BioNTech Announces Second Quarter 2024 Financial Results and Corporate Update

August 5, 2024

- *Announced positive data from multiple mRNA cancer vaccine clinical trials, including topline results from the ongoing Phase 2 evaluating FixVac candidate BNT111*
- *Launched updated variant-adapted COVID-19 vaccine in the European Union ("EU"), received approval in the United Kingdom and initiated rolling supplemental Biologics Licensing Application ("sBLA") with the United States Food and Drug Administration ("U.S. FDA")*
- *Reiterates guidance for total revenues in the range of €2.5-3.1 billion*
- *Reports second quarter 2024 revenues of €128.7 million, net loss of €807.8 million and loss per share of €3.36 ($3.62[1])*
- *Invested €525.6 million or approximately 90% of the Company's total R&D spend in Q2 in non-COVID-19 related activities, mainly oncology and mRNA; investments are in line with the reiterated full-year R&D expense guidance*
- *Ended the second quarter of 2024 with €18.5 billion in cash, cash equivalents and security investments*

Conference call and webcast scheduled for August 5, 2024, at 8:00 a.m. EDT (2:00 p.m. CEST)

MAINZ, Germany, August 5, 2024 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today reported financial results for the three and six months ended June 30, 2024, and provided an update on its corporate progress.

"The year to date has been marked by significant data updates across our oncology portfolio. These readouts reinforce the potential of our platform technologies including our individualized and off-the-shelf mRNA vaccine platforms, iNeST and FixVac. We have also advanced our strategy by initiating clinical trials evaluating novel combinations of synergistic drug candidates. Notably, we dosed the first patient in a trial evaluating the combination of the TROP2 antibody-drug conjugate BNT325/DB-1305 and the PD-L1-VEGF-A bispecific BNT327/PM8002, aiming to harness the potent anti-tumor activity of antibody drug conjugates along with the sustained benefit of immunomodulators," **said Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. "In addition, we have started commercializing variant-adapted COVID-19 vaccines for the upcoming season, while accelerating our clinical development efforts to realize the full potential of our technologies. We are making progress towards our goal of becoming a company with marketed medicines for cancer and infectious diseases."

Financial Review for Second Quarter and First Half of 2024

in millions €, except per share data	**Second Quarter 2024**	**Second Quarter 2023**	**First Half 2024**	**First Half 2023**
Revenues	128.7	167.7	316.3	1,444.7
Net Profit / (Loss)	(807.8)	(190.4)	(1,122.9)	311.8
(Loss) / Diluted Earnings per Share	(3.36)	(0.79)	(4.67)	1.28

Revenues reported were €128.7 million for the three months ended June 30, 2024, compared to €167.7 million for the comparative prior year period. For the six months ended June 30, 2024, revenues were €316.3 million, compared to €1,444.7 million for the comparative prior year period. The year-over-year change was mainly due to lower revenues from the sales of the Company's COVID-19 vaccines worldwide resulting from the continued shift in demand from a pandemic to a seasonal endemic COVID-19 vaccine market.

Cost of sales were €59.8 million for the three months ended June 30, 2024, compared to €162.9 million for the comparative prior year period. For the six months ended June 30, 2024, cost of sales were €118.9 million, compared to €258.9 million for the comparative prior year period. The change was mainly due to COVID-19 vaccine production in line with demand.

Research and development ("R&D") expenses were €584.6 million for the three months ended June 30, 2024, compared to €373.4 million for the comparative prior year period. For the six months ended June 30, 2024, R&D expenses were €1,092.1 million, compared to €707.4 million for the comparative prior year period. R&D expenses were mainly influenced by progressing clinical studies for the Company's late-stage oncology pipeline candidates. Further contributions to the increase came from wages, benefits and social security expenses resulting from an increase in headcount.

Sales, general and administrative ("SG&A") expenses [2], in total, amounted to €183.8 million for the three months ended June 30, 2024, compared to €137.9 million for the comparative prior year period. For the six months ended June 30, 2024, SG&A expenses were €316.4 million, compared to €261.9 million for the comparative prior year period. SG&A expenses were primarily driven by increased expenses for IT environment and wages, benefits, and social security expenses resulting from an increase in headcount.

