocarditis after a booster dose of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 has not yet been characterized.
- Rare cases of acute peripheral facial paralysis, uncommon incidence of insomnia, hyperhidrosis and night sweats, and unknown incidence of paresthesia, hypoesthesia and erythema multiforme have been identified in post-marketing experience.
- 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.
- Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.
- As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopaenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.
- The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may be lower in immunosuppressed individuals.
- As with any vaccine, vaccination with COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may not protect all vaccine recipients. Individuals may not be fully protected until 7 days after their second dose of the vaccine.
- Adverse reactions observed during clinical studies are listed below according to the following frequency categories: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000).
- Very common side effects: injection site pain, injection site swelling, tiredness, headache, muscle pain, chills, joint pain, diarrhea, fever
- Common side effects: injection site redness, nausea, vomiting
- Uncommon side effects: enlarged lymph nodes (more frequently observed after the booster dose), feeling unwell, arm pain, insomnia, injection site itching, allergic reactions such as rash or itching, feeling weak or lack of energy/sleep, decreased appetite, excessive sweating, night sweats
- Rare side effects: temporary one-sided facial drooping, allergic reactions such as hives or swelling of the face
- Very rare side effects: inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis), which can result in breathlessness, palpitations or chest pain, anaphylaxis, extensive swelling of vaccinated limbs, facial swelling, pins and needles/tingling, reduced sense of touch or sensation, a skin reaction that causes red spots or patches on the skin
- A large amount of observational data from pregnant women vaccinated with the initially approved COMIRNATY vaccine during the second and third trimester have not shown an increase in adverse pregnancy outcomes. While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen. COMIRNATY can be used during pregnancy. No effects on the breast-fed newborn/infants are anticipated since the systemic exposure of breast-feeding women to the initially approved COMIRNATY vaccine is negligible. Observational data from women who were breast-feeding after vaccination have not shown a risk for adverse effects in breast-fed newborns/infants. COMIRNATY can be used during breast-feeding.
- No data are available yet regarding the use of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 during pregnancy. Since differences between products are confined to the spike protein sequence, and there are no clinically meaningful differences in reactivity between those COMIRNATY variant adapted vaccines that have been clinically evaluated, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 can be used during pregnancy.
- No data are available yet regarding the use of COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 during breast-feeding. Observational data from women who were breast-feeding after vaccination with the initially approved COMIRNATY vaccine have not shown a risk for adverse effects in breast-fed newborns/infants. COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 can be used during breast-feeding.
- Interactions with other medicinal products or concomitant administration of COMIRNATY, COMIRNATY Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 with other vaccines has not been studied.
- Animal studies with COMIRNATY Original do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
- The safety of a COMIRNATY Original/Omicron BA.1 booster dose in individuals from 18 to ≤ 55 years of age is extrapolated from safety data from a subset of 315 adults 18 to ≤ 55 years of age who received a booster (fourth dose) of Omicron BA.1 30 µg (monovalent) after completing 3 doses of COMIRNATY. The most frequent adverse reactions in these participants 18 to ≤ 55 years of age were injection site pain (> 70%), fatigue (> 60%), headache (> 40%), myalgia (> 30%), chills (> 30%) and arthralgia (> 20%).
- In a subset from the Phase 3 study, 305 adults > 55 years of age who had completed 3 doses of COMIRNATY, received a booster of COMIRNATY Original/Omicron BA.1 after receiving Dose 3. The overall safety profile for the COMIRNATY Original/Omicron BA.1 booster (fourth dose) was similar to that seen after the COMIRNATY booster (third dose). The most frequent adverse reactions in participants greater than 55 years of age were injection site pain (> 50%), fatigue (> 40%), headache (≥ 30%), myalgia (> 20%), chills and arthralgia (> 10%). No new adverse reactions were identified for COMIRNATY Original/Omicron BA.1.
- The safety of a booster dose of COMIRNATY Original/Omicron BA.4-5 is inferred from safety data for a booster dose of COMIRNATY Original/Omicron BA.1, as well as for a booster dose of COMIRNATY Original.
- The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials. As with any vaccine, vaccination with Cominarty Original/Omicron BA.1 or COMIRNATY Original/Omicron BA.4-5 may not protect all vaccine recipients
- For complete information on the safety of COMIRNATY, COMIRNATY Original/Omicron BA.1 and COMIRNATY Original/Omicron BA.4-5, 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](mailto:EudraVigilance) or directly to BioNTech using email [rxinfo@biontech.de](mailto:rxinfo@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.

- Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
- Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is FDA-authorized under Emergency Use Authorization (EUA) for use in individuals 5 years of age and older as a single booster dose administered at least 2 months after either:
  - completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or
  - receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

\*Monovalent refers to any authorized and approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2 virus

## COMIRNATY® (COVID-19 Vaccine, mRNA)

- 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 as a third primary series dose to individuals 12 years of age and older who have certain kinds of immunocompromise
- The COVID-19 vaccine is FDA authorized under Emergency Use Authorization (EUA) for use in individuals 6 months and older to provide:
  - a 3-dose primary series to individuals 6 months through 4 years of age
  - a 2-dose primary series to individuals 5 years through 11 years of age
  - a third primary series dose to individuals 5 years through 11 years of age with certain kinds of immunocompromise

## EMERGENCY USE AUTHORIZATION

Emergency uses of the vaccines have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 6 months and older for the Pfizer-BioNTech COVID-19 Vaccine and 5 years and older for the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

