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 MARCH 2023

COMMISSION FILE NUMBER 001-39081

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

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

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

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

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

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On March 27, 2023, BioNTech SE (the "Company") issued a press release announcing its full year 2022 financial results and corporate update and details of a conference call to be held at 8:00 am EDT on March 27, 2023 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 the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Jens Holstein
Name: Jens Holstein
Title: Chief Financial Officer

Date: March 27, 2023

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech Announces Full Year 2022 Financial Results and Corporate Update
99.2	Fourth Quarter and Full Year 2022: Corporate Update and Financial Results

BioNTech Announces Fourth Quarter and Full Year 2022 Financial Results and Corporate Update

- *Expanded and advanced oncology pipeline to 20 programs in 24 ongoing clinical trials including five ongoing randomized Phase 2 clinical trials; multiple trials with registrational potential expected to be initiated in 2023 and 2024*
- *Announced licensing agreement with OncoC4 to complement the Company's oncology portfolio with clinical stage next-generation immune checkpoint modulator; a randomized Phase 3 trial planned to start in 2023*
- *Initiated Phase 1 trials for four mRNA vaccine candidates in the infectious disease field*
- *Approximately 2 billion doses of COMIRNATY® invoiced in 2022, including approximately 550 million doses of Omicron-adapted bivalent COVID-19 vaccines*
- *Fourth quarter and full year revenues of €4.3 billion[1] and €17.3 billion[1], respectively*
- *Full year net profit of €9.4 billion and fully diluted earnings per share of €37.77 ($39.77[2])*
- *Strong liquidity of €13.9 billion cash and cash equivalents; €1.8 billion gross profit share settlement was received in cash as of January 12, 2023*
- *Expect to authorize a share repurchase program of up to $0.5 billion during the remainder of 2023*

Conference call and webcast scheduled for March 27 at 8:00 am ET (2:00 pm CET)

MAINZ, Germany, March 27, 2023 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or the "Company") today reported financial results for the three months and full year ended December 31, 2022, and provided an update on its corporate progress.

"We made significant progress in 2022 by advancing our pipeline and launching the world's first Omicron BA.4/BA.5 adapted bivalent COVID-19 vaccine. In addition, multiple new modalities achieved encouraging clinical data and we progressed nine new programs into clinical trials," said **Prof**. **Ugur Sahin, M.D., CEO and Co-Founder of BioNTech.** "As we look to 2023 and beyond, we plan to continue investing in our transformation with a focus on building commercial capabilities in oncology and working towards registrational trials. Our mid-term goal is to seek approval for multiple oncology products in cancer indications with high unmet medical need."

Financial Review for the Fourth Quarter and Full Year 2022 Financial Results

in millions, except per share data	**Fourth Quarter 2022**	**Fourth Quarter 2021**	**Full Year 2022**	**Full Year 2021**
Total Revenues[1]	€4,278.3	€5,532.5	€17,310.6	€18,976.7
Net Profit	€2,278.7	€3,166.2	€9,434.4	€10,292.5
Diluted Earnings per Share	€9.26	€12.18	€37.77	€39.63

Total revenues reported were €4,278.3 million[1] for the three months ended December 31, 2022, compared to €5,532.5 million[1] for the comparative prior year period. For the year ended December 31, 2022, total revenues were €17,310.6 million[1], compared to €18,976.7 million[1] for the comparative prior year period. The change corresponds with the demand for COVID-19 vaccines.

Cost of sales were €183.5 million for the three months ended December 31, 2022, compared to €583.2 million for the comparative prior year period. For the year ended December 31, 2022, cost of sales were €2,995.0 million, compared to €2,911.5 million for the comparative prior year period. Cost of sales were impacted by expenses arising from inventory write-offs and expenses for production capacities derived from agreements with contract manufacturing organizations that became redundant. In addition, during the three months ended December 31, 2022, cost of sales were impacted by the release of provisions.

Research and development expenses were €509.8 million for the three months ended December 31, 2022, compared to €271.5 million for the comparative prior year period. For the year ended December 31, 2022, research and development expenses were €1,537.0 million, compared to €949.2 million for the comparative prior year period. The increase was mainly due to expenses in connection with the development and production of BioNTech's and Pfizer's Omicron-adapted bivalent COVID-19 vaccines and from progressing the clinical studies for BioNTech's pipeline candidates. The increase was further driven by a higher headcount in the R&D area and expenses incurred under BioNTech's share-based-payment arrangements.

General and administrative expenses were €122.9 million for the three months ended December 31, 2022, compared to €130.9 million for the comparative prior year period. For the year ended December 31, 2022, general and administrative expenses were €484.7 million, compared to €285.8 million for the comparative prior year period. The increase was mainly due to increased expenses for IT and purchased external services as well as an increase in headcount.

Income taxes were accrued in an amount of €893.9 million of tax expenses for the three months ended December 31, 2022, compared to €1,547.7 million of tax expenses for the comparative prior year period. For the year ended December 31, 2022, income taxes accrued were €3,519.7 million of tax expenses, compared to €4,753.9 million of tax expenses for the comparative prior year period. The derived annual effective income tax rate for the year ended December 31, 2022, was 27.2%.

Net profit was €2,278.7 million for the three months ended December 31, 2022, compared to €3,166.2 million for the comparative prior year period. For the year ended December 31, 2022, net profit was €9,434.4 million, compared to €10,292.5 million for the comparative prior year period.

Cash and cash equivalents were €13,875.1 million as of December 31, 2022. Subsequent to the end of the reporting period, the payment settling BioNTech's gross profit share for the third quarter of 2022 (as defined by the contract) in the amount of €1,816.5 million was received from our collaboration partner as of January 12, 2023. The contractual settlement of the gross profit share under the COVID-19 collaboration with Pfizer 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.

Shares Outstanding: Shares outstanding as of December 31, 2022, were 243,215,169.

"Our COVID-19 vaccine revenues, driven by the delivery of our Omicron-adapted bivalent vaccines, have ensured another strong financial performance in 2022," said **Jens Holstein, CFO of BioNTech**. "We believe that the Company's financial success in 2022 will provide a springboard to accelerate and build upon our diversified clinical pipeline and fuel our research and development in the coming years. The announced acquisition of InstaDeep and the recent license and collaboration agreement with OncoC4, which adds a clinical program to our existing portfolio aim to create future value for BioNTech mid- to long-term. We anticipate our COVID-19 franchise will further support our already existing financial strength in the years to come. As a science and innovation driven company, we plan to continue to invest heavily in R&D and are willing to invest in mergers and acquisitions as well as collaborations to create future growth for the Company."

Outlook for the 2023 Financial Year:

The Company's outlook contains the following components:

BioNTech COVID-19 Vaccine Revenues for the 2023 Financial Year:

Estimated BioNTech COVID-19 vaccine revenues for the 2023 financial year	~ €5 billion

This revenue estimate reflects expected revenues related to BioNTech's share of gross profit from COVID-19 vaccine sales in the collaboration partner's territories, from direct COVID-19 vaccine sales to customers in BioNTech's territory and expected revenues from sales to collaboration partners which may be influenced by costs like inventory write-offs once materialized and shared with the collaboration partner Pfizer.

Revenue guidance is based on various assumptions including but not limited to the expected transition from an advanced purchase agreement environment to commercial market ordering starting in 2023 and a regulatory recommendation to adapt the COVID-19 vaccines to address newly circulating variants or sublineages of SARS-CoV-2. The estimated BioNTech COVID-19 vaccine revenues reflect expected deliveries under existing or committed supply contracts and anticipated sales through traditional commercial orders. A re-negotiation of the existing supply contract with the European Commission is ongoing, with the potential for a rephasing of deliveries of doses across multiple years and/or a volume reduction. While a vaccine adaptation is expected to lead to an increased demand, fewer primary vaccinations and lowered population-wide levels of boosting are anticipated. Seasonal demand is assumed, moving expected revenue generation significantly to the second half of the year 2023.

Planned 2023 Financial Year Expenses and Capex:

R&D expenses	€2,400 million - €2,600 million
SG&A expenses	€650 million - €750 million
Capital expenditures	€500 million - €600 million

Estimated 2023 Financial Year Tax Assumptions:

BioNTech Group estimated annual cash effective income tax rate	~27%

Numbers reflect current base case projections, include potential effects caused or driven by additional collaborations or potential M&A transactions to the extent they have been disclosed and are calculated based on constant currency rates.

Operational Review of the Fourth Quarter and Key Post Period-End Events

COVID-19 Vaccine Programs – BNT162 (COMIRNATY)

Commercial updates

- In December 2022, BioNTech and Pfizer announced that approximately 2 billion doses of COMIRNATY were invoiced globally in 2022 between the two companies, including approximately 550 million doses of the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine, as of mid-December 2022.
- In January 2023, BioNTech and Pfizer announced that negotiations were ongoing for the re-phasing of delivery timelines for the COMIRNATY supply agreement with the European Commission (EC). The agreement with the EC was signed in May 2021 and a rephasing agreement was previously reached in May 2022.
- As part of BioNTech's and Pfizer's 2-billion-doses-pledge to support equitable access to medicines, the companies have delivered approximately 1.7 billion doses of COMIRNATY to low- and middle-income countries in line with demand. The deliveries include both the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine and the original COVID-19 vaccine.