Other operating result amounted to €266.7 million negative operating result during the three months ended June 30, 2024, compared to €56.8 million negative operating result for the comparative prior year period. For the six months ended June 30, 2023, other operating result amounted to €262.3 million negative operating result compared with €125.4 million negative operating result for the prior year period. This change was primarily due to the recording of a provision related to a contractual dispute.

Income taxes were accrued with an amount of €2.0 million of tax expenses for the three months ended June 30, 2024, compared to €221.8 million of realized tax income for the comparative prior year period. For the six months ended June 30, 2024, income taxes were realized with an amount of €14.7 million of tax income for the six months ended June 30, 2024, compared to €16.3 million of realized tax income for the comparative prior year period. The effective income tax rate for the six months ended June 30, 2024, was approximately 1.3%.

Net loss was €807.8 million for the three months ended June 30, 2024, compared to €190.4 million loss for the comparative prior year period. For the six months ended June 30, 2024, loss was €1,122.9 million for the six months ended June 30, 2024, compared to a profit of €311.8 million for the comparative prior year period.

Cash and cash equivalents plus security investments as of June 30, 2024, reached €18,485.1 million, comprising €10,376.7 million cash and cash equivalents, €6,916.7 million current security investments and €1,191.7 million non-current security investments. This position increased during the second quarter of 2024 largely attributable to a cash payment received from BioNTech's collaboration partner Pfizer Inc. ("Pfizer").

Loss per share was €3.36 for the three months ended June 30, 2024, compared to €0.79 for the comparative prior year period. For the six months ended June 30, 2024, loss per share was €4.67, compared to diluted earnings per share of €1.28 for the comparative prior year period.

Shares outstanding as of June 30, 2024 were 237,766,235, excluding 10,785,965 shares held in treasury.

"Our second quarter revenues correspond to the current demand of a seasonal endemic COVID-19 vaccine market," **said Jens Holstein, CFO of BioNTech**. "Supported by our strong financial position, we will continue to focus on our long-term growth strategy throughout the remainder of the year. This includes our clinical pipeline for individualized therapies, the build-out of our manufacturing capacities and capabilities to support additional late-stage trials as well as our commercialization activities. These investments build the foundation for the next stage of growth and the transformation of BioNTech into a multi-product company."

2024 Financial Year Guidance[3] Reiterated

The Company reiterates its prior outlook for the financial year:

Total revenues for the 2024 financial year	**€2.5 billion - €3.1 billion**

BioNTech expects revenues for the full 2024 financial year to be in the range of €2.5 to €3.1 billion. The range reflects certain assumptions and expectations, including, but not limited to: 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 BioNTech'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 Capex:

R&D expenses[4]	**€2.4 billion - €2.6 billion**
SG&A expenses	**€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 June 30, 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 six months ended June 30, 2024, as published by the German Central Bank (Deutsche Bundesbank).

[2] "SG&A expenses'' includes sales and marketing expenses as well as general and administrative expenses.

[3] Guidance excludes external risks that are not yet known and/or quantifiable. It does not include potential payments resulting from the outcomes of ongoing and/or future legal disputes or related activity, such as judgements or settlements, which may have a material effect on the Company's results of operations and/or cash flows. BioNTech continues to expect to report a loss for the 2024 financial year and expects to recognize the vast majority of its full year revenues mostly in the fourth quarter.

[4] 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.

