

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

FORM 6-K

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

FOR THE MONTH OF MAY 2024

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

**An der Goldgrube 12
D-55131 Mainz
Germany
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(Address of principal executive offices)

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

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

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

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On May 6, 2024, BioNTech SE (the “Company”) issued a press release announcing its first quarter 2024 financial results and corporate update and details of a conference call to be held at 8:00 am EDT on May 6, 2024 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: May 6, 2024

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	BioNTech Announces First Quarter 2024 Financial Results and Corporate Update
99.2	First Quarter 2024: Corporate Update and Financial Results

BioNTech Announces First Quarter 2024 Financial Results and Corporate Update

- *Advancing toward goal of ten or more potentially registrational trials running by the end of 2024: first patient dosed in Phase 3 clinical trial evaluating BNT323/DB-1303 in HR+ HER2-low chemotherapy-naïve metastatic breast cancer patients, and a second Phase 3 trial with BNT323/DB-1303 in recurrent endometrial cancer planned to start soon*
- *Presented clinical data at the American Association for Cancer Research ("AACR") Annual Meeting for individualized and off-the-shelf mRNA-based cancer vaccine candidates based on iNeST and FixVac platforms, including three-year follow-up data of an investigator-initiated trial in patients with resected pancreatic ductal adenocarcinoma ("PDAC")*
- *Planning to share additional clinical data from multiple clinical programs at the American Society of Clinical Oncology ("ASCO") Annual Meeting, including bispecific antibodies BNT311/GEN1046 (acasunlimab) and BNT327/PM8002 and antibody-drug conjugate ("ADC") BNT326/YL202*
- *Continued development and commercial preparation for a 2024 season variant-adapted COVID-19 vaccine*
- *First quarter 2024 revenues of €187.6 million, net loss of €315.1 million and loss per share of €1.31 (\$1.42¹)*
- *Maintained strong financial position with €16.9 billion in cash, cash equivalents and security investments*

Conference call and webcast scheduled for May 6, 2024, at 8:00 a.m. EDT (2:00 p.m. CEST)

MAINZ, Germany, May 6, 2024 (GLOBE NEWSWIRE) -- [BioNTech SE](#) (Nasdaq: BNTX, "BioNTech" or "the Company") today reported financial results for the three months ended March 31, 2024, and provided an update on its corporate progress.

"In the past weeks, we have reported positive preliminary data for both our individualized and off-the-shelf mRNA-based candidates which further underline the potential of our iNeST and FixVac platforms. We look forward to providing more updates this year across our oncology portfolio, including our bispecific antibody and ADC programs," said **Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "In the remainder of the year, we plan to develop and commercialize a variant-adapted COVID-19 vaccine and accelerate our clinical development activities towards realizing the full potential of our oncology pipeline with a view to becoming a commercial company with marketed medicines for cancer and infectious diseases."

Financial Review for the First Quarter 2024

<i>in millions €, except per share data</i>	First Quarter 2024	First Quarter 2023
Total Revenues	187.6	1,277.0
Net (Loss) / Profit	(315.1)	502.2
(Loss) / Diluted Earnings per Share	(1.31)	2.05

Total revenues reported were €187.6 million for the three months ended March 31, 2024, compared to €1,277.0 million for the comparative prior year period. The year-over-year change was mainly due to lower commercial revenues from the sales of BioNTech's COVID-19 vaccine worldwide resulting from endemic-level demand for COVID-19 vaccines.

Cost of sales were €59.1 million for the three months ended March 31, 2024, compared to €96.0 million for the comparative prior year period. The change was mainly due to recognizing lower cost of sales from BioNTech's decreased COVID-19 vaccine sales, which included the share of gross profit that BioNTech owes its collaboration partner Pfizer Inc. ("Pfizer") and royalty expenses based on BioNTech's sales. In addition, cost of sales was impacted by expenses arising from inventory write-offs and destruction of inventory.

Research and development ("R&D") expenses were €507.5 million for the three months ended March 31, 2024, compared to €334.0 million for the comparative prior year period. R&D expenses were mainly influenced by progressing clinical studies for pipeline candidates. The increase was further driven by an increase in wages, benefits and social security expenses resulting from an increase in headcount.

General and administrative ("G&A") expenses reached €117.0 million for the three months ended March 31, 2024, compared to €111.8 million for the comparative prior year period. G&A expenses were primarily driven by increased expenses for IT environment and wages, benefits, and social security expenses resulting from an increase in headcount.

Income taxes were realized with an amount of €16.7 million of tax income for the three months ended March 31, 2024, compared to €205.5 of tax expenses accrued for the comparative prior year period. The effective income tax rate for the three months ended March 31, 2024, was approximately 5.0% applicable on the negative income.

Net loss was €315.1 million for the three months ended March 31, 2024, compared to a net profit of €502.2 million for the comparative prior year period.

Cash and cash equivalents as well as security investments as of March 31, 2024, reached €16,939.3 million, comprising €8,976.6 million cash and cash equivalents and €7,962.7 million security investments, respectively.

Loss per share was €1.31 for the three months ended March 31, 2024, compared to diluted earnings per share of €2.05 for the comparative prior year period.

Shares outstanding as of March 31, 2024, were 237,725,735, excluding 10,826,465 shares held in treasury.

"We started the year making good progress across our oncology pipeline. We dosed the first patient in our second pivotal Phase 3 trial and aim to have ten or more potentially registrational trials by the end of 2024. Revenues in the first quarter reflect the seasonal demand for COVID-19 vaccines, and we expect to recognize approximately 90% of our full year revenues in the last months of 2024, mostly in Q4 of 2024. With a strong cash position of €16.9 billion, we are well positioned to invest in our

innovative R&D pipeline and scale the business for commercial readiness in oncology," said **Jens Holstein, CFO of BioNTech**. "We remain committed to seizing the opportunity to transform the way cancer and infectious diseases are treated, especially with our tremendous experience in using our mRNA platforms. We will focus the remainder of the year on executing and delivering on this vision with the aim to drive sustainable long-term growth and to create future value for patients, society and our shareholders."

Outlook for the 2024 Financial Year

The Company reiterates its prior outlook for the financial year:

Total revenues for the 2024 financial year	€2.5 billion - €3.1 billion
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BioNTech expects group revenues for the full 2024 financial year to be in the range of €2.5 to €3.1 billion. The range reflects certain assumptions, including, but not limited to, expectations regarding: the timing and granting of regulatory approvals and recommendations; COVID-19 vaccine uptake and price levels; inventory write-downs by BioNTech's collaboration partner Pfizer that would negatively influence the Company's revenues; seasonal variations in SARS-CoV-2 circulation and vaccination uptake, which are expected to lead to demand peaks in the autumn and winter compared to other seasons; and revenues from a pandemic preparedness contract with the German government as well as revenues from the BioNTech Group service businesses, namely InstaDeep Ltd., JPT Peptide Technologies GmbH, and in Idar-Oberstein at BioNTech Innovative Manufacturing Services GmbH. Generally, the Company continues to remain largely dependent on revenues generated in its collaboration partner's territories in 2024.

Planned 2024 Financial Year Expenses and Capex²:

R&D expenses ³	€2.4 billion - €2.6 billion
SG&A expenses ⁴	€700 million - €800 million
Capital expenditures for operating activities	€400 million - €500 million

The full interim unaudited condensed consolidated financial statements can be found in BioNTech's Report on Form 6-K for the period ended March 31, 2024, filed today with the United States Securities and Exchange Commission ("SEC") and available at <https://www.sec.gov/>.

Endnotes

¹ Calculated applying the average foreign exchange rate for the three months ended March 31, 2024, as published by the German Central Bank (Deutsche Bundesbank).

² Numbers reflect current base case projections and are calculated based on constant currency rates, and exclude external risks that are not yet known and/or quantifiable, including, but not limited to, the effects of ongoing and/or future legal disputes or related activity.

³ Numbers include effects identified from additional collaborations or potential M&A transactions to the extent disclosed and are subject to update due to future developments.

⁴ Anticipated expenses related to external legal advice in connection with certain legal litigations are not reflected in SG&A but in other operating expenses. Guidance does not include and may be impacted by potential payments resulting from the outcomes of ongoing or future contractual and legal disputes or related activity, such as judgments or settlements.

Operational Review of the First Quarter 2024, Key Post Period-End Events and 2024 Outlook**Omicron XBB.1.5-adapted Monovalent COVID-19 Vaccine (COMIRNATY®)**

BioNTech and Pfizer developed, manufactured and delivered their Omicron XBB.1.5-adapted monovalent COVID-19 vaccine, which has received multiple regulatory approvals, including full approvals, authorizations for emergency or temporary use, or marketing authorizations, in more than 40 countries and regions. BioNTech is now focused on preparing for variant strain vaccine adaptation to be ready for commercial launch ahead of the upcoming 2024/2025 vaccination season, pending approvals.

COVID-19 – Influenza Combination Vaccine Program

BNT162b2 + BNT161 is an mRNA-based combination vaccine program against COVID-19 and influenza being developed in collaboration with Pfizer. Top-line data from the Phase 1/2 trial ([NCT05596734](#)) demonstrated robust immune responses to influenza A, influenza B, and SARS-CoV-2 strains and that the safety profile of the candidates was consistent with the profile of the companies' COVID-19 vaccine. A Phase 3 clinical trial ([NCT06178991](#)) is ongoing.