Clinical development and regulatory updates

Original COVID-19 vaccine

- In October 2022, BioNTech and Pfizer received EC approval for the conversion of the conditional Marketing Authorization (CMA) to full Marketing Authorization (MA). The

conversion applies to all existing indications and formulations of the COMIRNATY product group authorized in the European Union, including Original/Omicron BA.1- and BA.4-5-adapted bivalent COVID-19 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 the original COVID-19 vaccine as a three-dose series for children aged six months through four years.
- In October 2022, BioNTech and Pfizer received EC approval for a fourth dose booster of the original COVID-19 vaccine in individuals 12 years of age and older at an interval of at least three months between the administration of the original COVID-19 vaccine and the last prior dose of a COVID-19 vaccine.

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

- In the second half of 2022, BioNTech and Pfizer received approval or authorization of a 30-µg booster dose of the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine for individuals aged 12 years and older, granted by the U.S. Food and Drug Administration (FDA) (August), European Commission (EC) (September), Health Canada (October), and Health Bureau of the Hong Kong Special Administrative Region of the People's Republic of China (November). The Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine was approved or authorized for use in more than 65 countries and regions in 2022. Authorization of a 10-µg booster dose of Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine in children five through 11 years of age was granted by U.S. FDA (EUA) (October) and EC (November).
- In November 2022, BioNTech and Pfizer reported updated 30-day clinical data from the randomized Phase 2/3 clinical trial evaluating the safety, tolerability and immunogenicity of the companies' Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine, given as a 30-µg booster dose. The data demonstrated a robust and broadly neutralizing immune response one month after a 30-µg booster dose. There was a substantially higher increase in Omicron BA.4/BA.5-neutralizing antibody titers compared to pre-booster levels 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.
- In November 2022, BioNTech and Pfizer announced results from an analysis examining the immune response induced by the Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine against newer Omicron sublineages with enhanced escape mechanisms, including BA.4.6, BA.2.75.2, BQ.1.1 and XBB.1. The published data (Zou et al. Neutralization of BA.4–BA.5, BA.4.6, BA.2.75.2, BQ.1.1, and XBB.1 with Bivalent Vaccine; N Engl J Med 2023; 388:854-857) indicated that the bivalent vaccine elicits a greater increase in neutralizing antibody titers than the original COVID-19 vaccine against these emerging Omicron sublineages.
- In December 2022, BioNTech and Pfizer received U.S. FDA EUA for their Original/Omicron BA.4-5-adapted bivalent COVID-19 vaccine as the third 3-µg dose in the three-dose primary series for children six months through four years of age.

Next-generation COVID-19 vaccine

- In November 2022, BioNTech and Pfizer initiated a Phase 1 clinical trial to evaluate the safety, tolerability and immunogenicity of BNT162b4, a next-generation COVID-19 vaccine candidate that aims to enhance SARS-CoV-2 T cell responses and potentially broaden protection against upcoming variants and increase durability of protection.

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

- In October 2022, BioNTech and Pfizer initiated a Phase 1 open-label, dose-finding clinical trial to evaluate the safety, tolerability and immunogenicity of a combination of the COVID-19 and influenza mRNA vaccines to help protect individuals against influenza and COVID-19 with a single injection. A data update from this trial is expected in 2023.
- In December, BioNTech and Pfizer received Fast Track Designation from the U.S. FDA for their mRNA-based combination vaccine candidate.

Fourth Quarter 2022 Infectious Disease Pipeline Update and Outlook

HSV-2 Vaccine Program – BNT163

- In December 2022, BioNTech initiated a Phase 1 clinical trial of BNT163, a herpes simplex virus (HSV) vaccine candidate for the prevention of genital lesions caused by HSV-2 and potentially HSV-1. The trial will evaluate the safety, tolerability and immunogenicity of BNT163. A data update is expected in 2H 2023.

Malaria Vaccine Program – BNT165

- In December 2022, BioNTech initiated a Phase 1 clinical trial of BNT165b1, the first candidate from the Company's BNT165 program to develop a multi-antigen malaria vaccine candidate. This first clinical trial (NCT05581641) will evaluate the safety, tolerability and exploratory immunogenicity of the vaccine candidate. A data update is expected in 2H 2023.

Shingles Vaccine Program – BNT167

- In February 2023, BioNTech and Pfizer initiated a randomized controlled, dose-selection Phase 1/2 clinical trial of BNT167, the companies' mRNA vaccine candidates against shingles (also known as herpes zoster). The clinical trial (NCT05703607) will evaluate the safety, tolerability, and immunogenicity of mRNA vaccine candidates against shingles. A data update is expected in 2023.

Fourth Quarter 2022 Oncology Pipeline Update and Outlook

- In 2022, BioNTech started five first-in-human clinical trials:
  - BNT116, a FixVac program for non-small cell lung cancer (NSCLC),
  - BNT141 and BNT142, two RiboMabs for CLDN18.2-positive and CLDN6-positive solid tumors and
  - BNT313, a HexaBody targeting CD27, and BNT322 (undisclosed target), two new antibody candidates from its collaboration with Genmab being evaluated in solid tumors.

BNT113, a candidate based on BioNTech's **FixVac off-the-shelf mRNA-based cancer immunotherapy approach,** is being developed as a first-line treatment for patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma, or HNSCC, expressing PD-L1. BNT113 has not previously been combined with anti-PD1 therapy.

- In December 2022, BioNTech presented preliminary safety data from the run-in portion (Part A) of the ongoing Phase 2 trial designed to demonstrate the safety of the combination of BNT113 and pembrolizumab at the annual European Society for Medical Oncology (ESMO) Immuno-Oncology Congress. As of July 5, 2022, of 15 treated patients, 12 had completed the safety run-in (pembrolizumab + four BNT113 doses). Data showed safety was acceptable and in line with the safety profile of BNT113 and pembrolizumab as single agents; no new safety signals were observed for the combination. The randomized Part B is ongoing.

Autogene cevumeran (BNT122) is a candidate based on an **individualized neoantigen-specific immunotherapy (iNeST) approach** developed for the treatment of adjuvant and metastatic cancers in collaboration with Genentech, a member of the Roche Group**.** Each autogene cevumeran dose includes up to 20 different neoantigens selected on a patient-by-patient basis.

- In 2023, BioNTech and Genentech are expecting a data update from an ongoing open-label Phase 2 trial evaluating the efficacy and safety of autogene cevumeran in combination with pembrolizumab versus pembrolizumab alone in patients with previously untreated advanced melanoma.
- A Phase 2 clinical trial of autogene cevumeran in the adjuvant setting in patients with pancreatic ductal adenocarcinoma (PDAC) is planned to open in 2023.

BNT211 is a chimeric antigen receptor (**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 is intended to drive *in vivo* expansion of transferred CAR-T cells to increase their persistence and efficacy.

- In 2023, BioNTech expects to provide a data update on the ongoing Phase 1/2 dose escalation and expansion, evaluating CLDN6 CAR-T cells with or without CLDN6 CARVac in patients with CLDN6-positive relapsed or refractory advanced solid tumors.
- In September 2022, BioNTech provided a data update from the ongoing study at the ESMO Congress, which demonstrated signs of anti-tumor activity and a manageable safety profile across both dose levels. An efficacy assessment of 21 evaluable patients showed an overall response rate, or ORR, of 33% and a disease control rate, or DCR, of 67% with one complete response, six partial responses and seven patients with stable disease. Particularly 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 DCR of 85%.
- The Company expects a Phase 2 study of BNT211 in patients with 2L+ platinum resistant testicular cancer to start in 2024.

BNT312 (GEN1042) is a **first-in-class bispecific antibody candidate** designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells.

- In December 2022, BioNTech and Genmab presented updated data from the safety run-in and expansion cohorts of the Phase 1/2 study of BNT312 combination therapy at the ESMO Immuno-Oncology Annual Congress. The data demonstrated that BNT312 + pembrolizumab (PEM) ± chemotherapy (CTx) was well tolerated with no reported dose-limiting toxicity. Most adverse events were grade 1/2 and manageable. BNT312 (GEN1042) + PEM + CTx showed encouraging early activity in patients with advanced/metastatic HNSCC, with responses observed in 4/4 evaluable patients. The observed immune activity mediated by BNT312 retained with combination therapy. Enrollment in this trial is ongoing in all cohorts (NSCLC, pancreatic ductal adenocarcinoma, and HNSCC).

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 of enhancing T cell activation, proliferation and differentiation without depleting T cells.

- In November 2022, the Company initiated a Phase 1 clinical trial to evaluate the safety, tolerability and preliminary efficacy of BNT313 for the treatment of malignant solid tumors.
- Preclinical data characterizing the mechanism of action of BNT313 were presented at the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in November 2022. In the *in vitro* experiments, BNT313 exhibited CD27 agonist activity independently of Fc gamma receptor-mediated crosslinking. BNT313 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-γ secretion of antigen-specific CD8+ T cells *in vivo*. Overall, the data supported a mechanism of action that distinguishes BNT313 from benchmark monoclonal antibodies targeting CD27.

Fourth Quarter 2022 and Subsequent Corporate Updates

- In November 2022, BioNTech's affiliate BioNTech Pharmaceuticals Asia Pacific Pte. Ltd. announced the signing of an agreement to acquire a GMP-certified manufacturing facility in Singapore which is planned to also serve as BioNTech's Regional Headquarters.
- In November 2022, BioNTech entered a multi-target research collaboration with Ryvu Therapeutics S.A. to develop and commercialize immunomodulatory small molecule candidates as well as standalone small molecules from Ryvu's STING agonist portfolio.
- In November 2022, the second tranche of BioNTech's share repurchase program of American Depositary Shares (ADSs) was authorized, with a value of up to $0.5 billion, commencing on December 7, 2022 and ending on March 17, 2023. In total, under both tranches of the share repurchase program, 9,166,684 ADSs were repurchased at an average price of $142.04, for a total consideration of approximately $1.3 billion (€1,268.4 million).