Operational Review of the Second Quarter 2024, Key Post Period-End Events and Outlook

Variant-adapted Monovalent COVID-19 Vaccines (COMIRNATY®)

- In April 2024, the World Health Organization ("WHO"), the European Medicines Agency ("EMA") and, subsequently, other health authorities, provided guidance highlighting that updated vaccines targeting Omicron JN.1 or JN.1 sublineages may contribute to maintaining protection against COVID-19 during the upcoming fall and winter seasons.
- On June 27, 2024, BioNTech and Pfizer announced that the Committee for Medicinal Products for Human Use ("CHMP") of the EMA recommended marketing authorization for the companies' Omicron JN.1-adapted monovalent COVID-19 vaccine (COMIRNATY® JN.1) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals six months of age and older. On July 3, 2024, the European Commission ("EC") adopted a decision following the CHMP's recommendation. Shortly following the EC decision, the updated vaccine was made available to ship to EU member states.
- On June 6, 2024, the U.S. FDA's Vaccines and Related Biological Products Advisory Committee ("VRBPAC") issued

guidance recommending the manufacturing of a JN.1-adapted monovalent COVID-19 vaccine for the 2024/2025 fall and winter seasons. On June 13, 2024, the U.S. FDA announced the KP.2 strain as the preferred JN.1-lineage for COVID-19 vaccines (2024-2025 Formula). In June 2024, BioNTech and Pfizer submitted regulatory applications to the U.S. FDA for the companies' Omicron JN.1-adapted monovalent vaccine, and initiated a rolling sBLA for an Omicron KP.2-adapted monovalent vaccine. The companies plan to prepare shipments in the United States of KP.2-adapted monovalent COVID-19 vaccines for fast delivery following potential regulatory approval, currently expected in September 2024.
- On July 24, 2024, the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") approved the companies' Omicron JN.1-adapted vaccine.

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 fully enrolled and data are expected later this year.

Select Oncology Pipeline Highlights

Cancer Vaccine Programs

BNT111 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 shared melanoma associated antigens.

- A randomized Phase 2 clinical trial (NCT04526899) being conducted in collaboration with Regeneron Pharmaceuticals Inc. ("Regeneron") is ongoing to evaluate BNT111 in combination with cemiplimab, BNT111 alone, or cemiplimab alone in anti-PD-1-/anti-PD-L1 refractory/relapsed, unresectable stage III or IV melanoma.
- In July 2024, BioNTech announced that the study met its primary efficacy outcome measure, demonstrating a statistically significant improvement in overall response rate ("ORR") in patients treated with BNT111 in combination with the anti-PD-1 checkpoint inhibitor, cemiplimab, as compared to a historical control in this indication and treatment setting. The ORR in the cemiplimab monotherapy arm was in line with the historical control of anti-PD-L1 or anti-CTLA-4 treatments in this patient group. The treatment was well tolerated and the safety profile of BNT111 in combination with cemiplimab in this trial was consistent with previous clinical trials assessing BNT111 in combination with anti-PD-L1-containing treatments. The Phase 2 trial will continue as planned to further assess the secondary endpoints which were not mature at the time of the primary analysis.
- BioNTech plans to present data from this trial at an upcoming medical conference.

BNT113 is a cancer vaccine candidate based on FixVac's platform encoding for shared antigens associated with Human Papilloma Virus ("HPV16+") head and neck cancer.

- A global, randomized Phase 2 clinical trial (NCT04534205) evaluating BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma expressing PD-L1 is ongoing.
- Data updates are expected to be presented at the 2024 Congress of the European Society of Medical Oncology ("ESMO") taking place from September 13-17, 2024 in Barcelona, Spain.

Abstract Title: Exploratory efficacy and translational results from the safety run in of AHEAD-MERIT, a phase II trial of first line pembrolizumab plus the fixed-antigen cancer vaccine BNT113 in advanced HPV16+ HNSCC
Poster Date: September 14, 2024
Presentation Number: 877P
Author: C. N. F. Saba

Abstract Title: HARE-40: A phase I/II trial of therapeutic HPV vaccine (BNT113) in patients with HPV16 driven carcinoma
Mini-oral Date & Time: September 16, 2024, 11:15 - 11:20 a.m. CEST
Presentation Number: 999MMO
Author: C. Ottensmeier

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. ("Genentech"), a member of the Roche Group ("Roche").