Select Oncology Pipeline Highlights*ADC Programs*

BNT323/DB-1303 is an ADC candidate targeting Human Epidermal Growth Factor 2 ("HER2") that is being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"). The program has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration ("FDA") for the treatment of advanced endometrial cancer in patients who progressed on or after treatment with immune checkpoint inhibitors.

BNT323/DB-1303 is being evaluated in a Phase 1/2 clinical trial ([NCT05150691](#)) in patients with advanced/unresectable, recurrent or metastatic HER2-expressing solid tumors. A potentially registrational cohort is enrolling HER2-expressing (IHC3+, 2+, 1+ or ISH-positive) patients with advanced/recurrent endometrial carcinoma and aims to recruit 140 patients. A confirmatory Phase 3 trial ([NCT06340568](#)) in this patient population is planned to start in 2024.

In January, the first patient was dosed in a pivotal Phase 3 trial ([NCT06018337](#)) evaluating BNT323/DB-1303 in patients with Hormone Receptor-positive ("HR+") and HER2-low metastatic breast cancer that have progressed on hormone therapy and/or cyclin-dependent kinase 4/6 ("CDK4/6") inhibition.

BNT325/DB-1305 is an ADC candidate targeting TROP2 that is being developed in collaboration with DualityBio. In January, BioNTech and DualityBio received Fast Track designation for BNT325/DB-1305 from the U.S. FDA for the treatment of patients with platinum-resistant ovarian epithelial, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens. A Phase 1/2 clinical trial ([NCT05438329](#)) is ongoing.

BNT326/YL202 is an ADC candidate targeting HER3 that is being developed in collaboration with MediLink Therapeutics (Suzhou) Co., Ltd. ("MediLink"). A multicenter, open-label, first-in-human

Phase 1 clinical trial ([NCT05653752](#)) evaluating BNT326/YL202 as a later-line treatment in patients with locally advanced or metastatic epidermal growth factor receptor ("EGFR")-mutated non-small cell lung cancer ("NSCLC") or HR+/HER2-negative breast cancer is ongoing in the United States and China. Preliminary data from this study are expected to be presented at the 2024 ASCO Annual Meeting.

Next-Generation Immune Checkpoint Immunomodulator Programs

BNT311/GEN1046 (acasunlimab) is a potential first-in-class bispecific antibody candidate combining PD-L1 checkpoint inhibition with 4-1BB costimulatory activation that is being developed in collaboration with Genmab A/S ("Genmab"). Data from a Phase 2 trial ([NCT05117242](#)) evaluating BNT311/GEN1046 in combination with pembrolizumab in pretreated NSCLC patients are expected to be presented at the 2024 ASCO Annual Meeting.

BNT327/PM8002 is an anti-VEGF-A antibody candidate fused to a humanized anti-PD-L1 VHH being developed in collaboration with Biotheus Inc. ("Biotheus"). BNT327/PM8002 is currently being evaluated in Phase 1 and Phase 2/3 clinical trials in China to assess the efficacy and safety of the candidate as monotherapy or in combination with chemotherapy in various indications. An Investigational New Drug application has been accepted by the U.S. FDA for further studies in the United States, and global trials are planned to start this year. Monotherapy data from the Phase 1/2 trials are planned to be presented at the 2024 ASCO Annual Meeting.

Cancer Vaccine Programs

BNT116 is based on BioNTech's FixVac platform, and is a wholly owned, systemically administered, off-the-shelf uridine mRNA-lipoplex based cancer vaccine candidate encoding six shared lung cancer associated antigens. A randomized, controlled Phase 2 clinical trial ([NCT05557591](#)) is ongoing to evaluate BNT116 in combination with cemiplimab versus cemiplimab alone as first-line treatment in patients with advanced NSCLC whose tumors express PD-L1 in $\geq 50\%$ of tumor cells.

In April 2024, data from a Phase 1 trial cohort ([NCT05142189](#)) were presented at the AACR Annual Meeting. Patients were treated with BNT116 in combination with docetaxel after progression on a PD-1/PD-L1 inhibitor and a platinum-based chemotherapy. Preliminary data of BNT116 in combination with docetaxel show encouraging antitumor activity, consistent induction of immune responses, a manageable safety profile, and no signs of additive toxicity. Efficacy results suggest that combination therapy with BNT116 and docetaxel was active with an overall response rate ("ORR") of 30% and a disease control rate ("DCR") of 85%.

Autogene cevumeran (BNT122) is a uridine mRNA-lipoplex based cancer vaccine candidate for individualized neoantigen-specific immunotherapy ("iNeST") being developed in collaboration with Genentech, Inc., a member of the Roche Group ("Genentech"). Autogene cevumeran is being evaluated in ongoing Phase 2 trials in adjuvant resected PDAC ([NCT05968326](#)), first-line melanoma ([NCT03815058](#)) and adjuvant colorectal cancer ("CRC") ([NCT04486378](#)). Epidemiologic data including post-operative circulating tumor DNA ("ctDNA") prevalence and prognostic value from a non-interventional, observational study ([NCT04813627](#)) in patients with resected high-risk stage II/III CRC are expected to be presented at the 2024 ASCO Annual Meeting. A Phase 2 clinical trial in an additional indication is planned.

In April 2024, long-term follow-up data from an investigator-initiated Phase 1 trial in patients with resected PDAC were presented at the AACR Annual Meeting. The data showed that the individualized mRNA cancer vaccine candidate autogene cevumeran continues to show polyspecific T cell responses up to three years after vaccination and that vaccine responses correlate with delayed tumor recurrence. The investigator-initiated, single center Phase 1 trial ([NCT04161755](#)) evaluated the safety of autogene cevumeran in sequential combination with the anti-PD-L1 immune checkpoint inhibitor atezolizumab and standard-of-care chemotherapy in 16 patients with resected PDAC. Data from the 1.5-year median follow-up were previously published in *Nature* ([Rojas, L.A et al. 2023](#)).

Cell Therapy Programs

BNT211 consists of two investigational medicinal products: a CAR-T cell product candidate targeting Claudin-6 ("CLDN6")-positive solid tumors, in combination with a CAR-T cell-amplifying RNA vaccine ("CARVac") encoding CLDN6. After determination of the recommended Phase 2 dose, BioNTech plans to initiate a pivotal trial in patients with germ cell tumors. BioNTech plans to present an analysis of real world evidence investigating overall survival and treatment patterns of patients with testicular germ cell tumors receiving palliative chemotherapy at the 2024 ASCO Annual Meeting.

Corporate Update for the First Quarter 2024 and Key Post Period-End Events

In February, BioNTech entered into a strategic collaboration with Autolus Therapeutics plc ("Autolus") aimed at advancing both companies' autologous CAR-T programs towards commercialization, pending regulatory authorizations. The collaboration also grants BioNTech the option to access a suite of Autolus's target binders and cell programming technologies.

In March, BioNTech announced that Annemarie Hanekamp will be joining the Company's Management Board as Chief Commercial Officer on July 1, 2024. Sean Marett, current Chief Business and Commercial Officer, will retire as planned from the Management Board while remaining a specialist advisor. Sean Marett's responsibilities as Chief Business Officer are being gradually transferred to James Ryan, Ph.D., Chief Legal Officer, who will also take on the role of Chief Business Officer at the end of the transition phase. BioNTech has also appointed a General Manager for the U.S. who has commenced building out commercial operations in the country and aims to establish further expertise in the Company's global commercial group to drive its first global product launch.

Upcoming Investor and Analyst Events

- Annual General Meeting: May 17, 2024
- Second Quarter 2024 Financial Results and Corporate Update: August 5, 2024
- Innovation Series (Digital & AI Day): October 1, 2024
- Innovation Series: November 14, 2024

Conference Call and Webcast Information

BioNTech invites investors and the general public to join a conference call and webcast with investment analysts today, May 6, 2024, at 8:00 a.m. EDT (2:00 p.m. CEST) to report its financial results and provide a corporate update for three months ended March 31, 2024.

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 Investors' section of the Company's website at www.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 global next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech 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 (CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapeutics, as well as 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 and specialized pharmaceutical collaborators, including Biotheus, DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, MediLink, OncoC4, Pfizer and Regeneron.

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/(loss) related to sales of BioNTech's COVID-19 vaccine, referred to as *COM/RNATY* 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; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; the targeted timing and number of

additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; discussions with regulatory agencies; BioNTech's expectations with respect to intellectual property; the impact of BioNTech's acquisition of InstaDeep Ltd. and its collaboration and licensing agreements; the development, nature and feasibility of sustainable vaccine production and supply solutions; and BioNTech's estimates of revenues, research and development expenses, selling, general and administrative expenses, and capital expenditures for operating activities. 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 based on BioNTech's current expectations and beliefs of future events, and are neither promises nor guarantees. 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 and adversely from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations regarding its COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors; 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 its product candidates; the ability of BioNTech's COVID-19 vaccines 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 COVID-19 on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of 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 other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and 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 Report on Form 6-K for the period ended March 31, 2024 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. These forward-looking statements speak only as of the date hereof. 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.