## IMPORTANT SAFETY INFORMATION

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), COMIRNATY® (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 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

- Individuals should not get COMIRNATY (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent if they have had a severe allergic reaction after a previous dose of COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine or any ingredient in these vaccines
- There is a remote chance that these vaccines 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, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital

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

- Severe allergic reactions: Non-severe allergic reactions such as rash, itching, hives, or swelling of the face; Myocarditis (inflammation of the heart muscle); Pericarditis (inflammation of the lining outside the heart); 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; Fainting in association with injection of the vaccine; Unusual and persistent irritability; Unusual and persistent poor feeding; Unusual and persistent fatigue or lack of energy; Unusual and persistent cool, pale skin
- Individuals should seek medical attention right away if they have any of the following symptoms: difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, dizziness, and weakness
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COMIRNATY® (COVID-19 vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine. The observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low
- These may not be all the possible side effects of the vaccine. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

Individuals should always ask their healthcare providers for medical advice about adverse events. Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-922-7897 or report online to [www.vaers.hhs.gov/reportevent.html](http://www.vaers.hhs.gov/reportevent.html). In addition, individuals can report side effects to Pfizer Inc. at [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling 1-800-428-1888

# Agenda

**01** 3rd Quarter 2022 Highlights  
Ugur Sahin, Chief Executive Officer

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**02** COVID-19 Vaccine & Pipeline Update  
Özlem Türeci, Chief Medical Officer

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Jens Holstein, Chief Financial Officer

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**04** Corporate Outlook  
Ryan Richardson, Chief Strategy Officer

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## Q3 Highlights: Corporate & Oncology Pipeline



### Corporate Updates

- Reported Q3 total revenues of €3.5 bn<sup>1</sup> and year-to-date revenues of €13 bn<sup>1</sup>
- Raised full year 2022 revenue guidance to the upper end of our prior range: €16-17 bn
- Signed letter of intent with Australia's State of Victoria to establish an mRNA research and innovation center and clinical scale BioNTainer manufacturing facility
- Expanded team to more than 4,000 employees around the world



### Oncology Pipeline Advancement




- Expanded Oncology pipeline to 19 clinical-stage programs in 24 ongoing clinical trials including five Phase 2 trials
  - Initiated Phase 1 clinical testing for three new programs: BNT116 (FixVac in NSCLC), BNT142 (RiboMab, CD3xCLDN6), BNT313<sup>2</sup> (Hexabody, CD27)
- Presented positive follow-up data from Phase 1/2 trial of CAR-T candidate BNT211 in solid tumors at ESMO

<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 nine months ended September 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K, filed on November 7, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

<sup>2</sup> Collaboration with Genmab



## Q3 Highlights: COVID-19 Vaccine / COMIRNATY

 <p>Strong global distribution</p>	<ul style="list-style-type: none"> <li>• First-to-market Omicron BA.4/BA.5-adapted bivalent vaccine</li> <li>• ~300 m doses of variant adapted vaccines invoiced<sup>1</sup></li> </ul>	
 <p>Rapid regulatory advancement</p>	<p>COMIRNATY (Original vaccine) Ongoing conversion to full approvals globally</p> <ul style="list-style-type: none"> <li>• Conversion to full marketing authorization in the EU<sup>2</sup></li> <li>• Label expansion in EU               <ul style="list-style-type: none"> <li>• 3 dose primary series in ages 6 months to &lt;5 years</li> <li>• 3<sup>rd</sup> dose booster for ages 5-11 years</li> <li>• 4<sup>th</sup> dose booster for ages 12+ years</li> </ul> </li> </ul>	<p>Omicron BA.4/BA.5-adapted bivalent vaccine booster Approvals in 45+ countries or regions worldwide</p> <ul style="list-style-type: none"> <li>• EU: Full Marketing Authorization for ages 12+ years<sup>3</sup></li> <li>• US: FDA EUA for ages 5+ years<sup>4</sup></li> </ul>
 <p>Broad and diverse clinical program</p>	<ul style="list-style-type: none"> <li>• Initiated Phase 2/3 trial of Omicron BA.4/BA.5-adapted bivalent booster in individuals 12+ and reported positive data from 18+ years cohorts at 30-day timepoint</li> <li>• Initiated Phase 1/2/3 trial of Omicron BA.4/BA.5-adapted booster in children 6 months to 11 years of age</li> <li>• Initiated Phase 1 trial with COMIRNATY / influenza combo mRNA vaccine<sup>5</sup></li> </ul>	

<sup>1</sup> As of mid of October 2022. Includes BA.1- and BA.4/5 bivalent adapted vaccines. - <sup>2</sup> Approved for prevention of COVID-19 as a 2-dose series in individuals 5 yrs of age and older and as a 3-dose series in individuals 6 months through 4 years of age, for all existing and future indications and formulations. - <sup>3</sup> COMIRNATY Original/Omicron BA.4/5 may be administered as a booster in people aged 12 years and older who have received at least a primary vaccination course against COVID-19. - <sup>4</sup> Bivalent (Original and Omicron BA.4/BA.5) is FDA-authorized under Emergency Use Authorization (EUA) for use in individuals 5 years of age and older as a single booster dose administered at least 2 months after either completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine. - <sup>5</sup> Collaboration with Pfizer