- Autogene cevumeran is being evaluated in ongoing Phase 2 trials in adjuvant resected pancreatic ductal adenocarcinoma ("PDAC") (NCT05968326), first-line melanoma (NCT03815058) and adjuvant colorectal cancer ("CRC") (NCT04486378). A Phase 2 clinical trial in an additional indication is planned.
- In June 2024, epidemiologic data were presented at the American Society of Clinical Oncology ("ASCO") Annual Meeting, including data on post-operative circulating tumor DNA ("ctDNA") prevalence and prognostic value in disease-free survival, from an observational study (NCT04813627) in patients with resected high-risk stage II/III CRC. These epidemiological and

prognostic data are supportive of the ongoing interventional Phase 2 clinical trial (NCT04486378).
- Also in June 2024, at the 2024 European Society for Medical Oncology Gastrointestinal Cancers ("ESMO-GI") Congress, immunogenicity data were presented from the biomarker cohort of the ongoing Phase 2 (NCT04486378) that enrolled patients irrespective of post-surgical ctDNA status. The data indicate that autogene cevumeran is highly immunogenic and induces *de novo* polyepitopic, *ex vivo* detectable T-cell responses in all evaluable patients with resected stage II (high risk) or III CRC after completion of adjuvant chemotherapy. Among patients included in the immunogenicity analysis, all (12/12) were disease-free at data cut off.
- Preliminary data from the ongoing Phase 2 clinical trial (NCT04486378) in stage II (high risk) and III ctDNA+ adjuvant CRC is expected in late 2025 or 2026.

Next-Generation Immune Checkpoint Immunomodulator Programs

BNT327/PM8002 is a bispecific antibody candidate combining PD-L1 checkpoint inhibition with VEGF-A neutralization and is being developed in collaboration with Biotheus Inc. ("Biotheus").

- BNT327/PM8002 is currently being evaluated in multiple Phase 2 and Phase 3 clinical trials in China to assess the efficacy and safety of the candidate as monotherapy or in combination with chemotherapy in various indications.
- In June 2024, at the 2024 ASCO Annual Meeting, monotherapy data were presented from an ongoing Phase 1/2 clinical trial (NCT05918445) for cohorts of patients with advanced cervical cancer ("CC"), platinum-resistant recurrent ovarian cancer ("PROC"), and advanced non-small cell lung cancer ("NSCLC").
    - Data on 48 patients with advanced CC showed an ORR of 42.2% (52.4% in patients with PD-L1-positive tumors), a disease control rate ("DCR") of 93.3%, and a median progression-free survival ("mPFS") of 8.3 months. Data on 39 patients with PROC showed an ORR of 20.6%, a DCR of 67.7%, and a mPFS of 5.5 months. Treatment related adverse events ("TRAEs") occurred in 95.4% of patients (83/87) with ≥ Grade 3 TRAEs in 36.8% (32/87) and 14.9% (13/87) of patients discontinued BNT327/PM8002 treatment due to TRAEs. Median follow-up time in patients with CC and PROC was 13.8 months and 14.8 months, respectively.
    - Data on 61 patients with non-squamous NSCLC were also presented. Data on 17 evaluable patients with untreated NSCLC wild-type and PD-L1-positive showed an ORR of 47.1%, a DCR of 100% and a mPFS of 13.6 months at a median follow-up of 11.3 months. Data on 36 evaluable patients with epidermal growth factor receptor ("EGFR")-mutant NSCLC after progression on prior EGFR-tyrosine kinase inhibitor treatment showed an ORR of 19.4%, a DCR of 69.4% and a mPFS of 5.5 months at a median follow-up of 12.6 months. Data from 8 evaluable patients with EGFR/anaplastic lymphoma kinase ("ALK") wild-type NSCLC that progressed after anti-PD-1/L1 therapy and platinum-based chemotherapy showed an ORR of 12.5%, a DCR of 62.5%, and a mPFS of 5.8 months at a median follow-up of 5.8 months. TRAEs occurred in 85.2% of patients (52/61) with ≥Grade 3 TRAEs in 19.7% (12/61), serious adverse events were observed in 24.6% (15/61) of patients, 8.2% (5/61) of patients discontinued BNT327/PM8002 treatment due to TRAEs.
- In June 2024, the first patient was dosed in the Phase 1/2 clinical trial (NCT05438329) evaluating the combination of BNT327/PM8002 with BNT325/DB-1305, an antibody-drug conjugate ("ADC") candidate targeting TROP-2. Additional trials with novel BNT327 and other ADC combinations are planned to begin this year.
- Two Phase 2 dose optimization studies are expected to start soon.
    - A Phase 2 clinical trial (NCT06449222) to evaluate the safety, efficacy, and pharmacokinetics of BNT327/PM8002 at two dose levels in combination with chemotherapy in the first- and second-line treatment of patients with locally advanced/metastatic triple negative breast cancer ("TNBC").
    - A Phase 2 clinical trial (NCT06449209) to evaluate BNT327/PM8002 in combination with chemotherapy in patients with untreated extended-stage small-cell lung cancer ("ES-SCLC") or small-cell lung cancer ("SCLC") progressed on first- or second-line treatment.
    - Data from these studies are expected as early as 2025.
- At the 2024 ESMO Congress the following datasets will be presented:

Abstract Title: A Phase II Safety and Efficacy Study of PM8002/BNT-327 in Combination with Chemotherapy in Patients with EGFR-mutated NSCLC
Mini-oral Presentation Date & Time: September 14, 2024, 10:25 - 10:30 a.m. CEST
Presentation Number: 1255MO
Author: Y-L. Wu

Abstract Title: A Phase Ib/II Study to Assess the Safety and Efficacy of PM8002/BNT327 in Combination with Nab-Paclitaxel for First Line Treatment of Locally Advanced or Metastatic Triple-Negative Breast Cancer
Mini-oral Presentation Date & Time: September 16, 2024, 08:35 - 08:40 a.m. CEST
Presentation Number: 348MO
Author: J. Wu

Abstract Title: A Phase Ib/IIa Trial to Evaluate the Safety and Efficacy of PM8002/ BNT327, a Bispecific Antibody Targeting PD-L1 and VEGF-A, as a Monotherapy in Patients with advanced renal cell carcinoma
Poster Date: September 15, 2024
Presentation Number: 1692P

Author: X. Sheng

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 for the treatment of solid tumors.

- A Phase 2, multi-center, randomized, open-label clinical trial (NCT05117242) of BNT311/GEN1046 (acasunlimab) as monotherapy and in combination with pembrolizumab is ongoing in patients with relapsed/refractory metastatic NSCLC and a tumor PD-L1 expression of tumor proportion score, or TPS, of ≥1% after treatment with standard of care therapy with an immune checkpoint inhibitor. The primary endpoint is ORR according to Response Evaluation Criteria in Solid Tumors, or RECIST v1.1. Secondary endpoints include duration of response ("DOR"), time to response ("TTR"), progression-free survival ("PFS"), overall survival "OS" and safety.
- Data from the ongoing Phase 2 trial (NCT05117242) evaluating BNT311/GEN1046 (acasunlimab) in combination with pembrolizumab in pretreated NSCLC patients were presented at the 2024 ASCO Annual Meeting. The results showed a 12-month OS rate of 69%, a median OS ("mOS") of 17.5 months, and a 30% ORR (confirmed ORR 17%) at the time of data cut-off in patients treated with the combination of BNT311/GEN1046 (acasunlimab) and pembrolizumab every 6 weeks. Anti-tumor activity was observed in patients with tumor proportion score ("TPS") of 1–49% and ≥50%, in patients with <6 months and ≥6 months of previous immune checkpoint inhibitor ("CPI") treatment, and in patients with squamous and non-squamous histology. Adverse events were consistent with the safety profiles of the individual drugs and TRAEs were primarily Grade 1 and 2.
- Updated data from this ongoing trial is expected to be presented at the 2024 World Conference on Lung Cancer ("WCLC") taking place from September 7-10, 2024 in San Diego, California, U.S.