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Interim Consolidated Statements of Profit or Loss

<i>(in millions €, except per share data)</i>	Three months ended March 31,	
	2024 <i>(unaudited)</i>	2023 <i>(unaudited)</i>
Revenues	187.6	1,277.0
Cost of sales	(59.1)	(96.0)
Research and development expenses	(507.5)	(334.0)
Sales and marketing expenses	(15.6)	(12.2)
General and administrative expenses	(117.0)	(111.8)
Other operating expenses ⁽¹⁾	(23.9)	(125.7)
Other operating income ⁽¹⁾	28.3	57.1
Operating income / (loss)	(507.2)	654.4
Finance income	180.1	82.3
Finance expenses	(4.7)	(29.0)
Profit / (Loss) before tax	(331.8)	707.7
Income taxes	16.7	(205.5)
Profit / (Loss) for the period	(315.1)	502.2
Earnings / (Loss) per share		
Basic earnings / (loss) for the period per share	(1.31)	2.07
Diluted earnings / (loss) for the period per share	(1.31)	2.05

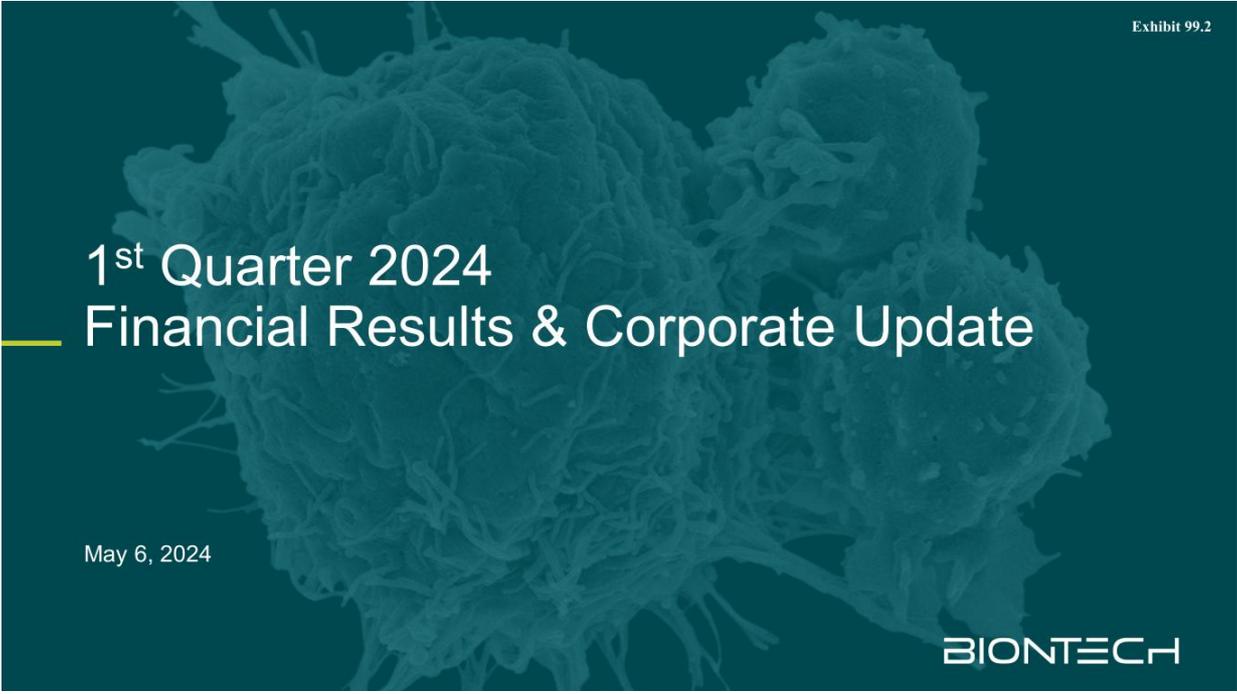
⁽¹⁾ Adjustments to prior-year figures due to change in functional allocation of general and administrative expenses and other operating expenses.

Interim Consolidated Statements of Financial Position

<i>(in millions €)</i>	March 31, 2024	December 31, 2023
Assets	<i>(unaudited)</i>	
Non-current assets		
Goodwill	368.7	362.5
Other intangible assets	821.7	804.1
Property, plant and equipment	802.6	757.2
Right-of-use assets	228.3	214.4
Other financial assets	1,587.2	1,176.1
Other non-financial assets	83.2	83.4
Deferred tax assets	91.0	81.3
Total non-current assets	3,982.7	3,479.0
Current assets		
Inventories	345.4	357.7
Trade and other receivables	1,639.8	2,155.7
Contract assets	12.1	4.9
Other financial assets	6,689.9	4,885.3
Other non-financial assets	337.0	280.9
Income tax assets	273.3	179.1
Cash and cash equivalents	8,976.6	11,663.7
Total current assets	18,274.1	19,527.3
Total assets	22,256.8	23,006.3
Equity and liabilities		
Equity		
Share capital	248.6	248.6
Capital reserve	1,228.9	1,229.4
Treasury shares	(10.8)	(10.8)
Retained earnings	19,448.2	19,763.3
Other reserves	(946.7)	(984.6)
Total equity	19,968.2	20,245.9
Non-current liabilities		
Lease liabilities, loans and borrowings	205.0	191.0
Other financial liabilities	40.6	38.8
Provisions	8.8	8.8
Contract liabilities	379.2	398.5
Other non-financial liabilities	9.6	13.1
Deferred tax liabilities	39.4	39.7
Total non-current liabilities	682.6	689.9
Current liabilities		
Lease liabilities, loans and borrowings	31.3	28.1
Trade payables and other payables	298.8	354.0
Other financial liabilities	152.4	415.2
Income tax liabilities	353.2	525.5
Provisions	247.0	269.3
Contract liabilities	361.3	353.3
Other non-financial liabilities	162.0	125.1
Total current liabilities	1,606.0	2,070.5
Total liabilities	2,288.6	2,760.4
Total equity and liabilities	22,256.8	23,006.3

Interim Consolidated Statements of Cash Flows

<i>(in millions €)</i>	Three months ended March 31,	
	2024 <i>(unaudited)</i>	2023 <i>(unaudited)</i>
Operating activities		
Profit / (Loss) for the period	(315.1)	502.2
Income taxes	(16.7)	205.5
Profit / (Loss) before tax	(331.8)	707.7
Adjustments to reconcile profit before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	38.3	31.4
Share-based payment expenses	16.3	8.6
Net foreign exchange differences	(28.7)	53.1
Loss on disposal of property, plant and equipment	—	0.2
Finance income excluding foreign exchange differences	(174.9)	(82.3)
Finance expense excluding foreign exchange differences	4.7	1.2
Government grants	(9.1)	(3.0)
Net gain on derivative instruments at fair value through profit or loss	1.7	76.2
Working capital adjustments:		
Decrease in trade and other receivables, contract assets and other assets	498.2	893.8
Decrease in inventories	12.3	15.5
Decrease in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	(288.0)	(861.6)
Interest received and realized gains from cash and cash equivalents	199.4	53.6
Interest paid and realized losses from cash and cash equivalents	(3.7)	(1.2)
Income tax paid	(258.8)	(844.9)
Share-based payments	(2.4)	(725.7)
Government grants received	9.2	—
Net cash flows used in operating activities	(317.3)	(677.4)
Investing activities		
Purchase of property, plant and equipment	(58.5)	(45.2)
Purchase of intangible assets and right-of-use assets	(78.4)	(9.6)
Investment in other financial assets	(4,895.1)	(680.6)
Proceeds from maturity of other financial assets	2,727.6	—
Net cash flows used in investing activities	(2,304.4)	(735.4)
Financing activities		
Payments related to lease liabilities	(7.8)	(9.3)
Share repurchase program	—	(282.0)
Net cash flows used in financing activities	(7.8)	(291.3)
Net decrease in cash and cash equivalents	(2,629.5)	(1,704.1)
Change in cash and cash equivalents resulting from exchange rate differences	6.8	(27.1)
Change in cash and cash equivalents resulting from other valuation effects	(64.4)	—
Cash and cash equivalents at the beginning of the period	11,663.7	13,875.1
Cash and cash equivalents as of March 31	8,976.6	12,143.9

A microscopic image of a cell cluster, likely a spheroid, rendered in a teal color. The cluster is composed of numerous individual cells, each with visible nuclei and cytoplasm, arranged in a roughly spherical pattern. The background is a solid teal color.

1st Quarter 2024 Financial Results & Corporate Update

May 6, 2024

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(loss) 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; expectations regarding anticipated changes in COVID-19 vaccine demand, including changes to the ordering environment and expected regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; discussions with regulatory agencies; BioNTech's expectations with respect to intellectual property; the impact of BioNTech's acquisition of InstatDeep Ltd. and its collaboration and licensing agreements; the development, nature and feasibility of sustainable vaccine production and supply solutions; and BioNTech's estimates of revenues, research and development expenses, selling, general and administrative expenses, and capital expenditures for operating activities. 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 based on BioNTech's current expectations and beliefs of future events, and are neither promises nor guarantees. 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 and adversely from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations regarding its COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors; 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 its product candidates; the ability of BioNTech's COVID-19 vaccines 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 COVID-19 on BioNTech's development programs, supply chain, collaborators and financial performance; unforeseen safety issues and potential claims that are alleged to arise from the use of 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 other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and 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 Report on Form 6-K for the period ended March 31, 2024 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. These forward-looking statements speak only as of the date hereof. 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.