- As of December 31, 2022, BioNTech had share capital registered in the commercial register ("Handelsregister") in the amount of €248,552,200, which was divided into 248,552,200 registered shares ("Namensaktien"), including an amount of €5,337,031 relating to 1,548,439 ordinary shares held in the form of ADSs and 3,788,592 ordinary shares, each held in treasury.
- In December 2022, BioNTech announced that the first six ISO-sized shipping containers for the BioNTainer have been completed in Europe, underwent quality checks by BioNTech experts and were being prepared for shipment to Kigali. The containers subsequently arrived in March 2023.
- In January 2023, BioNTech announced that it had entered into an agreement to acquire its long-standing strategic collaboration partner InstaDeep Ltd., enabling the creation of a fully integrated, enterprise-wide capability that leverages artificial intelligence (AI) and machine learning (ML) technologies across BioNTech's therapeutic platforms and operations. The transaction is expected to add approximately 240 highly skilled professionals to BioNTech's workforce, including teams in AI, ML, bioengineering, data science, and software development.
- In February 2023, BioNTech completed the construction of its first proprietary plasmid DNA manufacturing facility in Marburg.
- In March 2023, BioNTech entered into an exclusive worldwide licensing agreement with OncoC4, Inc. to co-develop and commercialize ONC-392, an anti-CTLA-4 monoclonal antibody as monotherapy or combination therapy in various cancer indications. The companies plan to start a Phase 3 trial (NCT05671510) of ONC-392 as monotherapy treatment in NSCLC patients who progress after PD-1/PD-L1 treatment in 2023. The transaction is expected to close in the first half of 2023, subject to customary closing conditions and regulatory clearance.

Environmental, Social, and Governance (ESG) overview

- BioNTech published its ESG report (Sustainability Report 2022) on March 27, 2023. The report can be found in the Investor Relations section of BioNTech's website.

Upcoming investor and analyst events

- The Annual General Meeting is scheduled for May 25, 2023.
- BioNTech expects to host an Innovation Series Day on November 7, 2023.

Endnotes

The full audited consolidated financial statements can be found in BioNTech's Annual Report on Form 20-F for the year ended December 31, 2022, filed with the SEC and available at https://www.sec.gov/ (the "Annual Report").

[1] BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.
[2] Calculated applying the average foreign exchange rate for the year ended December 31, 2022 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 March 27, 2023 at 8.00 a.m. EDT (2.00 p.m. CEST) to report its financial results and provide a corporate update for the fourth quarter and financial year 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.com/. 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

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; 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 and the availability of results; the timing and expected impact of the Company's planned acquisition of InstaDeep Ltd. and collaboration and licensing agreements with OncoC4, Inc. and others; the development of sustainable vaccine production and supply solutions, including BioNTainers, and the nature and feasibility of these solutions; and BioNTech's estimates of commercial and other revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, and shares outstanding. 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. These risks and uncertainties include, but are not limited to: 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 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 and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its 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; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Annual Report on Form 20-F for the year ended December 31, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at https://www.sec.gov/. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this 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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Statements of Profit or Loss

(in millions, except per share data)	Three months ended December 31, 2022 (unaudited)	Three months ended December 31, 2021 (unaudited)	Years ended December 31, 2022	Years ended December 31, 2021	Years ended December 31, 2020
Revenues					
Commercial revenues	€4,271.3	€5,525.9	€17,194.6	€18,874.0	€303.5
Research & development revenues	7.0	6.6	116.0	102.7	178.8
Total revenues	**€4,278.3**	**€5,532.5**	**€17,310.6**	**€18,976.7**	**€482.3**
Cost of sales	(183.5)	(583.2)	(2,995.0)	(2,911.5)	(59.3)
Research and development expenses	(509.8)	(271.5)	(1,537.0)	(949.2)	(645.0)
Sales and marketing expenses	(14.6)	(17.9)	(59.5)	(50.4)	(14.5)
General and administrative expenses	(122.9)	(130.9)	(484.7)	(285.8)	(94.0)
Other operating expenses	(376.2)	(67.1)	(407.0)	(94.4)	(2.4)
Other operating income	221.6	237.8	815.3	598.4	250.5
Operating income / (loss)	**€3,292.9**	**€4,699.7**	**€12,642.7**	**€15,283.8**	**€(82.4)**
Finance income	38.8	16.3	330.3	67.7	1.6
Finance expenses	(159.1)	(2.1)	(18.9)	(305.1)	(65.0)
Profit / (loss) before tax	**€3,172.6**	**€4,713.9**	**€12,954.1**	**€15,046.4**	**€(145.8)**
Income taxes	(893.9)	(1,547.7)	(3,519.7)	(4,753.9)	161.0
Profit for the period	**€2,278.7**	**€3,166.2**	**€9,434.4**	**€10,292.5**	**€15.2**
Earnings per share					
Basic profit for the period per share	€9.38	€12.96	€38.78	€42.18	€0.06
Diluted profit for the period per share	€9.26	€12.18	€37.77	€39.63	€0.06

Statements of Financial Position

(in millions)	December 31, 2022	December 31, 2021
Assets		
Non-current assets		
Intangible assets	€219.7	€202.4
Property, plant and equipment	609.2	322.5
Right-of-use assets	211.9	197.9
Other financial assets	80.2	21.3
Other non-financial assets	6.5	14.4
Deferred tax assets	229.6	—
Total non-current assets	**€1,357.1**	**€758.5**
Current assets		
Inventories	439.6	502.5
Trade and other receivables	7,145.6	12,381.7
Other financial assets	189.4	381.6
Other non-financial assets	271.9	113.4
Income tax assets	0.4	0.4
Cash and cash equivalents	13,875.1	1,692.7
Total current assets	**€21,922.0**	**€15,072.3**
Total assets	**€23,279.1**	**€15,830.8**
Equity and liabilities		
Equity		
Share capital	248.6	246.3
Capital reserve	1,828.2	1,674.4
Treasury shares	(5.3)	(3.8)
Retained earnings	18,833.0	9,882.9
Other reserves	(848.9)	93.9
Total equity	**€20,055.6**	**€11,893.7**
Non-current liabilities		
Lease liabilities, loans and borrowings	176.2	171.6
Other financial liabilities	6.1	6.1
Income tax liabilities	10.4	4.4
Provisions	8.6	184.9
Contract liabilities	48.4	9.0
Other non-financial liabilities	17.0	12.8
Deferred tax liabilities	6.2	66.7
Total non-current liabilities	**€272.9**	**€455.5**
Current liabilities		
Lease liabilities, loans and borrowings	36.0	129.9
Trade payables	204.1	160.0
Other financial liabilities	785.1	1,190.4
Refund liabilities	24.4	90.0
Income tax liabilities	595.9	1,568.9
Provisions	367.2	110.2
Contract liabilities	77.1	186.1
Other non-financial liabilities	860.8	46.1
Total current liabilities	**€2,950.6**	**€3,481.6**
Total liabilities	**€3,223.5**	**€3,937.1**
Total equity and liabilities	**€23,279.1**	**€15,830.8**

Statements of Cash Flows

	Three months ended December 31,		Years ended December 31,		
(in millions)	**2022** (unaudited)	**2021** (unaudited)	**2022**	**2021**	**2020**
Operating activities					
Profit for the period	€2,278.7	€3,166.2	€9,434.4	€10,292.5	€15.2
Income taxes	893.9	1,547.7	3,519.7	4,753.9	(161.0)
Profit before tax	**€3,172.6**	**€4,713.9**	**€12,954.1**	**€15,046.4**	**€(145.8)**
Adjustments to reconcile profit before tax to net cash flows:					
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	29.0	26.0	123.3	75.2	38.7
Share-based payment expenses	19.4	20.5	108.6	93.9	32.1
Net foreign exchange differences	847.8	(92.0)	625.5	(387.5)	41.3
Loss on disposal of property, plant and equipment	0.2	4.2	0.6	4.6	0.6
Finance income excluding foreign exchange differences	(38.8)	(0.3)	(265.3)	(1.5)	(1.6)
Finance expense excluding foreign exchange differences	2.1	2.2	18.9	305.2	22.3
Movements in government grants	0.3	20.6	0.3	(89.0)	92.0
Other non-cash income / (loss)	—	(2.2)	—	(2.2)	1.7
Unrealized net (gain) / loss on derivative instruments at fair value through profit or loss	(323.3)	32.4	(241.0)	57.3	—
Working capital adjustments:					
Decrease / (increase) in trade and other receivables, contract assets and other assets	(646.8)	(1,712.7)	4,369.9	(11,808.1)	(247.9)
Decrease / (increase) in inventories	(144.8)	(109.1)	62.9	(438.4)	(49.8)
Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	(674.6)	362.2	85.7	1,516.1	204.6
Interest received	22.8	0.2	29.3	1.2	1.4
Interest paid	(5.0)	(6.1)	(21.5)	(12.2)	(3.6)
Income tax received / (paid), net	(1,387.4)	(3,456.9)	(4,222.1)	(3,457.9)	0.5
Share-based payments	(44.3)	(2.4)	(51.8)	(13.4)	—
Net cash flows from / (used in) operating activities	**€829.2**	**€(199.5)**	**€13,577.4**	**€889.7**	**€(13.5)**
Investing activities					
Purchase of property, plant and equipment	(136.6)	(39.4)	(329.2)	(127.5)	(66.0)
Proceeds from sale of property, plant and equipment	0.2	2.0	0.6	3.4	1.2
Purchase of intangible assets and right-of-use assets	(7.9)	(14.0)	(34.1)	(26.5)	(19.4)
Acquisition of subsidiaries and businesses, net of cash acquired	—	(20.8)	—	(20.8)	(60.6)
Purchase of financial instruments	(16.7)	(19.5)	(47.8)	(19.5)	—
(Investment) / proceeds from maturity of other financial assets	—	(8.2)	375.2	(375.2)	—
Net cash flows used in investing activities	**€(161.0)**	**€(99.9)**	**€(35.3)**	**€(566.1)**	**€(144.8)**
Financing activities					
Proceeds from issuance of share capital and treasury shares, net of costs	—	—	110.5	160.9	753.0
Proceeds from loans and borrowings	0.2	—	0.8	—	156.0