# Rapid Omicron Response: ~ 2 Months from Regulator Recommendation to Launch

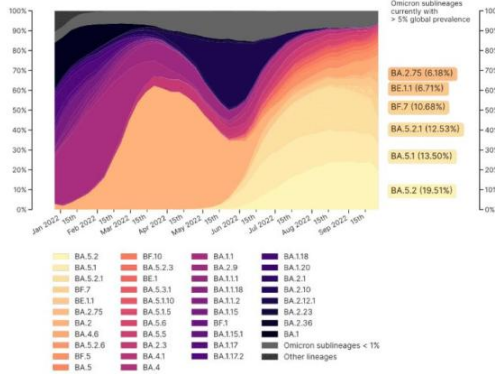


<sup>1</sup> as of October 25, 2022  
 VRBP = Vaccines and Related Biological Products; CMC = chemistry, manufacturing and controls; ICMRA = International Coalition of Medicines Regulatory Agencies

# Epidemiology and Scientific Data Support Need for Omicron BA.4/BA.5-Adapted Bivalent Booster

BA.4/BA.5 and sublineages continue to be dominant strains<sup>1</sup>

Timecourse of Omicron variant sublineage distribution 2022-10-04



<sup>1</sup> WHO Website: [www.who.int/en/about/who-tracking-sars-cov-2-variants](https://www.who.int/en/about/who-tracking-sars-cov-2-variants). Accessed 7 October 2022  
<sup>2</sup> Muik et al. Exposure to BA.4/BA.5 Spike glycoprotein drives pan-Omicron neutralization in vaccine-experienced humans and mice. bioRxiv 2022.09.21.508819  
 WT = wild-type; VoC = variant of concern

bioRxiv  
THE PREPRINT SERVER FOR BIOLOGY

New Results Follow this preprint

**Exposure to BA.4/BA.5 Spike glycoprotein drives pan-Omicron neutralization in vaccine-experienced humans and mice**

Alexander Muik, Bonny Gaby Liu, Maren Bacher, Ann-Kathrin Wallitsch, Aras Tokar, Carli Iris Cadima Couto, Aljosha Güler, Veera Manjari, Geneva J. Schmitt, Jonathan Mottl, Thomas Ziegenhals, Stephanie Fesser, Jonas Reinholz, Florian Wernig, Karla-Gerlinde Schraut, Hossam Hefesha, Hui Cai, Qi Yang, Kerstin C. Walzer, Janica Grosser, Stefan Strauss, Andrew Fitzgibbon, Kimberly Krüger, Orkun Özdemir, Katharina Grischke, Niko Kohmer, Sandra Cisek, Kera A. Swanson, Annette B. Vogel, Ozlem Turaci, Ugur Sahin

Original/Omicron BA.4/BA.5-adapted bivalent boosters may

- Provide broad protection against currently circulating Omicron sublineages and the WT virus<sup>2</sup>
- Confer robust protection against future emerging Omicron sublineages or new VoCs that are closer to the WT virus<sup>2</sup>

Original/Omicron adapted bivalent vaccines may enhance neutralization breadth

- Expansion of memory B cells against epitopes shared broadly among variants
- Expansion and preservation of T cell responses may protect against severe disease



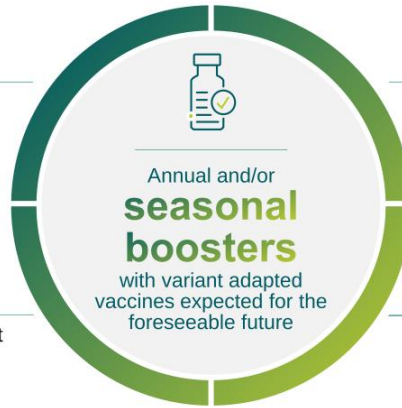
## Long-Term Need for Annually Adapted Boosters Anticipated

### Continuous evolution

of SARS-CoV-2 creates possibility of waves driven by new immune-evasive strains<sup>1,2,3</sup>

### Long-term health consequences

of COVID-19 infections significant, but still not fully understood



### Risk remains high

for severe COVID-19 in vulnerable populations<sup>3,4</sup>

### Booster vaccination restores

waning immunity<sup>5</sup>

<sup>1</sup> WHO Website. [www.who.int/en/factfiles/tracking-sars-cov-2-variants](https://www.who.int/en/factfiles/tracking-sars-cov-2-variants). Accessed 7 October 2022

<sup>2</sup> GISAID. <https://gisaid.org/>. Accessed 7 October 2022

<sup>3</sup> FDA VRBPAC. <https://www.fda.gov/media/159491/download>. Accessed 7 October 2022

<sup>4</sup> Office for National Statistics. <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/self-reported-covid-after-infection-with-the-omicron-variant/6may2022>. Accessed 7 October 2022

<sup>5</sup> Goldberg Y, et al. *N Engl J Med* 2022; 386:2205-2212. DOI: 10.1056/NEJMoa2211

## Framework in Place for Building a Sustainable Business for COVID-19 and Multi-Product Opportunities in Other Infectious Diseases



**Safety,  
Tolerability  
& Efficacy**



**Rapid  
Adaptation**



**Expert  
Regulatory  
Navigation**



**Continued  
Innovation**

Built on BioNTech's validated platform of proven science, discovery, development, manufacturing & commercialization

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## Multi-Pronged Strategy for Continued Innovation