1 1st Quarter 2024 Highlights
Ugur Sahin, Co-founder & Chief Executive Officer

2 Pipeline Update
Özlem Türeci, Co-founder & Chief Medical Officer

3 Financial Results
Jens Holstein, Chief Financial Officer

4 Strategic Outlook
Ryan Richardson, Chief Strategy Officer

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1

1st Quarter 2024 Highlights

Ugur Sahin, Founder & Chief Executive Officer

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2024 Strategic Priorities and Achievements in Q1 2024

Clinical Execution in Oncology

First patient dosed in Phase 3 clinical trial evaluating our HER2 ADC BNT323/DB-1303¹ in HR+/HER2-low breast cancer

Presented clinical data at AACR for our mRNA cancer vaccines autogene cevumeran (BNT122)² in PDAC and BNT116 in NSCLC

Received Fast Track designation for our TROP2-ADC BNT325/DB-1305¹ for the treatment of platinum-resistant ovarian epithelial cancer, fallopian tube cancer, or primary peritoneal cancer

Commercial Readiness in Oncology

Appointed Annemarie Hanekamp as Chief Commercial Officer starting in July

Appointed General Manager US who has commenced building out US commercial operations

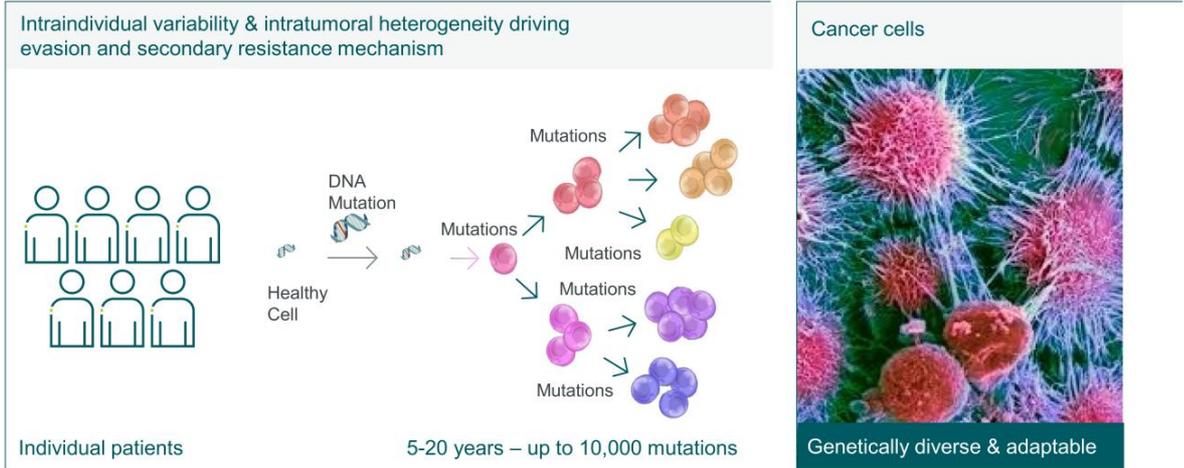
Appointed further expertise in global commercial group to drive first global product launch

COVID-19 Leadership

Advancing variant-adapted COVID-19 vaccine for the 2024/2025 season³

1. Partnered with Duality Biologics; 2 Partnered with Genentech, a member of the Roche group 3. Partnered with Pfizer.
HER2 = human epidermal growth factor receptor 2; ADC = antibody drug conjugate, HR = hormone receptor; AACR = American Association for Cancer Research; mRNA = messenger ribonucleic acid; PDAC = pancreatic ductal adenocarcinoma; NSCLC = non-small cell lung cancer; TROP2 = trophoblast cell-surface antigen 2.

Addressing the Fundamental Challenge in Cancer Treatment



Alexandrov L et al., Nature 2019; Kandoth C et al., Nature 2013; Yizhak K et al., Science 2019; Lim Z & Ma P, J Hematol Oncol 2019; Quazi MA et al., Ann Oncol 2017; Maryusk A et al., Cancer Cell 2023.

— Our Oncology Approach

Goals

Address the continuum of cancer

Bring novel therapies to cancer patients and establish new treatment paradigms

Open up novel options to combine platforms and therapies

Strategy

Portfolio covering compound classes with synergistic mechanisms of action

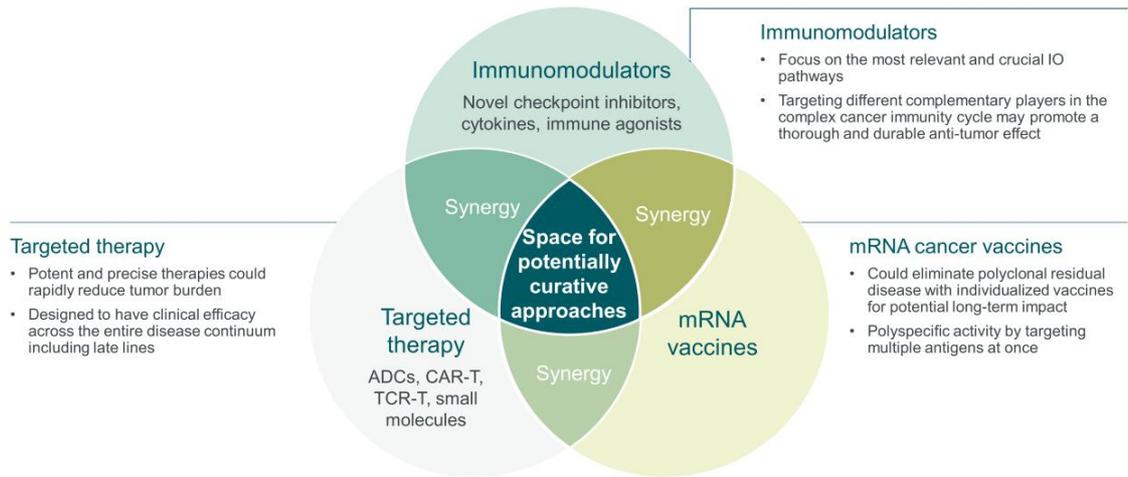
- Immunomodulators
- Targeted therapies
- Individualized and off-the-shelf mRNA vaccines

Programs across a wide range of solid tumors and stages of treatment

Programs with first-in-class and / or best-in-class potential

Unique therapeutic combinations

— Towards a Potentially Curative Approach to Cancer: Differentiated Combinations



ADC = antibody-drug conjugate; CAR = chimeric antigen receptor; TCR-T = T-cell receptor engineered T cell; IO = immune oncology.

— Our Next Stage of Growth in Oncology

2024

2025

2026+

10+ potentially registrational trials in 2024

Plan to start **combination trials**

Pivotal data updates in 2025 and beyond to support potential submissions

Build out **commercial organization** ahead of potential launches

Potential launches in multiple indications as early as 2026

2

Pipeline Update

Özlem Türeci, Co-Founder & Chief Medical Officer

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Our Multi-Platform Immuno-Oncology Pipeline Today

Phase 1	Phase 1/2	Phase 2	Phase 3
BNT116 Adv. NSCLC	BNT142 (CD3xCLDN6) Multiple CLDN6-pos. adv. solid tumors	BNT111* aPD(L)1-R/R melanoma, + cemiplimab	BNT316/ONC-392 (gotistobart) ⁴ (CTLA-4) anti-PD-1/PD-L1 experienced NSCLC
Autogene cevumeran (BNT122) ¹ Multiple solid tumors	BNT151 (IL-2 variant) Multiple solid tumors	BNT113 1L rel./met. HPV16+ PD-L1+ head and neck cancer, + pembrolizumab	BNT323/DB-1303 ⁵ (HER2) HR+/HER2-low met. breast cancer NEW
BNT152 + BNT153 (IL-7, IL-2) Multiple solid tumors	BNT211 (CLDN6) Multiple solid tumors	BNT116 ⁶ 1L adv. PD-L1 ≥ 50% NSCLC, + cemiplimab	BNT323/DB-1303 ⁵ (HER2) HER2-expressing rec. endometrial cancer PLANNED
BNT221 Refractory metastatic melanoma	BNT311/GEN1046 ³ (acaculimab; PD-L1x4-1BB) Multiple solid tumors	Autogene cevumeran (BNT122) ¹ 1L adv. melanoma, + pembrolizumab	
BNT321 (sLea) Metastatic PDAC	BNT312/GEN1042 ³ (CD40x4-1BB) Multiple solid tumors	Autogene cevumeran (BNT122) ¹ Adj. ctDNA+ stage II or III CRC	
BNT322/GEN1056 ³ Multiple solid tumors	BNT313/GEN1053 ³ (CD27) Multiple solid tumors	Autogene cevumeran (BNT122) ¹ Adj. PDAC, + atezolizumab + mFOLFIRINOX	
BNT326/YL202 ⁴ (HER3) Multiple solid tumors	BNT314/GEN1059 ³ (EpCAMx4-1BB) Multiple solid tumors NEW	BNT311/GEN1046 ³ (acaculimab; PD-L1x4-1BB) R/R met. NSCLC, +/- pembrolizumab	
	BNT316/ONC-392 (gotistobart) ⁴ (CTLA-4) mCRPC, + radiotherapy	BNT316/ONC-392 (gotistobart) ⁴ (CTLA-4) Plat.-R. ovarian cancer, + pembrolizumab	
	BNT316/ONC-392 (gotistobart) ⁴ (CTLA-4) Multiple solid tumors		
	BNT321 (sLea) adjuvant PDAC, +mFOLFIRINOX NEW		
	BNT323/DB-1303 ⁵ (HER2) Multiple solid tumors		
	BNT324/DB-1311 ⁵ (B7H3) Multiple solid tumors		
	BNT325/DB-1305 ⁵ (TROP2) Multiple solid tumors		
	BNT411 (TLR7) Multiple solid tumors		