Repayment of loans and borrowings	—	(50.7)	(18.8)	(52.6)	(1.6)
Payments related to lease liabilities	(9.2)	1.8	(41.1)	(14.1)	(12.7)
Share repurchase program	(55.7)	—	(986.4)	—	—
Dividends	—	—	(484.3)	—	—
Net cash flows from / (used in) financing activities	**€(64.7)**	**€(48.9)**	**€(1,419.3)**	**€94.2**	**€894.7**
Net increase in cash and cash equivalents	603.5	(348.3)	12,122.8	417.8	736.4
Change in cash and cash equivalents resulting from exchange rate differences	(152.1)	15.3	59.6	64.7	(45.3)
Cash and cash equivalents at the beginning of the period	13,423.7	2,025.7	1,692.7	1,210.2	519.1
Cash and cash equivalents at December 31	**€13,875.1**	**€1,692.7**	**€13,875.1**	**€1,692.7**	**€1,210.2**

Financial Results & Corporate Update

4th Quarter and Full Year 2022

27.03.2023

BIONTECH

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; 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 and the availability of results; and BioNTech's estimates of commercial and other revenues, cost of sales, research and development expenses, sales and marketing expenses, general and administrative expenses, capital expenditures, income taxes, and shares outstanding. 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. These risks and uncertainties include, but are not limited to: 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 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 and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its 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, risks relating to the global financial systems and markets; and other factors not known to BioNTech at this time. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's annual report on Form 20-F for the full year ended December 31, 2022 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at https://www.sec.gov/. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this 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 (COVID19) in the population aged 6 months and older. In people from 5 years of age 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. There is a pediatric formulation containing 3 micrograms per dose available for infants and children 6 months to 4 years of age. In this age group, COMIRNATY can be given as primary vaccination consisting of three doses (of 3 micrograms each); the first two doses are given 3 weeks apart, followed by a third dose given at least 8 weeks after the second dose. In addition, the MA has been expanded to include a booster dose (third dose) of 30 micrograms at least 3 months after the second dose in individuals 12 years of age and older. A booster dose of COMIRNATY 10 micrograms may be given to children from 5 to 11 years of age at least 6 months after the primary vaccination course. 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 its rigorous evaluation of COMIRNATY, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available. COMIRNATY® ▼(the Pfizer-BioNTech COVID-19 vaccine), Bivalent: COMIRNATY Original/Omicron BA.1, COMIRNATY Original/Omicron BA.4-5 In addition, COMIRNATY has also been granted standard MA for two Omicron subvariant 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 (30 micrograms per dose) 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. A booster dose of COMIRNATY Original/Omicron BA.4-5 (10 micrograms per dose) may be given to people aged from 5 years to 11 years after primary vaccination or a booster dose with a COVID19 vaccine. 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. From post-marketing experience very rare adverse reactions of myocarditis and pericarditis, Rarecases of acute peripheral facial paralysis; uncommon incidence of insomnia, hyperhidrosis and night sweats, dizziness common incidence of vomiting, very common diarrhoea and unknown incidence (wecan not be estimated from available data) anaphylaxis, of paraesthesia, hypoaesthesia and erythema multiforme, extensive swelling of vaccinated limb, facial swelling (in vaccine recipients with a history of injection of dermatological fillers) and heavy menstrual bleeding(most case appeared to be non-serious and temporary in nature) have been identified after 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,paresthesia, hypoesthesia 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 thrombocytopenia 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 and identified after post authorization experience 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, , headache, muscle pain, chills, joint pain, diarrhea, fever, chills, fatigue
- 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, dizziness, injection site itching, allergic reactions such asrash,itching, urticaria or angioedema, feeling weak or lack of energy/sleepy, decreased appetite, excessive sweating, night sweats
- Rare side effects: temporary one-sided facial drooping
- 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.
- Not known indicence (cannot be estimated from the available data): anaphylaxis, extensive swelling of vaccinated limbs; facial swelling, pins andneedles/tingling, reduced sense of touch or sensation, a skin reaction that causes red spots or patches on the skin, heavy menstrual bleeding
- 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/infant are anticipated since the systemic exposure of breast-feeding woman 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 reactogenicity 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.
- In an analysis of Study 3 (Phase 2/3), 1,776 infants (1,178 Comirnaty 3 mcg and 598 placebo) were 6 to 23 months of age. The most frequent adverse reactions in infants 6 to 23 months of age that received any primary course dose included irritability (>60%), drowsiness (> 40%), decreased appetite (> 30%), tenderness at the injection site (> 20%), injection site redness and fever (> 10%).
- The most frequent adverse reactions in children 2 to 4 years of age that received any primary course dose included pain at injection site and fatigue (> 40%), injection site redness and fever (> 10%).
- The overall safety profile of Comirnaty in participants 5 to 11 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in children 5 to 11 years of age that received 2 doses were injection site pain (> 80%), fatigue (> 50%), headache (> 30%), injection site redness and swelling (≥ 20%), myalgia, chills, and diarrhoea (> 10%).
- The overall safety profile for the booster dose was similar to that seen after the primary course. The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (> 70%), fatigue (> 40%), headache (> 30%), myalgia, chills, injection site redness and swelling (> 10%)
- The overall safety profile of Comirnaty in adolescents 12 to 15 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in adolescents 12 to 15 years of age that received 2 doses were injection site pain (> 90%), fatigue and headache (> 70%), myalgia and chills (> 40%), arthralgia and pyrexia (> 20%)
- The most frequent adverse reactions in participants 16 years of age and older that received 2 doses were injection site pain (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 40%), chills (> 30%), arthralgia (> 20%), pyrexia and injection site swelling (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age.
- The 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 Study 4 (Phase 3) ,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 in individuals 18 years of age and older, as well as for a booster dose of COMIRNATY Original in individuals 5 years of age and older.
- 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 Comirnaty 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 or directly to BioNTech using email medinfo@biontech.de, telephone +49 6131 9084 0, or via the website www.biontech.de

BIONTECH

Safety Information

AUTHORIZED USE IN THE U.S.

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 years 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:
  - the first 2 doses of the 3-dose primary series for children 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 and older with certain kinds of immunocompromise

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) to prevent COVID-19 as:
  - the third dose of the 3-dose primary series following 2 doses of the monovalent* Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age; or
  - a single booster dose in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with 3 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine; or
  - a single booster dose at least 2 months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 5 years of age and older.

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

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Warnings:
  - Management of Acute Allergic Reactions: Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent
  - Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html)
  - Myocarditis and Pericarditis: Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent are relevant because these vaccines are manufactured using the same process.
  - Postmarketing data with authorized or approved Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the 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. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).
  - Syncope
  - Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.
  - Altered Immunocompetence
  - Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Limitation of Effectiveness
  - Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.
- Adverse reactions reported with the vaccine include:
  - Adverse Reactions in Clinical Trials
  - Adverse reactions following administration of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, injection site swelling, fever, injection site redness, lymphadenopathy, nausea, malaise, pain in extremity, rash, decreased appetite, vomiting, diarrhea (see Full EUA Prescribing Information).
  - Adverse Reactions Identified in Post Authorization Experience
  - Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), syncope, and dizziness have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.
  - Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
  - Additional adverse reactions, some of which may be serious, may become apparent with post-authorization use of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Use with Other Vaccines
  - There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, with other vaccines.

BIONTECH


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BIONTECH


1
4th Quarter and Full Year 2022 Highlights
Ugur Sahin, Chief Executive Officer
BIONTECH

Continued Leadership against COVID-19 in 2022

~2 billion doses
invoiced in 2022[1]

~550 million doses
of variant adapted vaccines shipped[2]

>60%
market share[3]

Broadest label
amongst COVID-19 vaccines[4]

1. Partnered with Pfizer, 2. As of Dec. 16, 2022, 3. Pfizer/BioNTech cumulative global COVID19 market share across reporting countries; CDC, ECDC OWID data as of Nov 2022, 4. in the USA, EU and UK.