Abstract Title: Dosing Regimen for Acasunlimab (DuoBody-PD-L1x4-1BB) In Combination with Pembrolizumab
Poster Presentation Date & Time: September 9, 2024, 18:30-20:00 PDT
Presentation Number: 845
Author: G. Bajaj

Abstract Title: Acasunlimab Alone or in Combination with Pembrolizumab for Previously Treated Metastatic Non-Small Cell Lung Cancer
Mini-oral Presentation Date & Time: September 10, 2024, 15:07 - 15:12 PDT
Presentation Number: 1309
Author: L. Paz-Ares

- While the emerging clinical profile of BNT311/GEN1046 (acasunlimab) is encouraging, for reasons relating to portfolio strategy, BioNTech opted not to participate in the further development of the program, including a planned Phase 3 trial. BioNTech and Genmab A/S ("Genmab") will continue their collaboration under the existing agreements which was expanded in 2022.

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").

- 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 with HER2-expressing (IHC3+, 2+, 1+ or ISH-positive) patients with advanced/recurrent endometrial carcinoma has completed enrollment. Data from this cohort are expected in 2025.
- A confirmatory Phase 3 trial (NCT06340568) in patients with advanced endometrial cancer is planned to start in 2024.
- A pivotal Phase 3 trial (NCT06018337) evaluating BNT323/DB-1303 in patients with Hormone Receptor-positive ("HR+") and HER2-low metastatic breast cancer ("BC") that have progressed on hormone therapy and/or cyclin-dependent kinase 4/6 ("CDK4/6") inhibition is ongoing.
- Topline data from the ongoing Phase 3 trial in HR+ and HER2-low metastatic BC that have progressed on hormone therapy and/or CDK4/6 inhibition are expected as early as 2025.

BNT324/DB-1311 is an ADC candidate targeting B7H3 that is being developed in collaboration with DualityBio.

- A first-in-human, open-label Phase 1/2a clinical trial (NCT05914116) evaluating BNT324/DB-1311 in patients with advanced solid tumors is ongoing.
- In June 2024, BioNTech and DualityBio announced that BNT324/DB-1311 was granted Fast Track designation by the U.S. FDA for the treatment of patients with advanced/unresectable or metastatic castration-resistant prostate cancer who have progressed on or after standard systemic regimens.
- In July 2024, the U.S. FDA granted Orphan Drug designation to BNT324/DB-1311 for the treatment of patients with advanced or metastatic esophageal squamous cell carcinoma.

BNT326/YL202 is an ADC candidate targeting HER3 that is being developed in collaboration with MediLink Therapeutics (Suzhou) Co., Ltd. ("MediLink").

- A multicenter, international, open-label, first-in-human Phase 1 clinical trial (NCT05653752), sponsored by MediLink, evaluating BNT326/YL202 as a later-line treatment in patients with locally advanced or metastatic EGFR-mutated NSCLC or HR+ and HER2-negative BC is on partial clinical hold by the U.S. FDA, as announced on June 17, 2024. BioNTech and MediLink are working to address the U.S. FDA's requirements and resolve the partial clinical hold.
- Preliminary data from this study were presented at the 2024 ASCO Annual Meeting. BNT326/YL202 demonstrated encouraging activity in heavily pretreated locally advanced/metastatic NSCLC and BC with an ORR of 42.3% (22 out of 52 evaluable patients) and a DCR of 94.2% (49/52), with responses seen from the first dose level at 0.5 mg/kg. The safety profile of BNT326/YL202 was consistent with its mechanism of action and dose-dependent. The most common TRAEs were due to hematologic toxicity and gastrointestinal disorders. 7.3% (4/55) of patients discontinued treatment due to TRAEs, and there were 3 treatment-related Grade 5 events (deaths) at higher doses. Further clinical development is expected to focus on dose levels below 4.0 mg/kg, where the safety profile was manageable and encouraging clinical activity was observed.

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.

- A first-in-human, open-label, multi-center Phase 1 dose escalation and dose expansion basket trial (NCT04503278) evaluating CLDN6 CAR-T cells as monotherapy or in combination with CLDN6 CARVac in patients with CLDN6-positive relapsed or refractory solid tumors, including ovarian cancers and testicular germ cell tumors, is ongoing.
- A data update is expected to be presented at the 2024 ESMO Congress.