Legend
mRNA
Cell therapy
Next generation IO
ADCs
Small molecules

1. Partnered with Genentech, member of Roche Group; 2. Partnered with Regeneron; 3. Partnered with Genmab; 4. Partnered with OncoC4; 5. Partnered with DualityBio; 6. Partnered with MedLink Therapeutics.

*Two phase 1/2 clinical trials in patients with solid tumors are ongoing in combination with immune checkpoint inhibitor +/- chemotherapy

NSCLC = non-small cell lung cancer; SCLC = small cell lung cancer; mCRPC = metastatic castration resistant prostate cancer; HPV = human papillomavirus; PDAC = pancreatic ductal adenocarcinoma; CRC = colorectal cancer; CLDN = claudin; IL = interleukin; 1L = first line; R/R = relapsed/refractory; HER2/HER3 = human epidermal growth factor 2/3; sLea = sialyl-Lewis X antigen; TROP2 = trophoblast cell-surface antigen 2; TNBC = triple negative breast cancer.

Focus on Clinical Trial Execution in Oncology



On track to have 10+ potentially registrational trials by YE 2024

1. Partnered with OncoC4; 2. Partnered with DualityBio; 3. Partnered with Genentech, member of the Roche group. * Includes BNTX trials and partnered trials. PD-1 = programmed cell death protein 1; HR = hormone receptor; HER2 = human epidermal growth factor receptor 2; NSCLC = non-small cell lung cancer; PDAC = pancreatic ductal adenocarcinoma; CRC = colorectal cancer; HPV = human papillomaviruses; HNSCC = head and neck squamous cell carcinoma.

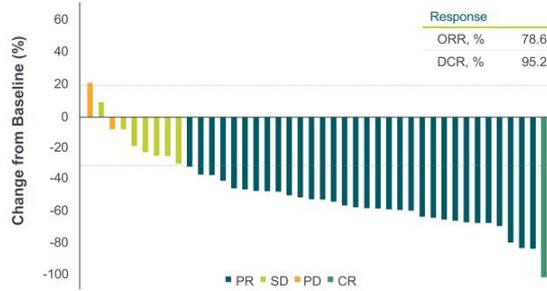
BNT327/PM8002¹: a PD-L1/VEGF- A Targeting Bispecific Antibody

● Ongoing trials across several indications and favorable safety profile established in > 600 patients

● Plan to start 2 pivotal trials in end 2024/begin 2025

● Strong single compound activity, and high ORRs observed in combination with CTx in various indications

Phase 2 (NCT05918133): clinical activity of BNT327/PM8002 in combination with nab-paclitaxel in 1L TNBC
Jiong Wu et al. Presented at SABCS 2023. Poster#PS08-06

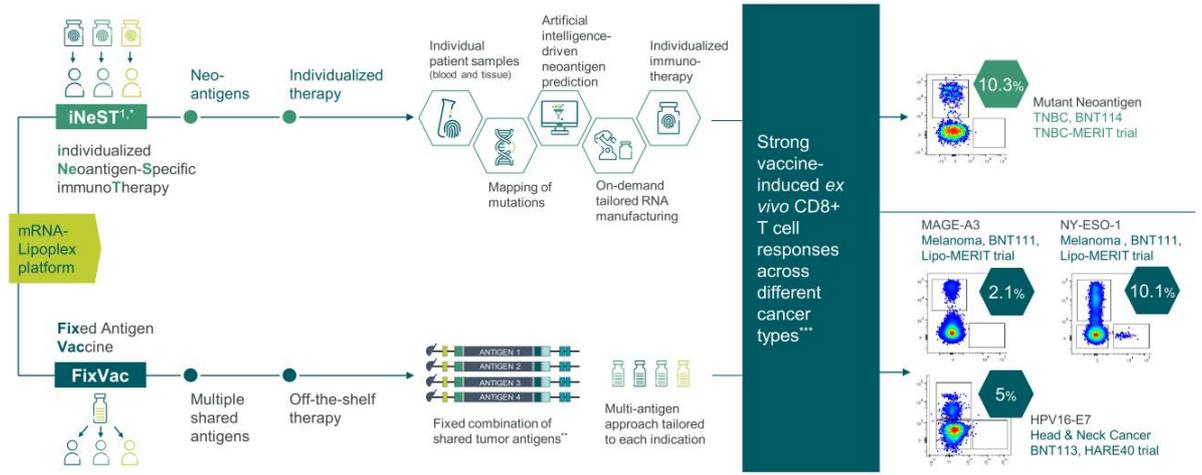


Phase 2 (NCT05879068): clinical activity of BNT327/PM8002 in combination with paclitaxel in 2L SCLC
Ying Cheng et al. Presented at ESMO 2023. Poster#1992P



1. Partnered with Biotheus; PD-L1 = programmed cell death ligand 1; VEGF-A = vascular endothelial growth factor A; CTx = chemotherapy; 1/2L = first/second-line; TNBC = triple-negative breast cancer; SCLC = small cell lung cancer; SABCS = San Antonio Breast Cancer Symposium; ESMO = European Society for Medical Oncology; ORR = objective response rate; DCR = disease control rate; ITT = intention-to-treat; IO = immuno oncology; CTFI = chemotherapy-free interval; TTP = time to progression; PR = partial response; SD = stable disease; PD = progressive disease; CR = complete response.

BioNTech – Full Exploitation of Cancer Vaccine Target Space

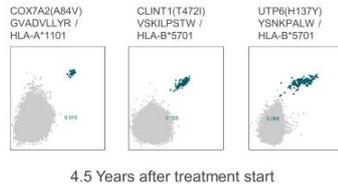


1. iNeST is being developed in collaboration with Genentech, a member of the Roche Group. *autogene cevumeran (BNT122); ** Amount of tumor antigens varies across programs; *** T cell responses analyzed by ex vivo multimer staining analysis in blood. TNBC = triple-negative breast cancer; MAGE = melanoma-associated antigen; NY-ESO-1 = New York esophageal squamous cell carcinoma-1; HPV = human papillomavirus E7.

High-Magnitude, Sustained Immunity upon Neoantigen mRNA Vaccination

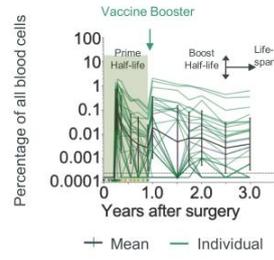
Vaccine-induced T cells persist over multiple years

T cells are high-magnitude



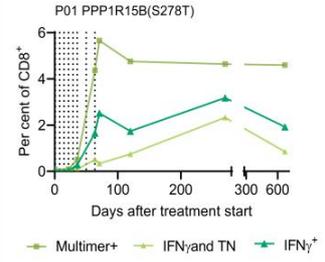
Melanoma
Sahin et al, NATURE 2017 & data on file

T cells are multiclonal



Adjuvant PDAC
Rojas et al, NATURE 2023

T cells are functional



Adjuvant TNBC
Türeci, CICON 2023/ESMO 2020

HLA = human leukocyte antigen; IFN = interferon; PDAC = pancreatic ductal adenocarcinoma; TNBC = triple-negative breast cancer; CICON = International Cancer Immunotherapy Conference; ESMO = European Society for Medical Oncology.