Continued Execution in Oncology and Infectious Diseases R&D in 2022

Clinical data updates across platforms:

BNT211 cell therapy for solid tumors
BNT312[1] next-gen immune checkpoint modulator
BNT122[2] individualized mRNA immunotherapy
BNT113 FixVac in HPV16+ HNSCC

5 new clinical programs

First-in-human:

BNT116 Lung cancer FixVac
BNT141 Ribomab CLDN18.2
BNT142 Ribomab CD3xCLDN6
BNT313[1] Hexabody CD27
BNT322[1] Antibody Undisclosed target

Immuno-oncology

3 COVID-19 vaccine trials[3]

BNT162b2, BA.1-adapted vaccine
BNT162b2, BA.4-5-adapted vaccine
BNT162b4 + BNT162b2

Phase 1 trials for 4 mRNA vaccines

including first-in-human against multiple pathogens:

COVID-19+Flu[4] (BNT162b2+BNT161) | HSV-2[5] (BNT163) | Malaria (BNT165) | Shingles[3] (BNT167)

Infectious diseases

1. Partnered with Genmab, 2. Partnered with Genentech, member of Roche Group, 3. Partnered with Pfizer, 4. Collaboration withPFE and subject to reaching agreement with our partners, 5.Partnered with University of Pennsylvania
CLDN = Claudin, NSCLC = Non-small cell lung cancer, HNSCC = head and neck squamous cell carcinoma, HSV = Herpes simplex virus, HPV = Human papillomaviruses

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Continued to Transform BioNTech

Broadened pipeline[1]

Oncology:

20 programs in 24 ongoing trials

Infectious disease:

6 programs in 10 ongoing trials

Grew team by[2]

>1,500 employees

Strong financials

€13.9 bn

Cash and cash equivalents[3]

Expanded partnerships

4 new collaborations

accessing a variety of technologies[2]

1. As of February 2023, 2. As of December 31, 2022
3 The payment settling our gross profit share for the third quarter of 2022 (as defined by the contract) in the amount of €1,816.5 million was received from our collaboration partner subsequent to the end of the reporting period as of January 12, 2023.

BIONTECH

Enhancing Our Disruptive Technology Toolkit to Fight Human Diseases

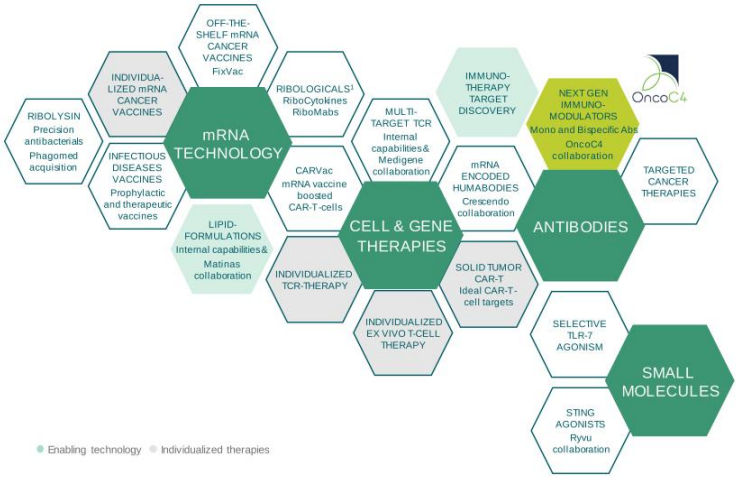
Core principles of our technology strategy

Technology agnostic approach rooted in deep fundamental understanding of biology

Build novel platforms with the ability to produce multiple product candidates

Open up new combination opportunities which leverage synergistic mechanisms of action

Enable individualization of treatment



1. mRNA encoded cancer-targeting antibodies and cytokines

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2023 Strategic Priorities

COVID-19 franchise[1]

Sustain leadership in COVID-19

Advance next-gen vaccines

COMIRNATY® COVID-19 mRNA Vaccine

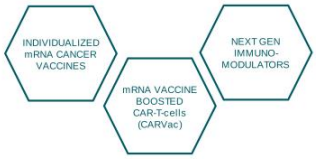
Next-generation vaccine candidate programs:

Variant-adapted	T-cell enhancing	Combination
BNT162b2[1]	BNT162b4 +BNT162b2	COVID-19+Flu[2] BNT162b2+BNT161

Immuno-oncology

Advance disruptive platforms for solid tumors

Initiate multiple potentially registrational trials



Focus programs:

BNT122[3]	BNT211	BNT312[4]
adj. CRC 1L Melanoma	CLDN6+ tumors	BNT311[4] ONC-392[5] Solid tumors

Infectious diseases

Initiate and accelerate clinical programs for high need indications

Ongoing clinical trials:

HSV-2[6] BNT163	Malaria BNT165	Shingles[1] BNT167

Program advancing to clinic:

Tuberculosis[7] BNT164

1. Partnered with Pfizer, 2. Collaboration with PFE and subject to reaching agreement with our partners, 3. Partnered with Genentech, member of Roche Group, 4. Partnered with Genmab, 5. Partnered with OncoC4, 6. Collaboration with University of Pennsylvania, 7. Collaboration with Bill & Melinda G. oundation, 6.

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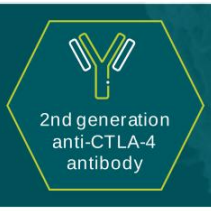
Anti-CTLA-4 Antibody: A Promising New Addition to our Growing Immuno-Oncology Checkpoint Portfolio

Phase 3-Ready Program & Broad Combination Potential with BioNTech mRNA Vaccine Candidate Programs

- First FDA approval of ipilimumab in 2011
- Today 2 products approved in 7 cancer indications[1]
- Approved as monotherapy and/or combination therapy
- Lasting remissions observed in a fraction of responding patients[2]
- Narrow therapeutic window: Toxicities limit dose and duration needed for optimal efficacy[2]



ONC-392: a differentiated anti-CTLA-4 antibody program

- Designed to preserve CTLA-4 recycling and regulatory T-cell function in healthy tissue
- Could allow for more effective dosing regimen and more successful tumor killing leading to potentially improved therapeutic index
- Planned to be developed as monotherapy in some advanced solid tumor indications

1. As of March 2023; 2. Refers to approved anti-CTLA-4 monoclonal antibodies.
CTLA-4 = cytotoxic T-lymphocyte protein 4; FDA = Food and Drug Administration

The transaction is expected to close in the first half of 2023, subject to customary closing conditions and regulatory clearance.

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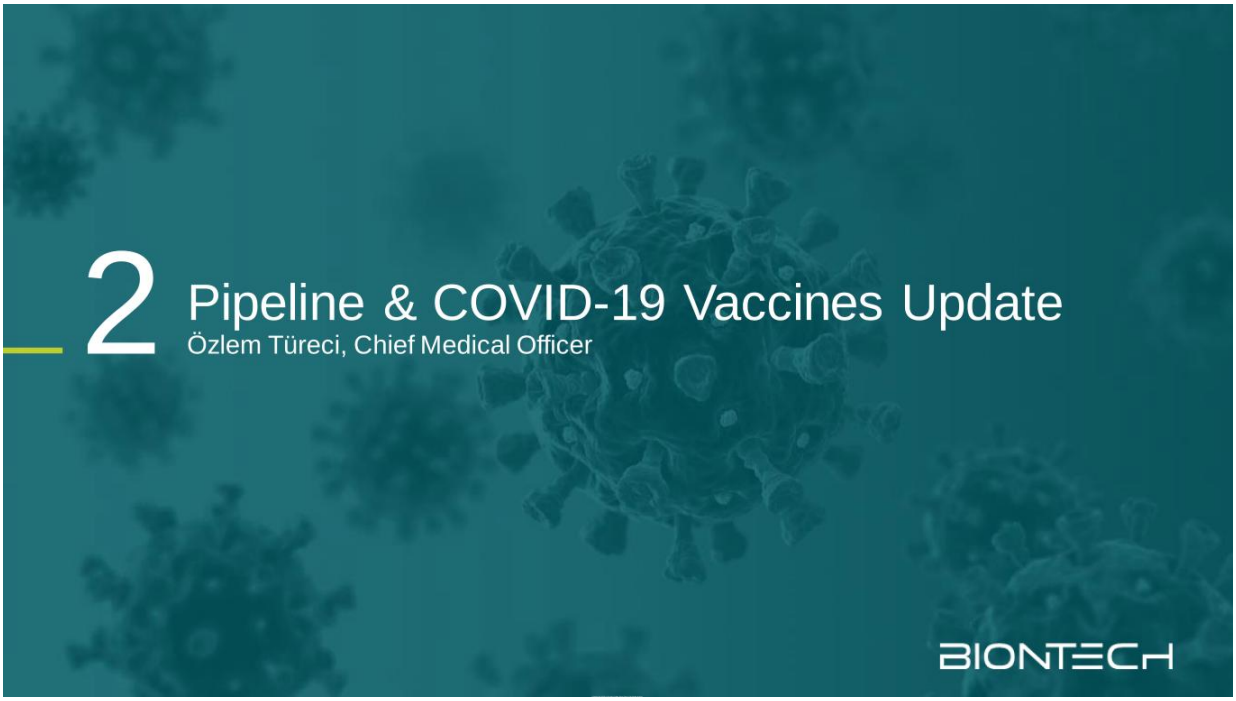
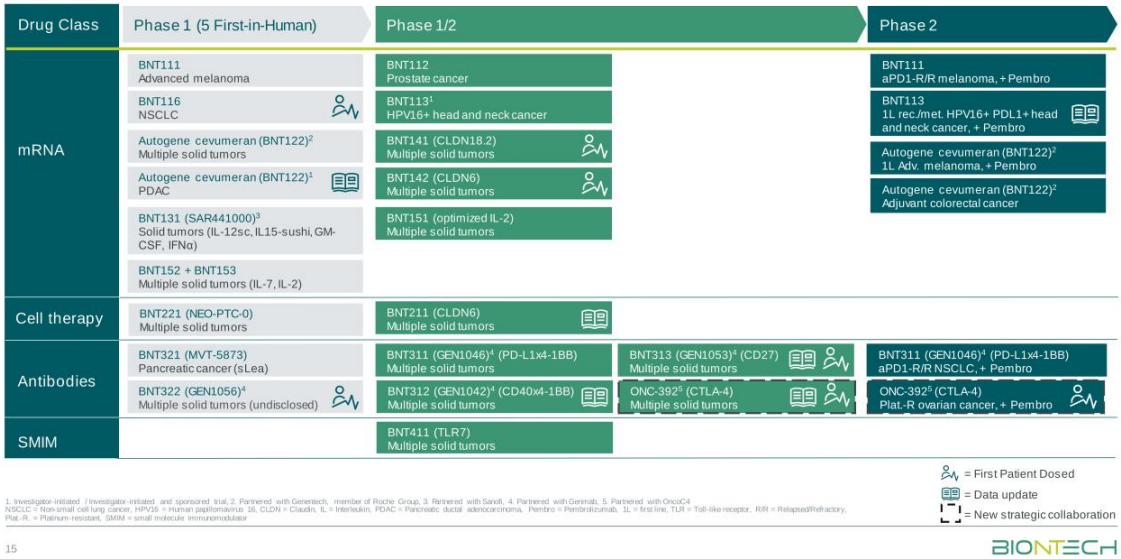