### Variant Adapted Vaccines

Vaccine Boosters to Address  
Evolving Virus

### Novel Combinations

Vaccine for Seasonal Protection  
with Convenient Single-Dose  
Administration

### Next- Generation Constructs

Vaccines Designed for Extended  
Durability and Breadth of  
Protection

Innovation supported by insights from continuous variant surveillance and robust clinical program

## Omicron BA.4/BA.5-Adapted Bivalent Vaccine Approved in 45+ Countries<sup>1</sup>

	FDA EUA <sup>2</sup>	EC Marketing Authorization <sup>3</sup>	FDA Submission	EMA Submission	Phase 1/2/3 Clinical Trial
<b>BA.4/5-Adapted</b>					
Ages 12+ yrs	✓	✓	✓	✓	Ongoing <sup>4</sup>
Ages 5-11 yrs	✓		✓	✓	Ongoing <sup>5</sup>
Ages 6 mo-4 yrs			Planned for 1Q 2023	Planned for 1Q 2023	Ongoing <sup>5</sup>
<b>BA.1-Adapted</b>					
Ages 12+ yrs		✓		✓	✓

<sup>1</sup> As of October 25, 2022

<sup>2</sup> Bivalent (Original and Omicron BA.4/BA.5) is FDA-authorized under Emergency Use Authorization (EUA) for use in individuals 5 years of age and older as a single booster dose administered at least 2 months after either completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

<sup>3</sup> COMIRVATI (Original/Omicron BA.4/5) or COMIRVATI (Original/Omicron BA.1), and may be administered as a booster in people aged 12 years and older who have received at least a primary vaccination course against COVID-19.

<sup>4</sup> Phase 2/3 trial of Omicron BA.4/BA.5 adapted bivalent booster in individuals 12+ years old

<sup>5</sup> Phase 1/2/3 trial of Omicron BA.4/BA.5 adapted booster in children 6 months – 11 years of age



## Positive Data from 30 Day Time Point in Omicron BA.4/BA.5-Adapted Vaccine Study

### Randomized, controlled, Phase 2/3 trial in healthy volunteers aged 12 and older

#### Study design:

- N=900
- Previously received at least 3 vaccine doses
- Ages 18+: 30- $\mu$ g or 60- $\mu$ g booster
- Ages 12-17: 30- $\mu$ g booster
- Original vaccine served as comparator arm

#### Primary endpoints:

- Safety, tolerability and immunogenicity



### Updated data from sentinel cohort >18 years

#### Sentinel cohort (n=40/group):

- Bivalent Original/BA.4/5 30- $\mu$ g: 18-55 years of age
- Bivalent Original/BA.4/5 30- $\mu$ g: >55 years of age
- Comparator group: Original BNT162b2 30- $\mu$ g (>55 years of age)

Safety and tolerability profile of bivalent booster remains favorable and similar to original vaccine

Omicron BA.4/BA.5-adapted bivalent vaccine substantially increased Omicron BA.4/BA.5 neutralizing antibody titers above pre-booster levels in adults 18+

## Omicron BA.4/BA.5 Adapted Bivalent Vaccine Demonstrates Strong Immune Response in Adults 18+

Assay Sampling time point: 1 month	Vaccine Group (as randomized)						
	Age	BNT162b2 Bivalent (WT/OMI BA.4/BA.5) <sup>1</sup> 30 µg				BNT162b2 <sup>1</sup> 30 µg	
		18-55 Years	>55 Years		>55 Years		
Baseline SARS-CoV-2 Status	n	GMFR (95% CI)	n	GMFR (95% CI)	n	GMFR (95% CI)	
SARS-CoV-2 FFRNT – Omicron BA.4/BA.5 - NT50 (titer)	All	38	9.5 (6.7, 13.6)	36	13.2 (8.0, 21.6)	40	2.9 (2.1, 3.9)
	Positive	20	6.0 (3.5, 10.1)	19	6.7 (3.5, 12.7)	20	2.8 (1.9, 4.1)
	Negative	18	16.0 (10.8, 23.7)	17	28.3 (15.2, 52.8)	20	3.0 (1.8, 4.9)
SARS-CoV-2 FFRNT – reference strain - NT50 (titer)	All	38	5.1 (3.5, 7.3)	36	5.8 (3.9, 8.6)	40	3.0 (2.1, 4.3)
	Positive	20	3.1 (2.0, 4.9)	19	3.5 (2.1, 6.0)	20	2.0 (1.4, 2.9)
	Negative	18	8.8 (5.4, 14.4)	17	10.2 (6.3, 16.6)	20	4.4 (2.3, 8.2)

Improved responses with bivalent vaccine most pronounced in elderly and baseline negative individuals

## Initiated Phase 1 Combination Trial of Influenza mRNA Vaccine + Omicron BA.4/BA.5-Adapted Bivalent COVID-19 Vaccine<sup>1</sup>

Quadrivalent Influenza (qFlu) mRNA vaccine (2 type A strains, 2 type B strains selected annually)

+ Omicron BA.4/BA.5 adapted bivalent COVID-19 vaccine



30 µg qFlu  
+  
30 µg Omicron  
BA.4/BA.5



30 µg qFlu  
+  
60 µg Omicron  
BA.4/BA.5



60 µg qFlu  
+  
30 µg Omicron  
BA.4/BA.5



30 µg qFlu



60 µg qFlu



Standard of Care  
Flu Vaccine (control  
arm) N=30

N~180 adults aged 18-64

Primary endpoints: safety, tolerability and immunogenicity

Flu + COVID-19 vaccine combination may offer convenient seasonal administration  
for protection in a single shot