Growing Portfolio of Cancer Vaccine Candidates Across Multiple Solid Tumors

Six ongoing Phase 2 trials with cancer vaccine candidates in multiple disease settings

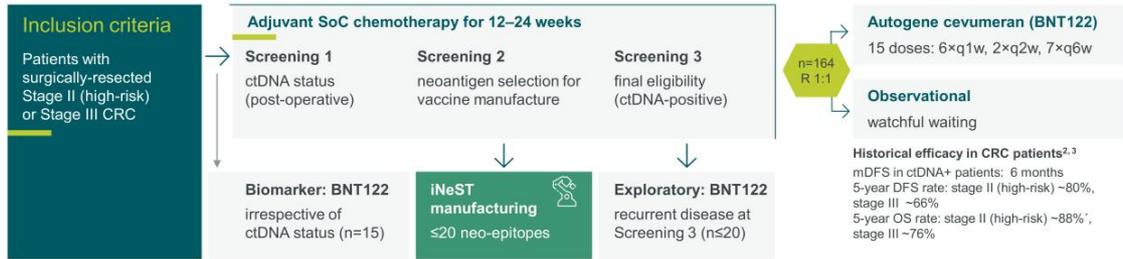
Individualized vaccine: iNeST ¹				FixVac				
Adjuvant		1L	R/R	R/R	Post-adj.	Neo-adj, mCR	1L	Multiple settings
CRC Phase 2	PDAC Phase 2	Melanoma Phase 2	Solid Tumors Phase 1	Melanoma Phase 2	TNBC Phase 1	Prostate Cancer Phase 1/2	HPV16+ HNSCC Phase 2	NSCLC Phase 1 & 2
Autogene cevumeran (BNT122) Monotherapy	Autogene cevumeran (BNT122) + Atezolizumab	Autogene cevumeran (BNT122) + Pembrolizumab	Autogene cevumeran (BNT122) + Atezolizumab	BNT111 +/- Cemiplimab	BNT114	BNT112 Monotherapy & + Cemiplimab + ADT	BNT113 + Pembrolizumab vs. Pembrolizumab	BNT116 Monotherapy & Cemiplimab or CTx
Study ongoing	Study started in Q4 2023 Data presented from investigator-initiated Ph 1 study at ASCO 2022 & AACR 2024 and published (Rojas et al. Nature.2023)	Enrollment completed Analysis of PFS as primary endpoint will be based on events and define when we will report results	Enrollment completed Data presented at AACR 2020 Manuscript in preparation	Enrollment completed, study is ongoing Data presented from Ph1 at SITC 2021 and published (Sahin et al., Nature 2020)	Manuscript in preparation	Discontinued Data presented at SITC 2021	Study ongoing Data presented at ESMO-IO 2022	Ph 1 study ongoing Data presented at SITC 2023 and AACR 2024 Ph 2 in 1L NSCLC started in Q3 2023 ²

1. Partnered with Genentech, member of Roche Group; 2. Sponsored by Regeneron.

iNeST = individualized Neoantigen Specific Immunotherapy; 1L = first line; R/R = relapsed/refractory; CRC = colorectal cancer; PDAC = pancreatic ductal adenocarcinoma; TNBC = triple-negative breast cancer; HPV = human papillomavirus; HNSCC = head and neck squamous carcinoma; NSCLC = non-small cell lung cancer; ADT = androgen deprivation therapy; CTx = chemotherapy; PFS = progression-free survival; ASCO = American Society of Clinical Oncology; AACR = American Association for Cancer Research; SITC = Society for Immunotherapy of Cancer; ESMO-IO = European Society for Medical Oncology Immunology.

Autogene Cevumeran (BNT122)¹ Investigated in a Phase 2 Randomized Trial vs Watchful Waiting in Adjuvant Colorectal Cancer

Phase 2, multi-site, open-label, randomized, controlled trial (NCT04486378)



Key endpoints

Primary: Disease-free survival

Efficacy: RFS, TTR, TTF, OS

Change in ctDNA status



Status

- First patient dosed (randomized cohort): December 2021
- Study on track

1. Partnered with Genentech, member of Roche Group. 2. Kotani et al. Nature 2023; Nakamura et al. ESMO 2023; 3. André T et al. J Clin Onc. 2015

CT = computer tomography; CRC = colorectal cancer; SoC = standard of care; qkw = every X week(s); ctDNA = circulating tumor DNA; (m)DFS = (median) disease-free survival; OS = overall survival; RFS = relapse-free survival; TTR = time to response; TTF = time to treatment failure.

Autogene Cevumeran (BNT122)¹ Investigated in a Phase 2 Randomized Trial vs SoC in Resected PDAC

IMCODE003: Phase 2, open-label, multicenter, randomized trial (NCT05968326)

Inclusion criteria

- Patients with resected PDAC
- No prior systemic anti-cancer treatment for PDAC
- No evidence of disease after surgery

Stratification factors

- Resection margin
- Nodal involvement

Randomization

6-12 weeks following surgery

Screening Part A

Determine ≥5 neo-epitopes from blood and tumor samples for custom manufacture of BNT122

Screening Part B

Confirm patient eligibility based IN/EX criteria

n=260
R 1:1

Treatment phases and dosing schedules

During the study, patients are monitored at scheduled intervals until recurrence of PDAC, occurrence of new cancers, or unacceptable toxicity, whichever occurs first.

Autogene cevumeran (BNT122) + atezolizumab + mFOLFIRINOX

mFOLFIRINOX

Historical efficacy of mFOLFIRINOX monotherapy²

mDFS = 21.4 months, 5-year DFS = 26.1%
mOS = 53.5 months, 5-year OS = 43.2%



Key endpoints

Primary: DFS

Secondary: DFS rates, OS, OS rates and safety



Status

- Recruitment ongoing
- FPD October 2023

1. Partnered with Genentech, member of Roche Group; 2. Conroy T. et al. JAMA Onc. 2022.

SoC = standard of care; PDAC = pancreatic ductal adenocarcinoma; (m)DFS = (median) disease-free survival; (m)OS = (median) overall survival; FPD = first patient dosed

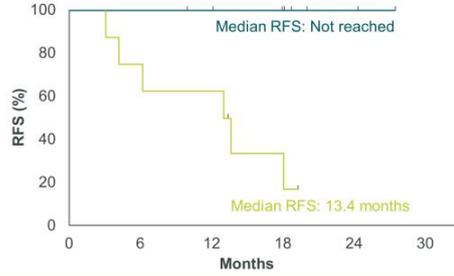
Autogene Cevumeran (BNT122)¹ Vaccine Response Correlates with Delayed PDAC Recurrence

Phase 1, investigator-initiated trial in resectable PDAC: 3-year follow-up data

Balachandran V et al. Presented at AACR 2024. # CT025 & Rojas et al. Nature. 2023.

1.5-year median follow-up

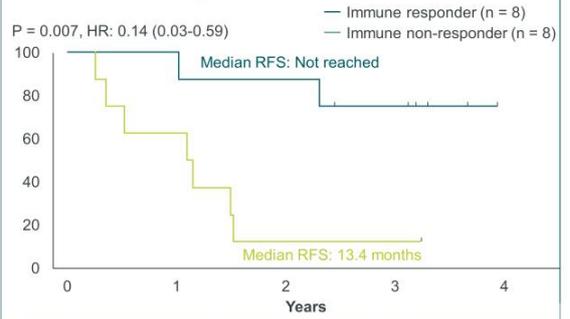
P = 0.003, HR: 0.08 (0.01-0.4)



At risk	0	6	12	18	24	30
Responder	8	8	7	6	2	0
Non-responder	8	6	5	2	0	0

3-year median follow-up

P = 0.007, HR: 0.14 (0.03-0.59)

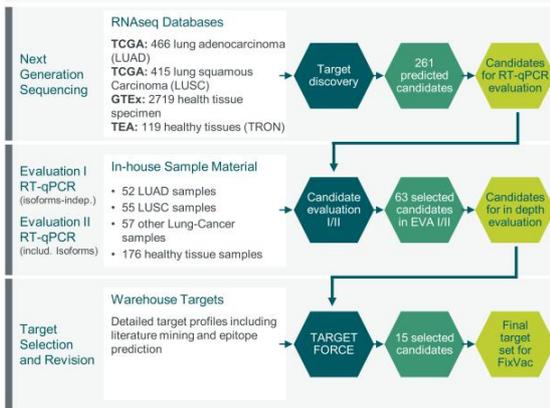


At risk	0	1	2	3	4
Immune responder (n = 8)	8	8	7	5	0
Immune non-responder (n = 8)	8	5	1	1	0

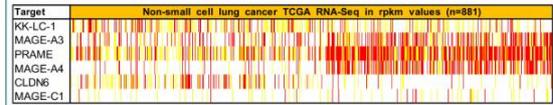
1. Partnered with Genentech, member of Roche Group.
 PDAC = Pancreatic ductal adenocarcinoma; OS = overall survival, RFS = relapse-free survival.

FixVac: Identification of Shared Tumor Antigen (TAA) Sets that Cumulatively Cover a Major Proportion of Patients

Target selection for BNT116 – lung cancer¹



Expression of tumor-associated antigens^{2,3,4}



In silico analysis of transcript abundance of the six BNT116 TAAs in an NSCLC cohort



In-house assessment of expression of the six BNT116 TAAs, Mage-A3, CLDN6, KK-LC-1, PRAME, MAGE-A4, and MAGE-C1 in a cohort from clinical routine using RT-qPCR (n=184)

~ 85% of NSCLC patients express ≥1 TAA
> 60% of NSCLC patients express ≥2 TAAs

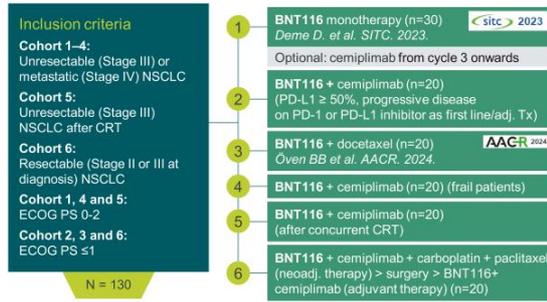
Data on file.