2
Pipeline & COVID-19 Vaccines Update
Özlem Türeci, Chief Medical Officer
BIONTECH

Multiple Clinical Data Readouts Reported at Major Medical Meetings in 2022

Platform	iNeST	CARVac	FixVac	Next-generation immuno-modulators
Program	BNT122[1] Pancreatic ductal adenocarcinoma[2]	BNT211 CLDN6+ solid tumors	BNT113 HPV16+ HNSCC	BNT312 (GEN1042)[3] Multiple solid tumors
Data update	ASCO Ph1 in adjuvant PDAC: • A fraction of patients have high magnitude de-novo, neoantigen-specific T-cell responses which are associated with significantly longer RFS.	ESMO Ph1/2: • Manageable safety profile • Objective responses across different tumor types • Patients with testicular cancer reached an ORR of 57% and a DCR of 85% (1CR, 3PR, 2SD)	ESMO IMMUNO-ONCOLOGY Ph2 (Part A): • Safety profile acceptable and in line with BNT113 and pembrolizumab monotherapy	ESMO IMMUNO-ONCOLOGY Ph1/2: • BNT312 + PEM ± CTx was well tolerated • Early activity in advanced/ metastatic HNSCC (2CR, 2PR)
Next steps	• Ph2 trial in adjuvant PDAC to start in 2023	• Data update from Ph1/2 trial in CLDN6+ advanced solid tumors in 2023 • Ph2 trial in 2L platinum resistant testicular cancer to start in 2024	• Ph2 trial (Part B) is ongoing	• Data update from Ph1/2 trial in multiple solid tumors expected in 2023

1. Partnered with Genentech, member of Roche Group, 2. Investigator initiated study, 3. Partnered with Genmab
HPV = Human papilloma virus, HNSCC = Head and neck squamous-cell carcinoma, PDAC = Pancreatic ductal adenocarcinoma, RFS = Relapse-free survival, ORR = Objective response rate, DCR = Disease control rate, CR = Clinical response, PR = Partial response, SD = Stable disease, PEM = Pembrolizumab, CTx = Chemotherapy

Oncology Pipeline: Significant Progress and Expansion in 2022



1. Investigator-initiated / investigator-initiated and sponsored trial, 2. Partnered with Genentech, member of Roche Group, 3. Partnered with Sanofi, 4. Partnered with Gemmab, 5. Partnered with OncoC4
NSCLC = Non-small cell lung cancer, HPV16 = Human papillomavirus 16, CLDN = Claudin, IL = Interleukin, PDAC = Pancreatic ductal adenocarcinoma, Pembro = Pembrolizumab, 1L = first line, TLR = Toll-like receptor, R/R = Relapsed/Refractory, Plat.-R. = Platinum-resistant, SMIM = small molecule immunomodulator

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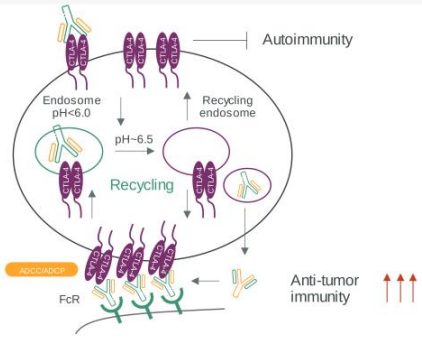
Differentiated Mechanism with Potential to Become Best-in-Class Anti-CTLA-4 Antibody

Avoiding lysosomal degradation of CTLA-4 for safer and more effective immunotherapy may lead to an uncoupling of cancer therapeutic effect from immunotherapy-related adverse effects

ONC-392 designed to:

- Allow regular recycling of antibody and CTLA-4 molecule
- Enhance anti-tumor immunity
- Reduce immune-related adverse events



Liu Y. et al. Abstract # 231, SITC 2021. Du et al. Uncoupling therapeutic from immunotherapy-related adverse effects for safer and effective anti-CTLA-4 antibodies in CTLA4 humanized mice. Cell Res. 2018 Apr; 28(4): 416–432. Du et al. A reappraisal of CTLA-4 checkpoint blockade in cancer immunotherapy. Cell Res. 2018 Apr; 28(4): 433–447.

FcR = fragment crystallizable region, CTLA-4 = cytotoxic T-lymphocyte-associated protein 4, ADCC = antibody-dependent cell-mediated cytotoxicity, ADCP = antibody-dependent cellular phagocytosis

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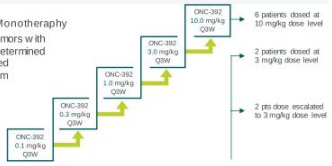
MoA Designed to Allow Higher Dosing & Longer Duration of Treatment with ONC-392

PRESERVE-001: Study Design and Safety (NCT04140526)

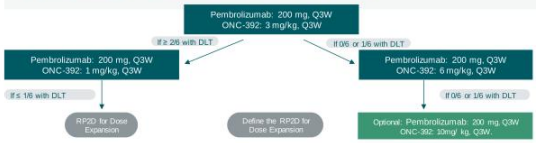
Monotherapy: Dose Finding
(Li T. et al. Poster #949, Presented at SITC 2021)

Objective: To estimate MTD or RP2D for Monotheraphy

Patients with advanced or metastatic solid tumors with measurable or non-measurable disease as determined by RECIST version 1.1, who have progressed despite standard of care therapy, or for whom no standard therapies exist



Combination: Dose Escalation
(Hu-Lieskovan et al. Poster #594. Presented at SITC 2022)



Dose expansion tested in multiple cancer types including:

IO naive NSCLC	IO R/R NSCLC	IO naive Melanoma	IO R/R Melanoma

Safety data and study conclusions

- ONC-392 dosed as mono-therapy and in combination with pembrolizumab were well tolerated
  - TRAE were manageable, no DLTs, MTD not reached
  - Monotherapy RP2D: 10 mg/kg, Combination RP2D: 6 mg/kg
- Preliminary data demonstrated lower irAE rate than observed for comparable IO or IO-IO combinations
- Safety profile of ONC-392 allows for higher dosing and longer duration of treatment in monotherapy and in combination with pembrolizumab

Q3W = Every three weeks; MTD = Maximum tolerated dose; RP2D = Recommended phase 2 dose; DLT = Dose limiting toxicity; TRAE = Treatment related adverse event; NSCLC = Non-small cell lung cancer; irAE = immune-related adverse event, IO = immuno-oncologic, R/R = relapsed/refractory

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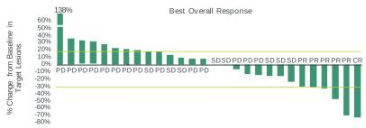
ONC-392 as a Single Agent and Combination Therapy in Multiple Solid Tumors

PRESERVE-001: Clinical Efficacy (NCT04140526)

Monotherapy (10 mg/kg) in platinum-resistant ovarian cancer patients

Hays J et al. Poster #564. Presented at SITC 2022



- 14/28 pts. with clinical activity
  - CR/PR/SD/PD = 1/5/8/14
  - ORR=21%, DCR=50%

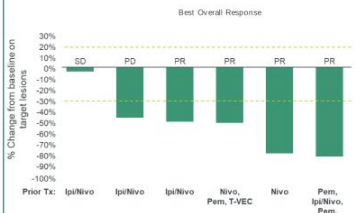
ONC-392 (3 or 6 mg/kg) in combination with pembrolizumab

Hu-Lieskovan et al. Poster #594. Presented at SITC 2022

- 8/10 pts. with clinical activity
  - At 3 mg/kg (6 pts.): 2 PR, 3 SD
  - At 6 mg/kg (4 pts.): 1 PR, 2 SD

ONC-392 (6mg/kg) in combination with pembro in R/R Melanoma

Hu-Lieskovan et al., Poster #594. Presented at SITC 2022



- 6 pts. with clinical activity
  - 5 PR, 1 SD

ONC-392 Development Plan

Phase 2 ongoing

ONC-392 (CTLA-4), NCT05446298

Plat.-resistant ovarian cancer + pembrolizumab

Phase 3 planned

ONC-392 (CTLA-4), NCT05671510

aPD1-R/R NSCLC, Monotherapy

*irAE= immune-related adverse event, CR = Complete remission; PR = Partial response; SD = Stable disease; PD = Progressive Disease; ORR = Objective response rate; DCR = Disease control rate, Ipi = Ipilimumab, Nivo = Nivolumab, Pem = Pemetrexed, Tx = Treatment, T-VEC = Talimogen laherparepvec, Atezo = atezolizumab, R/R = Relapsed/Refractory