## Next Generation Vaccine Approaches to Provide Durable, Broad Protection

### Engineered Spike Protein Vaccines

Multiple candidates being explored

- Designed to elicit more broadly neutralizing antibodies
- Potential to protect against multiple, not-yet-seen coronavirus variants
- Potential to be combined with T cell enhancing vaccine



Additional trial initiations planned for:  
Engineered spike protein candidates

### BNT162b4: T Cell Enhancing Vaccine Candidate

Targets highly-conserved non-spike proteins and aims to

- Increase immune resilience
- Enhance and broaden T cell response
- Provide memory T cell persistence
- Enhance B cell response durability



Start Phase 1 expected in 4Q 2022:

BNT162b4 + Omicron BA.4/BA.5-adapted  
bivalent vaccine

Constructs designed to engage different arms of the immune system including antibodies and T cells

## Infectious Disease Pipeline: Multiple Opportunities Built on Proven Platform

	Indication	Product candidate	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Milestones 2022	
mRNA vaccines partnered w/Pfizer	COVID-19 <sup>1</sup>	COMIRNATY®							
		BNT162b2(Original/Omicron BA.4/BA.5-adapted bivalent)						Launch + Data updates	✓
		BNT162b2 (Original/Omicron BA.1-adapted bivalent)						Launch + Data updates	✓
		BNT162b4 (T cell enhancing)						Start Phase 1: 4Q 2022	
	Covid-19 – Influenza combination <sup>1</sup>	BNT162b5 (Enhanced spike antigen)						Phase 2 started in July 2022	✓
		BNT162b2+BNT161 (qFlu + BA.4/BA.5-adapted bivalent)						Phase 1 initiated in October 2022	✓
Influenza <sup>2</sup>	BNT161						Data update in July 2022 Phase 3 started in September 2022	✓	
Shingles <sup>1</sup>	Un-named program						Start Phase 1: 4Q 2022		
10+ other infectious disease programs	HSV 2 <sup>2</sup>	BNT163						Start Phase 1: 4Q 2022	
	Tuberculosis <sup>3</sup>	BNT164						Start Phase 1: early 2023	
	Malaria	BNT165						Start Phase 1: 4Q 2022 / early 2023	
	HIV <sup>3</sup>	Un-named program							
	Additional mRNA vaccine programs <sup>3</sup>	Un-named programs							
	Precision antibacterials	Un-named programs							

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<sup>1</sup> Collaboration with Pfizer

<sup>2</sup> University of Pennsylvania collaboration

<sup>3</sup> Collaboration with Bill & Melinda Gates Foundation. BioNTech holds worldwide distribution rights except developing countries where BMG holds distribution rights.

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## 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						
		BNT116	NSCLC 2L+						FPD in July 2022 ✓
	iNeST	Autogene cevumeran (BNT122) <sup>1</sup>	1L melanoma						Data update exp. 1H 2023
			Adjuvant colorectal cancer						
	Intratumoral immunotherapy	SAR441000 (BNT131)	Solid tumors						
			Adjuvant pancreatic ductal adenocarcinoma <sup>2</sup>						Data update June 2022 ✓
	RiboMabs	BNT141	Multiple solid tumors (CLDN18.2)						FPD in Jan. 2022 ✓
			Multiple solid tumors (CD3×CLDN6)						FPD in July 2022 ✓
RiboCytokines	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 Sept. 2022 ✓
		BNT212	Pancreatic, other cancers (CLDN18.2)						
	Neoantigen-based T cells	BNT221	Multiple solid tumors						
	TCR engineered T cells	To be selected	All tumors						
Antibodies	Next-gen immune checkpoint modulators	GEN1046 (BNT311)	Metastatic NSCLC (PD-L1×4-1BB)						
			Multiple solid tumors (PD-L1×4-1BB)						
		GEN1042 (BNT312)	Multiple solid tumors (CD40×4-1BB)						Data update 4Q 2022
	Targeted cancer antibodies	GEN1053 (BNT313)	Malignant solid tumors (CD27)						Initiated in Nov. 2022 ✓
BNT321		Pancreatic cancer (sLea)							
SMIM	Toll-like receptor binding	BNT411	Solid tumors (TLR7)						

20 <sup>1</sup> Collaboration with Genentech, a member of the Roche Group  
<sup>2</sup> Investigator-initiated Phase 3 trial  
 FPD = First patient dosed, SMIM = small molecule immunomodulators, NSCLC = non-small cell lung cancer

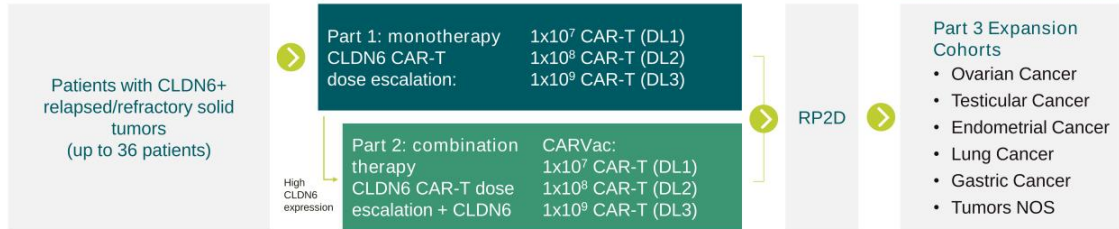
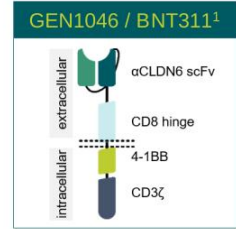
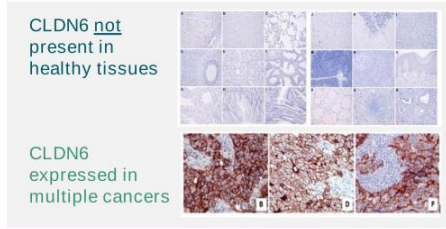
# BNT211: CAR-T Cell Program with Potential Targeting Multiple High-Need Solid Tumors