TAA = tumor-associated antigen; RT-qPCR = real-time quantitative polymerase chain reaction; NSCLC = non-small cell lung cancer; TCGA = The Cancer Genome Atlas; GTEX = genotype-tissue expression; TEA = tissue engineering acoustophoretic; TRON = Helmholtz Institute for Translational Oncology; KK-LC-1 = Kita-Kyushu lung cancer antigen 1; MAGE = melanoma-associated antigen; PRAME = preferentially expressed antigen in melanoma; CLDN = claudin.

BNT116: Broad Evaluation in NSCLC as Monotherapy and in Combination

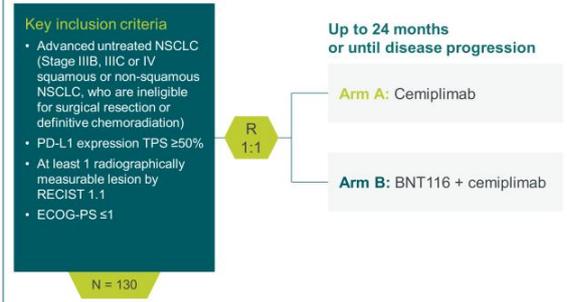
LuCa-MERIT-1:

FIH, Open Label Phase I Trial Evaluating Safety, Tolerability, and Preliminary Efficacy of **BNT116 Alone and in Combinations in NSCLC** (NCT05142189)



EmpowerVax-Lung¹:

Phase 2 Study of **Cemiplimab in Combination with BNT116 vs. Cemiplimab Monotherapy** in First-Line Treatment of Patients with Advanced NSCLC with **PD-L1 ≥50%** (NCT05557591)



Primary Endpoints: DLT occurrence during Cycle 1, safety
Secondary Endpoints: ORR, DoR, DCR, DDC, PFS, OS
OS follow-up every 3 months for up to 24 months after end of treatment

Primary Endpoint: ORR
Secondary Endpoints: OS, PFS, DOR, TEAEs, SAEs

1. Sponsored by Regeneron, NSCLC = non-small cell lung cancer; FIH= first in human; PD-L1 = programmed cell death ligand 1; TPS = tumor proportion score; RECIST = Response Evaluation Criteria in Solid Tumors; ECOG PS = eastern cooperative oncology group performance status; DLT = dose limiting toxicity; ORR = overall response rate; DoR = duration of response; DCR = disease control rate; DDC = duration of disease control; PFS = progression-free survival; OS = overall survival; TEAE = treatment emergent adverse events; SAE = serious adverse event; CRT = chemoradiotherapy.

Preliminary Results of BNT116 Show Encouraging Antitumor Activity and Manageable Safety Profile in Combination with Docetaxel

Phase 1 FIH study (NCT05142189): Clinical activity and tolerability

Öven BB. et al. Presented at AACR 2024. #CT051.

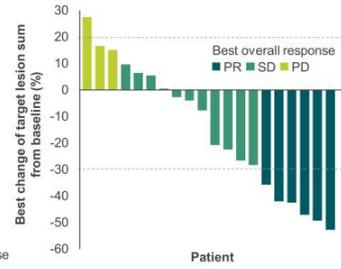
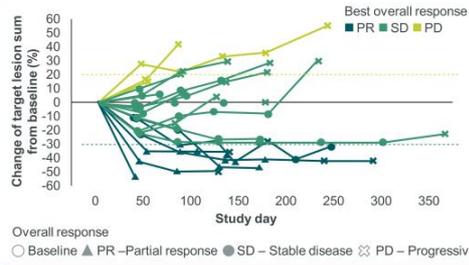
Cohort 3

BNT116 + docetaxel (n=20)

ORR, n (%) 6 (30)

DCR, n (%) 17 (85)

mPFS, m 4.4



BNT116 + docetaxel shows activity in heavily pretreated patients with NSCLC

Safety:

- Manageable safety profile, comparable to other FixVac candidates
- No signs of the combination treatment increasing the severity or duration of the adverse events were observed.

Historical efficacy of docetaxel monotherapy (Garon et al. Lancet. 2014):

- ORR ~10%
- mPFS ~ 3 months
- mOS ~ 9 months

FIH = first in human; ORR = objective response rate; DCR = disease control rate; (m)PFS = (median) progression-free survival; (m)OS = (median) overall survival; PR = partial response; SD = stable disease; PD = progressive disease; NSCLC = non-small cell lung cancer.

BioNTech at ASCO 2024

2024 ASCO
ANNUAL MEETING

Across portfolio
Data for making informed
decisions about the
direction of further
development

Related Program	Indication	Study
 BNT311/ GEN1046 (acasunlimab) ¹	2L non-small cell lung cancer	Phase 2
 BNT327/PM8002 ²	Cervical cancer and platinum-resistant ovarian cancer	Phase 1/2
 BNT327/PM8002 ²	Non-small cell lung cancer	Phase 1/2
 BNT326/YL202 ³	Non-small cell lung cancer & breast cancer	Phase 1
 Autogene cevumeran (BNT122) ⁴	Colorectal cancer	Epidemiological study
 BNT211	Germ cell tumors	Real-world data

1. Partnered with Genmab; 2. Partnered with Biotheus; 3. Partnered with MedLink; 4. Partnered with Genentech, a member of the Roche group.



3 Financial Results

Jens Holstein, Chief Financial Officer

BIONTECH

Q1 2024 Key Financial Figures¹

Total revenues	(Loss) before tax
€ 188 m	€ (332) m
(Loss) per Share	Total cash plus security investments ²
€ (1.31)	€ 16.9 bn

1. Financial information is prepared and presented in Euros and numbers are rounded to millions and billions of Euros in accordance with standard commercial practice.

2. Consists of cash and cash equivalents of €9,976.6 million and security investments of €7,962.7 million, as of March 31, 2024.

Q1 2024 Financial Results

	Three months ended March 31 st	Three months ended March 31 st
(in millions €, except per share data) ¹	2024	2023
Revenues ²	187.6	1,277.0
Cost of sales	(59.1)	(96.0)
Research and development expenses	(507.5)	(334.0)
Sales and marketing expenses	(15.6)	(12.2)
General and administrative expenses	(117.0)	(111.8)
Other operating income less expenses ³	4.4	(68.6)
Operating income / (loss)	(507.2)	654.4
Finance income less expenses	175.4	53.3
Profit / (Loss) before tax	(331.8)	707.7
Income taxes	16.7	(205.5)
Profit / (Loss) for the period	(315.1)	502.2
Earnings / (Loss) per share		
Basic earnings / (loss) for the period per share	(1.31)	2.07
Diluted earnings / (loss) for the period per share	(1.31)	2.05

1. Numbers have been rounded, numbers presented may not add up precisely to the totals and may have been adjusted in the table context. Presentation of the consolidated statements of profit or loss has been condensed.
2. BioNTech's profit share is estimated based on preliminary data shared between Pfizer and BioNTech as further described in BioNTech's Report on Form 6-K for the three months ended March 31, 2024, filed on May 6, 2024. Any changes in the estimated share of the collaboration partner's gross profit will be recognized prospectively. Total revenues consist of COVID-19 vaccine revenues and other revenues as further described in BioNTech's Report on Form 6-K.
3. Adjustments to prior-year figures relate to costs for external legal advice in connection with certain legal litigations from general and administrative expenses to other operating expense to reflect changes in the internal reporting also in the external reporting.

2024 Financial Year Guidance Reiterated¹

		FY 2024 Guidance
FY 2024 revenues	Total revenues	€2,500 – €3,100 m
	R&D expenses ²	€2,400 – €2,600 m
FY 2024 expenses, operating income and capex ⁴	SG&A expenses ³	€700 – €800 m
	Capital expenditure for operating activities	€400 – €500 m
	Revenue guidance considerations: Top-line sensitivity mainly dependent on the following factors	<ul style="list-style-type: none"> • Vaccination rates and price levels in markets where significant Comirnaty sales are expected • Inventory write-downs • Anticipated revenues related to service businesses, including InstaDeep, JPT Peptide Technologies, IMFS and from the German pandemic preparedness agreement

¹ Excluding external risks that are not yet known and/or quantifiable, including, but not limited to, the effects of ongoing and/or future legal disputes or related activity.

² Numbers include effects identified from additional in-licensing arrangements, collaborations or potential M&A transactions to the extent disclosed and are subject to update due to future developments.

³ Anticipated expenses related to external legal advice in connection with legal litigations is not reflected in SG&A but in other operating expenses for the 2024 financial year. Guidance does not include and may be impacted by potential payments resulting from the outcomes of ongoing or future legal disputes or related activity, such as judgments or settlements.

⁴ The Company does not expect to report a positive net income figure for the 2024 financial year and expects the majority of our 2024 global revenues for Comirnaty to be recorded in the second half of the year.