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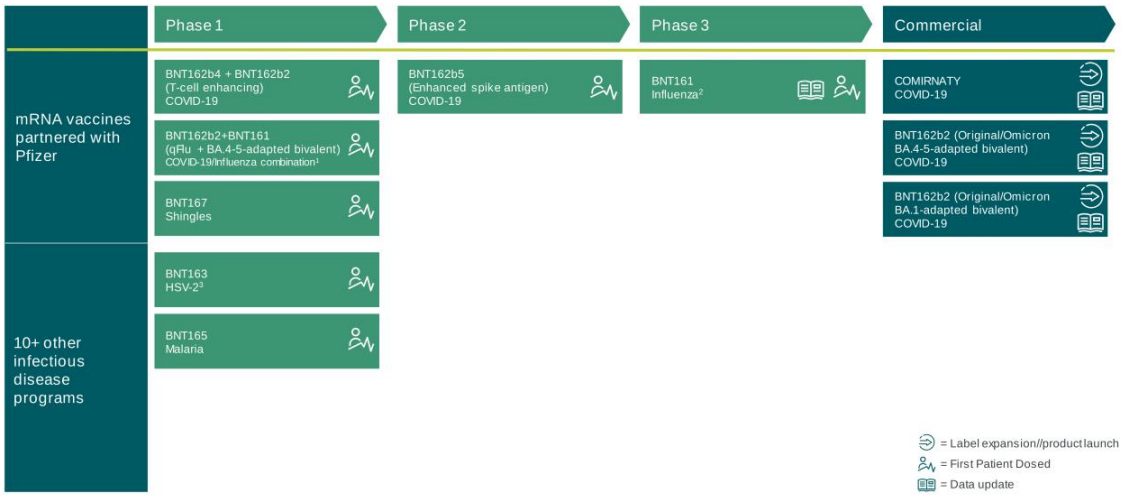
Infectious Disease Pipeline: Expansion in 2022



1. Collaboration with PFE and subject to reaching agreement with our partners, 2. Exclusive license to Pfizer, 3. Collaboration with University of Pennsylvania, HSV = Herpes simplex virus

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Broadest Label of COVID-19 Vaccines

			Europe (full MA)			U.S. (BLA and EUA)		
			Population			Population		
Vaccine	Strain	Use	≥ 6 months	≥ 5 years	≥ 12 years	≥ 6 months	≥ 5 years	≥ 12 years
COMIRNATY[1]	Original strain	Primary	✓	✓	✓	✓	✓	✓
	Original strain + Omicron BA.4-5 variant adapted	Booster		✓	✓	✓*	✓	✓
	Original strain + Omicron BA.1 variant adapted	Booster			✓			

■ MA/BLA Approval granted
■ EUA granted

* As third dose following 2 x Original

1. Partnered with Pfizer
MA = Marketing authorization, BLA = Biologics license application, EUA = Emergency use application

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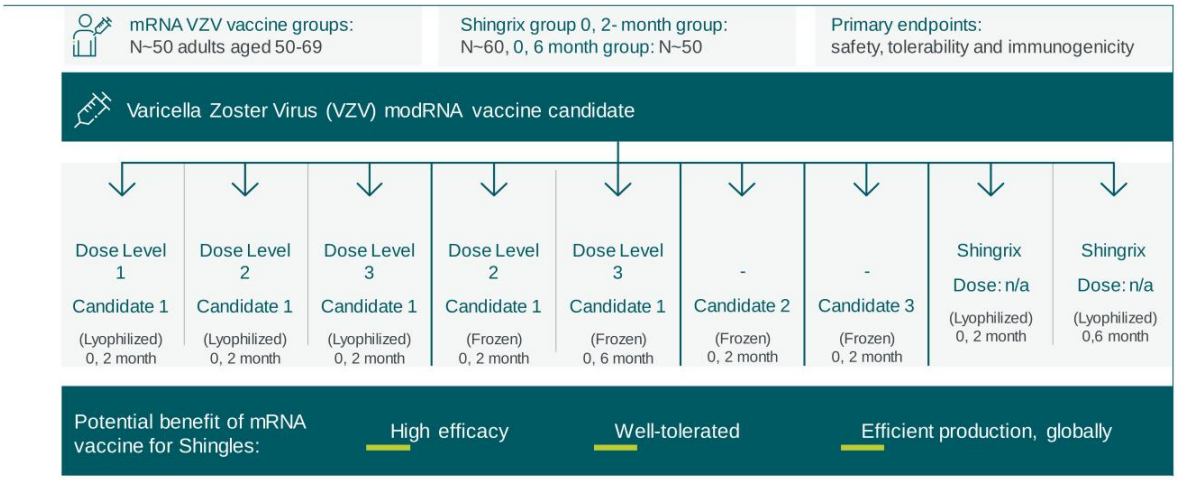
Initiated Phase 1/2 Trial of Varicella Zoster Virus modRNA Vaccine Candidate[1]



1 Trial being conducted by Pfizer as part of the ongoing collaboration, NCT05703607


3
Financial Results
Jens Holstein, Chief Financial Officer
BIONTECH

FY 2022 Key Highlights

Total revenues[1] € 17.3 bn	Operating cashflow € 13.6 bn
Diluted EPS € 37.77	Cash and cash equivalents[2] € 13.9 bn

1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2022 filed on March 27, 2023 with the SEC. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.
2. The payment settling our gross profit share for the third quarter of 2022 (as defined by the contract) in the amount of €1,816.5 million was received from our collaboration partner subsequent to the end of the reporting period as of January 12, 2023.

FY Financial Year Guidance vs. Actuals

		Guidance update (as published in Q3 2022 Financial Results and Corporate Update)	Actuals FY 2022
FY 2022 COVID-19 vaccine revenues	Estimated BioNTech COVID-19 vaccine revenues[1]	€16 – 17 bn	**€17.1 bn**
FY 2022 expenses and capex	R&D expenses	€1,400 – 1,500 m	**€1,537 m**
	SG&A expenses	€450 – 550 m	**€544 m**
	Capital expenditure	€450 – 550 m	**€363 m**
FY 2022 tax assumptions	BioNTech Group estimated annual effective income tax rate	~ 27%	(IFRS) ~ 27% (cash-effective)[2] ~ 24%

1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2022 filed on March 27, 2023 with the SEC. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.
2. Reduction in cash effective tax rate due to IAS 12.68c as a result of tax deductibility of sharebased payment settlement.

Full Year 2022 COVID-19 Vaccine Revenues

Share of gross profit from COVID-19 vaccine sales in the Pfizer and Fosun Pharma territory (100% gross margin)[1]

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

COVID-19 vaccine sales to collaboration partners[2]

FY 2022 revenues in line with our expectations

1. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in the Annual Report on Form 20-F for the year ended December 31, 2022 filed on March 27, 2023 with the SEC. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.
2. Represents sales to collaboration partners of products manufactured by BioNTech and reflects manufacturing costs and variances to the extent identified.

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Q4 and FY 2022 Financial Results – Profit or Loss

(in millions, except per share data)[1]	Three months ended December 31		Years ended December 31	
	2022	2021	2022	2021
Commercial revenues[2]	€4,271.3	€5,525.9	€17,194.6	€18,874.0
Research & development revenues	7.0	6.6	116.0	102.7
Total revenues	**€4,278.3**	**€5,532.5**	**€17,310.6**	**€18,976.7**
Cost of sales	(183.5)	(583.2)	(2,995.0)	(2,911.5)
Research and development expenses	(509.8)	(271.5)	(1,537.0)	(949.2)
Sales and marketing expenses	(14.6)	(17.9)	(59.5)	(50.4)
General and administrative expenses	(122.9)	(130.9)	(484.7)	(285.8)
Other operating income less expenses	(154.6)	170.7	408.3	504.0
Operating income	**€3,292.9**	**€4,699.7**	**€12,642.7**	**€15,283.8**
Finance income less expenses	(120.3)	14.2	311.4	(237.4)
Income taxes	(893.9)	(1,547.7)	(3,519.7)	(4,753.9)
Profit for the period	**€2,278.7**	**€3,166.2**	**€9,434.4**	**€10,292.5**
Earnings per share				
Basic profit for the period per share	€9.38	€12.96	€38.78	€42.18
Diluted profit for the period per share	€9.26	€12.18	€37.77	€39.63

1. Numbers have been rounded, numbers presented may not add up precisely to the totals and may have been adjusted in the tabl context. Presentation of the consolidated statements of profit or loss has been condensed.
2. 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, 2022 filed on March 27, 2023 with the SEC. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively.

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Full Year 2022 Return to Shareholders

Dividend 2022

Dividend in the amount of €0.5 bn paid

Share Repurchase Program

Repurchase American Depositary Shares (ADS) in the amount of up to $1.5 bn

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 $1.0 bn began May 2, 2022, and ended October 10, 2022 amounting to $1.0 bn

Second tranche worth up to $0.5 bn commenced on December 7, 2022, and ended on March 17, 2023 amounting to $0.3 bn

Total net consideration of approximately $1.3 bn under the program

Period	Number of acquired ADSs	Percentage of share capital[1]	Average price (in $)	Volume (in million $)
May 2, 2022 to March 17, 2023	9,166,684	3.7%	142.04	1,302

1. 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).