## 2nd generation CAR

- Directed against CLDN6
  - Cancer specific carcino-embryonic antigen
  - Expressed in multiple solid cancers with high medical need

## CARVac

- Drives in vivo expansion, persistence and efficacy of CAR-T cells



21 Reinhard K, et al. Science 2020; 367:446-453  
 CLDN6 = Claudin-6; CAR-T cells = chimeric antigen receptor engineered T cells; scFv = single chain variable fragment; RP2D = recommended Phase 2 dose; NOS = not otherwise specified.

# BNT211: Follow-up Data of Novel CAR-T Cell Program in Solid Tumors Presented at ESMO 2022

## Safety

CLDN6 CAR-T cells as monotherapy or combined with CARVac **well tolerated** at dose levels evaluated to date ( $1 \times 10^7$  and  $1 \times 10^8$  CAR-T)

- Mostly grade 1-2 CRS seen in 45% of patients, manageable by administration of tocilizumab if needed
- 2 DLTs observed, both patients fully recovered and showed clinical benefit
- MTD not reached yet



## Efficacy

Dose-dependent expansion of CAR-T cells achieved in all patients translating into clinical activity:

ORR 33%, DCR of 67% in evaluable patients (n=21;  $1 \times 10^7$  and  $1 \times 10^8$  CAR-T)<sup>1</sup>

- 1 CR, 6 PR, 7 SD

Testicular cancer patients (n=7)<sup>2</sup> with particularly encouraging responses at  $1 \times 10^8$  CAR-T:

- ORR 57%, DCR 85%
- 1 CR, 3 PR, 2 SD



BNT211 continues to show encouraging efficacy and safety profiles

<sup>1</sup> Including lymphodepletion free cohort; <sup>2</sup> Excluding lymphodepletion free cohort

Data cut-off: August 15, 2022

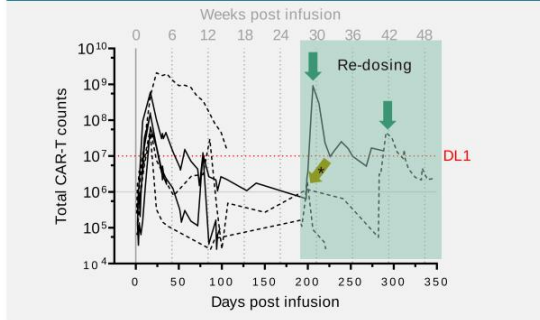
DL1:  $1 \times 10^7$  CAR-T; DL2:  $1 \times 10^8$  CAR-T

CLDN6 = Claudin-6; DLT = dose-limiting toxicity; MTD = maximum tolerated dose; CRS = cytokine release syndrome; CR = complete response; DCR = disease control rate; DL = dose level; ORR = overall response rate; PR = partial response; RP2D = recommended Phase 2 dose; SD = stable disease

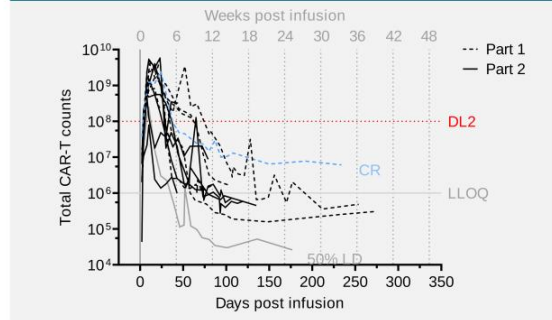


## Dose Dependent CAR-T Expansion Seen in All Patients

DL1 ( $1 \times 10^7$  CLDN6 CAR-T)



DL2 ( $1 \times 10^8$  CLDN6 CAR-T)

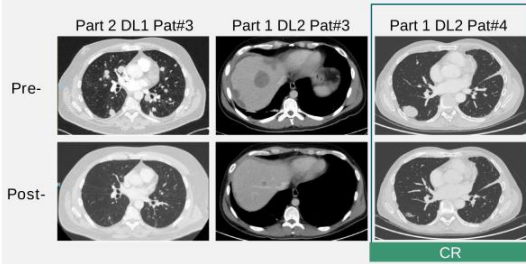


Strong persistence of CAR-T observed for more than 100 days, with some patients showing persistence for more than 200 days

23 Two patients were treated with CAR-T without prior LD and engraftment was unsuccessful.  
 \*Redosing without prior LD  
 Data cut-off: 15 Jun 2022. CR = complete response; DL = dose level; LD = lymphodepletion; LLOQ = lower limit of quantification.