IMFS = BioNTech's Innovative Manufacturing Services

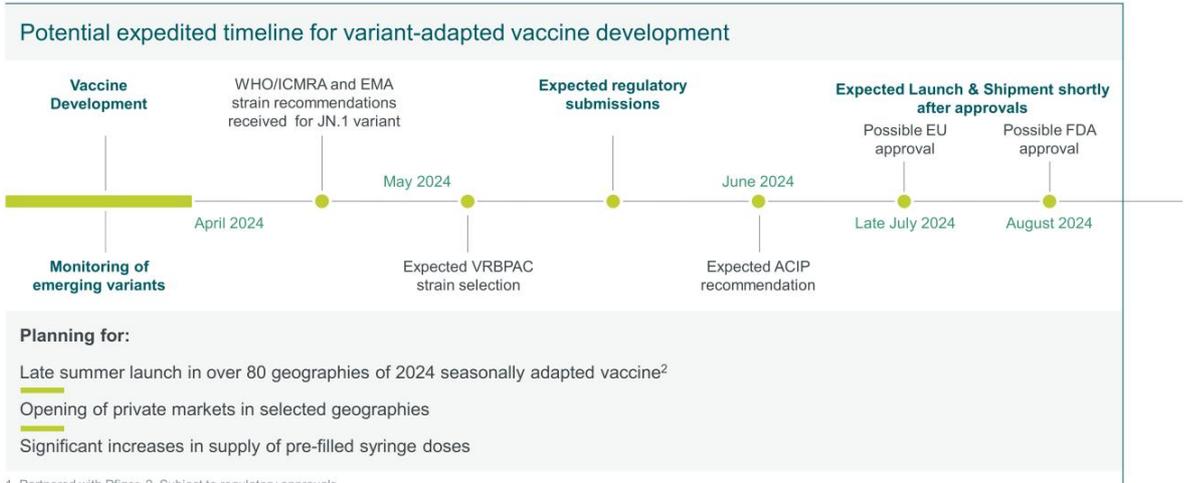
4

Strategic Outlook

Ryan Richardson, Chief Strategy Officer

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COVID-19 Vaccine Market Dynamics and Outlook¹



1. Partnered with Pfizer. 2. Subject to regulatory approvals.

WHO = World Health Organisation; ICMRA = International Coalition of Medicines Regulatory Authorities; EMA = European Medicines Agency; VRBPAC = Vaccines and Related Biological Products Advisory Committee; ACIP = Advisory Committee on Immunization Practices; FDA = Food and Drug Administration.

Innovative and Diversified Pipeline Poised to Drive Long-Term Growth

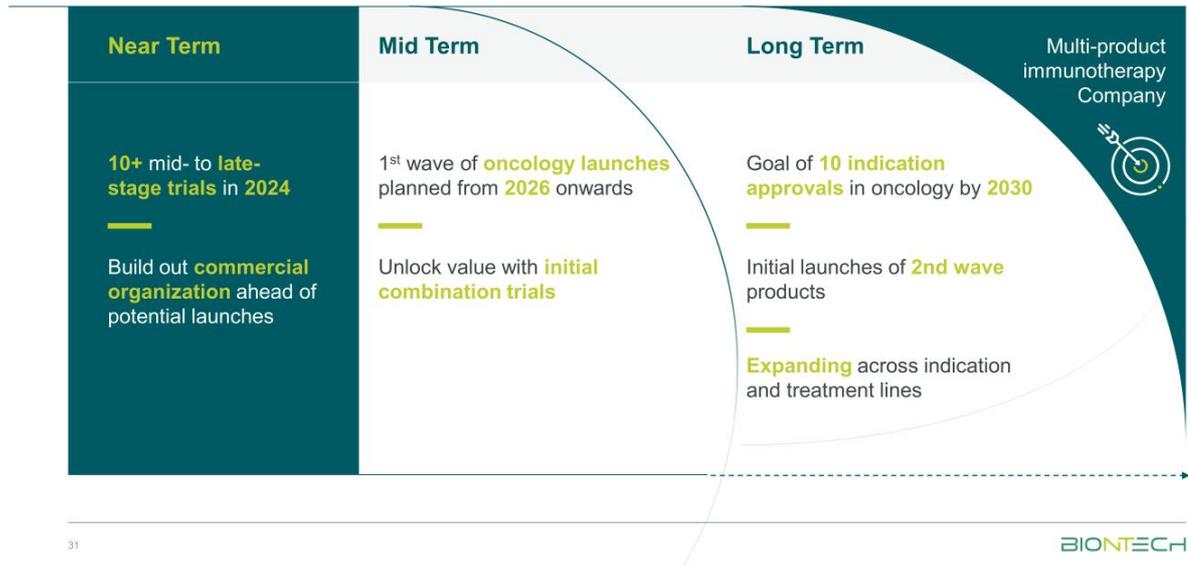
Investing in innovative therapies across drug classes with blockbuster potential

Drug Class	Data Update(s) Expected in 2024 or 2025	Potential First Submission Year	Potential Market Opportunity ¹
 mRNA cancer vaccines	✓	2027	Establish new pillar of individualized and off-the-shelf treatments with potential to address adjuvant and metastatic stage cancers, incl. CRC, PDAC, melanoma and NSCLC
 Immunomodulators	✓	2027	Multiple potential next generation checkpoint immunomodulator backbones with potential to address NSCLC, HNSCC, TNBC, and SCLC
 ADCs	✓	2026	Multiple fast follower and first-to-market opportunities with potential to address BC, NSCLC, EC, and PROC patients
 Cell Therapies ²	✓	2027	First-in-class potential for CAR-T + mRNA vaccine combination therapy with potential to address CLDN6+ testicular, ovarian and lung cancers
 Infectious Disease (Non-COVID)	✓	2028	Infectious Disease vaccines with potential to address shingles, HSV, malaria, TB, mpox and HIV

1. Listed indications reflect indications currently included in ongoing or planned clinical trials conducted by BioNTech or partners, including some indications only in Phase 1/2 clinical trials. Potential commercial opportunities of investigational programs are subject to the timing and successful outcome of clinical development, regulatory approval, and commercialization. BNT programs considered in each drug class: mRNA cancer vaccines: autogene cevumeran (BNT122), BNT116, BNT111, BNT113; Immunomodulators: BNT316, BNT311, BNT312, BNT327, BNT321; Antibody Drug Conjugates (ADCs): BNT323, BNT325, BNT324, BNT326; Cell Therapies: BNT211; Non-Covid ID: BNT163, BNT164, BNT165, BNT166, BNT167.

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Investing Through Waves of Innovation with the Aim to Transform Medicine

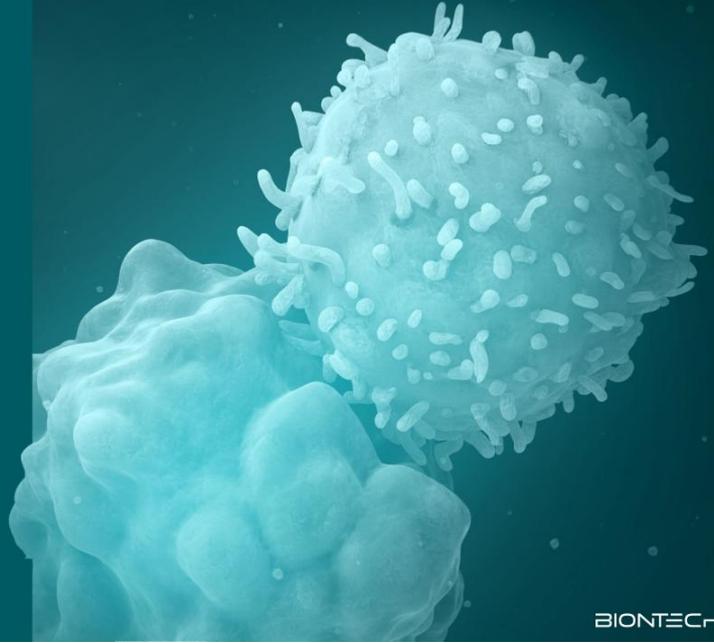


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Save the date

Annual General Meeting
May 17, 2024

Innovation Series: Digital & AI
October 1, 2024

Innovation Series
November 14, 2024



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— Thank you

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Appendix

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Advancing our Pipeline: Select Data Milestones in 2024

	Program	Indication	Targeted Milestone
Oncology	BNT311/GEN1046 (acasinimab) ¹	R/R met. NSCLC, +/- pembrolizumab	Phase 2 data
	BNT312/GEN1042 ¹	Multiple solid tumors	Ph1/2 expansion cohort data
	BNT316/ONC-392 (gotistobart) ²	Multiple solid tumors	Ph1/2 expansion cohort data
	BNT323/DB-1303 ³	Multiple solid tumors	Ph1/2 expansion cohort data
	BNT325/DB-1305 ³	Multiple solid tumors	Ph1/2 data
	BNT327/PM8002 ⁴	Multiple solid tumors	Phase 2 data
Infectious Disease	BNT162b2 ⁵	COVID-19, Omicron XBB.1.5 monovalent vaccine	Phase 2/3 data
	BNT167 ⁵	Shingles	Phase 1 trial update

1. Partnered with Genmab; 2. Partnered with OncoC4; 3. Partnered with DualityBio; 4. Partnered with Biotheus; 5. Partnered with Pfizer.
NSCLC = non-small cell lung cancer, R/R = relapsed/refractors.