2023 Financial Guidance Key Assumptions and Considerations

- Expected transition from an advanced purchased agreement environment to commercial market ordering starting in 2023 and a regulatory recommendation to adapt the COVID-19 vaccines to newly circulating variants or sublineages of SARS-CoV-2
- Revenue guidance reflects expected deliveries under existing or committed supply contracts and anticipated sales through traditional commercial orders
- Re-negotiation of the existing supply contract with the European Commission is ongoing with the potential for a rephasing of dose deliveries across multiple years and/or volume reduction
- While need for a new variant-adapted vaccine increasing the demand is expected, fewer primary vaccinations and lowered population-wide levels of boosting are anticipated
- Seasonal demand assumed, moving expected revenue generation significantly to the second half of the year 2023

2023 Financial Year Guidance

COVID-19 vaccine revenues for FY 2023[1]	Estimated BioNTech COVID-19 vaccine revenues	~ €5 bn
Planned FY 2023 expenses and capex[1]	R&D expenses	€2,400 – 2,600 m
	SG&A expenses	€650 – 750 m
	Capital expenditure	€500 – 600 m
Estimated FY 2023 tax assumptions	BioNTech Group estimated annual cash effective income tax rate	~ 27%

1. Numbers reflect current base case projections, include potential effects caused by or driven from additional collaboration or potential M&A transactions to the extent they have been disclosed and are calculated based on constant currency rates.

Capital Allocation Framework

R&D activities

Main focus remains the acceleration of our R&D activities in oncology and infectious diseases

M&A and business development

Strengthen pipeline, technology platforms and digital capabilities by collaborations and potential complementary M&A

Return capital to shareholders

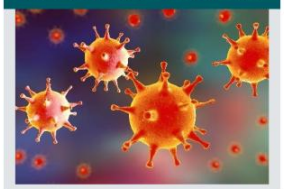
Expect to authorize a share repurchase program of up to $0.5 bn during the year 2023


4
Strategic Outlook
Ryan Richardson, Chief Strategy Officer
BIONTECH

2023 Strategic Outlook

COVID-19 franchise

Infectious disease pipeline



Oncology pipeline

Mid-term Growth Potential for COVID-19 Vaccine Franchise

- First commercial market opening expected in 2H 2023 in the United States, likely to be shaped by ACIP and VRBPAC recommendations
  - Assume that VRBPAC strain selection in May/June will be relevant for 2H booster supply in 2023
- Transition from pandemic to steady state market expected to take several years
- Growth potential for COVID-19 franchise from 2025, driven by shift to commercial market and the potential introduction of next-generation vaccines and novel combinations

COVID-19 vaccine pipeline

BNT162b4 + BNT162b2 (T-cell enhancing) COVID-19[1] ✓

BNT162b2+BNT161 (qRu + BA.4-5-adapted bivalent) COVID-19/Influenza combination[2] ✓

Additional variant-adapted vaccine COVID-19[1]

✓ = Data update expected in 2023

1. Partnered with Pfizer, 2. Collaboration with PFE and subject to reaching agreement with our partners
ACIP = Advisory Committee on Immunization Practices; VRBPAC = Vaccines and Related Biological Products Advisory Committee

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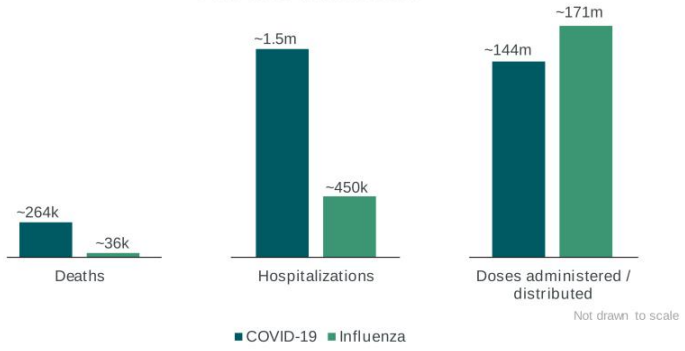
2022 COVID-19 Deaths and Hospitalizations Greatly Exceeded Those from Influenza in the United States

COVID-19 continues to cause mortality, hospitalization and long-term complications

- A leading cause of death worldwide, estimated to exceed 6.8 million deaths[1]
- A leading cause for respiratory disease hospitalization in the United States[2]
- Evidence suggesting that patients with the SARS-CoV-2 Omicron variant had a higher risk of in-hospital mortality than those with influenza[3]
- Estimated to be >65 million long COVID sufferers worldwide (more than 10% of COVID survivors)[4,5]

Death, hospitalizations and administered/distributed vaccine doses in the U.S.: COVID-19 vs. Influenza in 2022[6-8]



1. WHO Coronavirus (COVID-19) Dashboard. 2. Since October 2022: https://www.cdc.gov/coronavirus/2019-ncov/cvd-data/covid-dview/index.html; 3. Portmann et al. Jama Netw Open. 2023;6(2):e2255599; 4. Huerne K, Filion KB, Grad R, Ernst P, Gershon AS, Eisenberg MJ. Epidemiological and Clinical Perspectives of Long COVID Syndrome. Am J Med Open. 2023 Jan 18;9:100033. doi: 10.1016/j.ajmo.2023.100033. 5. Davis H et al. Nature Reviews Microbiology. 2023;21,133-146; 6. https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm; 7. https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-doses-distributed.html 8. https://gis.cdc.gov/grasp/covidnet/covid19_5.html

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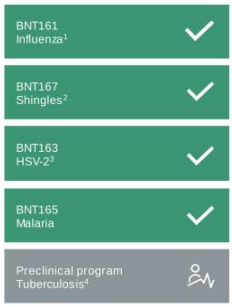
Advancing Broader Infectious Disease Vaccine Portfolio

- Advancing 2 additional clinical stage mRNA vaccine programs partnered with Pfizer and multiple wholly owned infectious disease vaccines
- Focused on prophylactic vaccines against diseases of high global incidence and causing significant mortality and/or morbidity
- Targeting diseases with no marketed vaccine or room for differentiation over existing vaccines
- Multiple additional trial starts expected in the next 12 months

Infectious disease pipeline



✓ = Data update expected in 2023

= First Patient Dosed expected in 2023

1. Licenced to Pfizer, 2. Partnered with Pfizer, 3. Collaboration with University of Pennsylvania, 4. Collaboration with Bill & Melinda Gates Foundation
HSV-2 = Herpes Simplex Virus 2,

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2023 Strategic Outlook in Oncology

- Multiple trials with registrational potential expected to be initiated in 2023-2024
- Build-out of oncology commercial capabilities to accelerate in 2023-2024
- Goal of commercial readiness in the United States, European Union and other selected regions to support first potential oncology launches from 2026 onwards, subject to regulatory approvals
- Anticipate further M&A and/or product candidate in-licensing to complement organic pipeline advancement
- Aim to deliver multiple oncology product approvals from 2026 onwards

Mid-stage oncology pipeline

1. Partnered with Genentech, member of Roche Group, 2. Partnered with Genmab, 3. Partnered with OncoC4
NSCLC = Non-small cell lung cancer, CLDN = Claudin, HPV16 = Human papillomavirus 16, 1L = first line, R/R = Relapsed/Refractory, Plat.-R = Platinum-resistant

Phase 1 Phase 2 ✓ = Data update expected in 2023

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Multiple Late- and Early-Stage Pipeline Milestones Expected in 2023

Modality	Indication	Program	Select milestones	Anticipated timing
mRNA vaccines for infectious disease	COVID-19[1]	BA.4-5-adapted bivalent	Pediatric label expansion	2H 2023
	COVID-19 – influenza Combination[1,2]	BA.4-5-adapted bivalent+ BNT161	Phase 1 data update	2023
	Malaria	BNT163	Phase 1 data update	2H 2023
	HSV-2[3]	BNT165	Phase 1 data update	2H 2023
	Shingles[1]	BNT167	Phase 1 FPD	FPD in February 2023
	Tuberculosis[4]	BNT164	Phase 1 FPD	H1 2023
iNeST individualized mRNA vaccines	1L melanoma[5]	Autogene Cevumeran (BNT122)	Phase 2 data update	2023
	Adjuvant CRC[5]	Autogene Cevumeran (BNT122)	Phase 2 data update	-
	Adjuvant PDAC[6]	Autogene Cevumeran (BNT122)	Phase 2 FPD	2023
Next-gen immune checkpoint modulators	Multiple solid tumors[7]	BNT311 (PD-L1x4-1BB)	Expansion cohort data update	2023
	Multiple solid tumors[7]	BNT312 (CD40x4-1BB)	Expansion cohort data update	2023
	2L NSCLC[8]	ONC-392 (CTLA-4)	Phase 3 FPD	2023
Cell therapies	CLDN6+ solid tumors	BNT211	Phase 1 data update	2023
	2L+ testicular cancer	BNT211	Phase 2 FPD	2024

1. Partnered with Pfizer; 2. Collaboration with Pfizer and subject to reaching agreement with our partners, 3. Partnered with University of Pennsylvania; 4. Collaboration with Bill & Melinda Gates Foundation; 5. Partnered with Genentech, a member of Roche Group; 6. Investigator-initiated trial; 7. Collaboration with Genmab, 8. Collaboration with OncoC4
FPD = First Patient Dosed, CRC = Colorectal cancer, PDAC = Pancreatic ductal adenocarcinoma, HSV = Herpes simplex virus, NSCC = Non-small cell lung cancer, CLDN6 = Claudin 6, 1L = first line, 2L = second line

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SAVE THE DATE
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Annual General Meeting
May 25, 2023
Innovation Series Day
November 7, 2023

Thank you