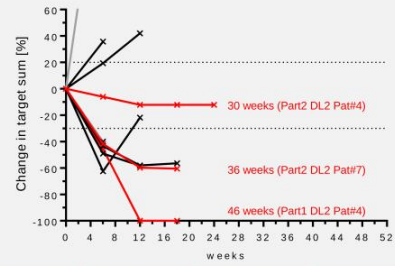
# Robust Tumor Shrinkage and Durable Responses observed in Testicular Cancer Patients

## Selected scans of responses in various patients



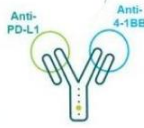
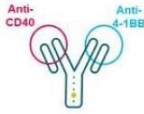

- One testicular cancer patient investigator-assessed as CR after 12 weeks (metabolic response in PET-CT and tumor-marker negative)
- CR confirmed at 18 and 52 weeks

## Deepening of responses over time



	DL1 w/ LD	DL2 w/ LD	Total w/ LD
Testicular, n	4	7	11
ORR, %	25	57	45
DCR, %	25	85	54

## Rapid Advancement of Next Generation Immuno-Modulators for Cancer

GEN1046 / BNT311 <sup>1</sup>	GEN1042 / BNT312 <sup>1</sup>	GEN1053 / BNT313 <sup>1</sup>
 <p data-bbox="347 450 603 488">Phase 2: R/R NSCLC Phase 1/2: Advanced solid tumors</p> <p data-bbox="347 517 603 575">Bispecific antibody: Conditional 4-1BB co-stimulation while blocking PD-(L)1 axis</p>	 <p data-bbox="715 456 970 495">Phase 1/2: Advanced solid tumors • Data update at ESMO I/O 2022</p> <p data-bbox="715 510 970 568">Bispecific antibody: Combines targeting and conditional activation of CD40 and 4-1BB on immune cells</p>	 <p data-bbox="1082 450 1385 501">Phase 1/2: Solid tumors • Initiated Phase 1/2 in November • Preclinical data and MOA at SITC 2022</p> <p data-bbox="1082 510 1337 548">Monospecific HexaBody<sup>2</sup> targeting CD27 on naive and activated T cells</p>

Designed to prime and activate anti-tumor T cell and Natural Killer cell function

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

# Agenda

**01** 3rd Quarter 2022 Highlights  
Ugur Sahin, Chief Executive Officer

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**02** COVID-19 Vaccine & Pipeline Update  
Özlem Türeci, Chief Medical Officer

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**03** Financial Results  
Jens Holstein, Chief Financial Officer

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**04** Corporate Outlook  
Ryan Richardson, Chief Strategy Officer

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## Key Highlights for 3Q 2022

### Total Revenues<sup>1</sup>



**€3.5 bn**

### Operating Result



**€2.4 bn**

### Diluted EPS



**€6.98**

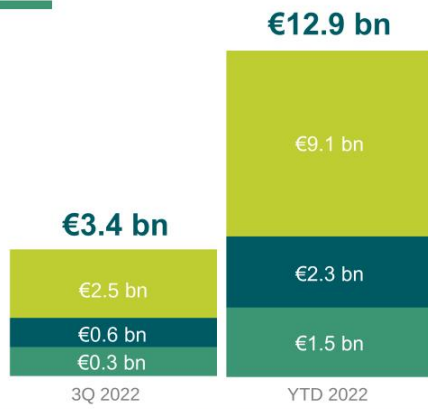
### Cash and Trade Receivables



**€13.4 bn + €7.3 bn**

<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 nine months ended September 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K, on November 7, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

## 3Q and YTD 2022 COVID-19 Vaccine Revenues



Share of gross profit from COVID-19 vaccine sales in the Pfizer and Fosun Pharma territory (100% gross margin)<sup>1</sup>

Direct COVID-19 vaccine sales to customers in BioNTech's territory

COVID-19 vaccine sales to collaboration partners of products manufactured by BioNTech

3Q 2022 revenues in line with our expectations

<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 nine months ended September 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K on November 7, 2022. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

## 3Q and YTD 2022 Financial Results – Profit or Loss

(in millions, except per share data) <sup>1</sup>	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Commercial revenues <sup>2</sup>	€3,394.8	€6,040.1	€12,923.3	€13,348.1
Research & development revenues	66.4	47.2	109.0	96.1
<b>Total revenues</b>	<b>€3,461.2</b>	<b>€6,087.3</b>	<b>€13,032.3</b>	<b>€13,444.2</b>
Cost of sales	(752.8)	(1,211.4)	(2,811.5)	(2,328.3)
Research and development expenses	(341.8)	(260.4)	(1,027.2)	(677.7)
Sales and marketing expenses	(12.8)	(10.5)	(44.9)	(32.5)
General and administrative expenses	(141.0)	(68.2)	(361.8)	(154.9)
Other operating income less expenses	174.7	186.7	562.9	333.3
<b>Operating income</b>	<b>€2,387.5</b>	<b>€4,723.5</b>	<b>€9,349.8</b>	<b>€10,584.1</b>
Finance income less expenses	56.6	(56.1)	431.7	(251.6)
Income taxes	(659.2)	(1,456.4)	(2,625.8)	(3,206.2)
<b>Profit for the period</b>	<b>€1,784.9</b>	<b>€3,211.0</b>	<b>€7,155.7</b>	<b>€7,126.3</b>
<b>Earnings per share</b>				
Basic profit for the period per share	€7.43	€13.14	€29.47	€29.22
Diluted profit for the period per share	€6.98	€12.35	€27.70	€27.46

<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 nine months ended September 30, 2022, filed as an exhibit to BioNTech's Current Report on Form 6-K on November 7, 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 Update

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

Estimated BioNTech COVID-19 vaccine revenues	€ 16 – 17 bn (previously € 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	~27% (previously ~28%) <sup>2</sup>
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30 <sup>1</sup> Ranges reflect current base case projections and do not include potential effects caused by or driven from additional collaborations or potential M&A transactions.  
<sup>2</sup> BioNTech Group estimated annual effective income tax rate decreased from 31.6% (FY 2021) to ~27% (FY 2022) due to decreasing average trade tax rates and one-time effect resulting from share-based payment expenses.



## Share Repurchase Program

- Repurchase American Depositary Shares (ADS) in the amount of up to \$ 1.5 bn
- Term of up to two years
- Repurchased ADSs are to be used in whole or in part to satisfy upcoming settlement obligations under share-based payment arrangements
- First tranche worth up to \$ 1 bn began May 2, 2022, and ended October 10, 2022
- Second tranche worth up to \$ 0.5 bn commencing December 7, 2022, has been approved in November

Period	Number of acquired ADS	Percentage of share capital <sup>1</sup>	Average price (in \$)	Volume (in million \$)
May 2, 2022 to October 10, 2022	6,945,513	2.8%	143.98	1,000.0

31 <sup>1</sup> For the share repurchase, the "percentage of share capital" ratio is calculated based on the shares issued as of April 30, 2022 (248,552,200 ordinary shares).

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## Outlook for COVID-19 Vaccine Franchise

### 2022 year-to-date recap

~300 m variant adapted vaccine doses invoiced since August 2022 with approvals in >45 countries or territories<sup>1,2</sup>

### Outlook for Full Year 2022 and beyond

#### Full-year 2022 deliveries:

- Up to 2.1 bn doses expected to be invoiced globally
- Expect to fulfill 105 m dose US contract and 650 m dose EU contract by year-end

#### 2023/24 market outlook:

- Hybrid public-private market expected to develop in 2023 and beyond
- United States market to shift to commercial model as early as 1Q 2023, with list price between \$110 - \$130 expected per single dose vial for adults
- Global demand expected to be second-half weighted, driven by seasonality of vaccine administration

<sup>1</sup> Distribution of COVID-19 vaccine in collaboration with Pfizer  
<sup>2</sup> As of mid of October 2022; includes BnA1- and BnA1-F variant adapted vaccines

## Select COVID-19 and Infectious Disease Pipeline Milestones

	Program	Milestone	Anticipated Timeline
COVID-19	BNT162b2 + BNT161 (BA.4/BA.5-adapted bivalent + qIRV)	Phase 1 FPD	November 2022
	BNT162b5 (Enhanced spike antigen) <sup>1</sup>	Phase 2 data	4Q 2022
	BNT162b4 (T cell enhancing) <sup>1</sup>	Phase 1 FPD	4Q 2022
	Additional next-generation vaccines <sup>1</sup>	Multiple Phase 1 trials	4Q 2022
Other BioNTech-Pfizer collaboration programs	mRNA Shingles vaccine <sup>1</sup>	Phase 1 FPD	4Q 2022
Other BioNTech Infectious Disease vaccine programs	BNT163 (mRNA HSV2 vaccine) <sup>2</sup>	Phase 1 FPD	4Q 2022
	BNT164 (mRNA tuberculosis vaccine) <sup>3</sup>	Phase 1 FPD	early 2023
	BNT165 (mRNA malaria vaccine)	Phase 1 FPD	4Q 2022 / early 2023

2023 Outlook  
Up to 5 new Infectious Disease trial initiations

34 <sup>1</sup> Partnered with Pfizer  
<sup>2</sup> University of Pennsylvania collaboration  
<sup>3</sup> Collaboration with BMGF  
 HSV 2 = Herpes simplex virus type 2; FPD = first patient dosed

## Select Oncology Pipeline Milestones

	Program	Milestone	Anticipated Timeline
First-in-Human Trial Starts	BNT313 (GEN1053)	Phase 1/2 in solid tumors FPD <sup>1</sup>	November 2022
	BNT116 FixVac	Phase 1/2 in 1L NSCLC in combo with cemiplimab FPD <sup>2</sup>	4Q 2022
Data Updates	BNT312 (GEN1042)	Phase 1/2 in solid tumors data <sup>1</sup>	ESMO IO 2022
	Autogene cevumeran / BNT122 (iNeST)	Phase 2 in combo with pembrolizumab in frontline melanoma data <sup>3</sup>	1H 2023

2023 Outlook  
Up to 10 Oncology clinical trial updates

35 <sup>1</sup> Collaboration with Genmab  
<sup>2</sup> Trial sponsored by Regeneron  
<sup>3</sup> Collaboration with Genentech, a member of the Roche group

## 2023 Outlook

### Once in a generation opportunity to transform medicine

#### Continue to invest for the long-term in leading COVID-19 vaccine franchise

Expand reach of vaccine franchise and deliver data for next-generation candidates



#### Rapidly expand and accelerate innovative pipeline

Catalyst-heavy 2023 expected with multiple late-stage data readouts and FIH trial starts



#### Build on and leverage strong financial position

Re-investing to transform capabilities, accelerate organic growth complemented by bolt-on BD/M&A



Focused on creating long-term value to patients, shareholders and society

THANK YOU



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