Abstract Title: Updated results from BNT211-01 (NCT04503278), an ongoing, first-in-human, Phase 1 study evaluating safety and efficacy of CLDN6 CAR T cells and a CLDN6-encoding mRNA vaccine in patients with relapsed/refractory CLDN6+ solid tumors
Mini-oral Presentation Date & Time: September 15, 2024, 15:45 - 15:55 CEST
Presentation Number: 611O
Author: J. B. Haanen

- A pivotal Phase 2 trial in patients with testicular germ cell tumors is expected to start in 2025 based on encouraging data in this patient group observed in the Phase 1 trial.
- BioNTech presented 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. This analysis will inform the design of the Company's planned pivotal clinical trial to evaluate BNT211 in patients with germ cell tumors.

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

- In May 2024, BioNTech expanded its strategic partnership with the Coalition for Epidemic Preparedness Innovations ("CEPI") to contribute to building a sustainable and resilient end-to-end African vaccine ecosystem. CEPI is committing up to US $145 million to support BioNTech in broadening the scope of the manufacturing facility in Kigali, Rwanda. These capabilities will contribute to BioNTech and CEPI's efforts to better prepare for potential future epidemic and pandemic threats in Africa.
- On July 1, 2024, Annemarie Hanekamp joined the Company's Management Board as Chief Commercial Officer and James Ryan, Ph.D., Chief Legal Officer, also assumed the role of Chief Business Officer.

Upcoming Investor and Analyst Events

- Innovation Series (AI Day): October 1, 2024
- Third Quarter 2024 Financial Results and Corporate Update: November 4, 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, August 5, 2024, at 8:00 a.m. EDT (2:00 p.m. CEST) to report its financial results and provide a corporate update for the second quarter of 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 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; BioNTech's expectations regarding potential future commercialization in oncology, including goals regarding timing and indications; 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 collaboration and licensing agreements; the development, nature and feasibility of sustainable vaccine production and supply solutions; BioNTech's estimates of revenues, research and development expenses, selling, general and administrative expenses and capital expenditures for operating activities; and BioNTech's expectations of net profit / (loss). 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 June 30, 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

	Three months ended June 30,		Six months ended June 30,	
(in millions €, except per share data)	**2024** *(unaudited)*	**2023** *(unaudited)*	**2024** *(unaudited)*	**2023** *(unaudited)*
Revenues	128.7	167.7	316.3	1,444.7
Cost of sales	(59.8)	(162.9)	(118.9)	(258.9)
Research and development expenses	(584.6)	(373.4)	(1,092.1)	(707.4)
Sales and marketing expenses	(12.9)	(18.1)	(28.5)	(30.3)
General and administrative expenses [(1)]	(170.9)	(119.8)	(287.9)	(231.6)
Other operating expenses [(1)]	(290.8)	(77.1)	(314.7)	(202.8)
Other operating income	24.1	20.3	52.4	77.4
Operating income / (loss)	**(966.2)**	**(563.3)**	**(1,473.4)**	**91.1**
Finance income	167.7	152.4	345.3	208.9
Finance expenses	(7.3)	(1.3)	(9.5)	(4.5)
Profit / (Loss) before tax	**(805.8)**	**(412.2)**	**(1,137.6)**	**295.5**
Income taxes	(2.0)	221.8	14.7	16.3
Profit / (Loss) for the period	**(807.8)**	**(190.4)**	**(1,122.9)**	**311.8**
Earnings / (Loss) per share				
Basic earnings / (loss) for the period per share	(3.36)	(0.79)	(4.67)	1.29
Diluted earnings / (loss) for the period per share	(3.36)	(0.79)	(4.67)	1.28

(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

(in millions €)	**June 30, 2024** *(unaudited)*	**December 31, 2023**
Assets		
Non-current assets		
Goodwill	372.4	362.5
Other intangible assets	862.3	804.1
Property, plant and equipment	868.6	757.2
Right-of-use assets	256.4	214.4
Other financial assets	1,386.1	1,176.1
Other non-financial assets	108.2	83.4
Deferred tax assets	102.3	81.3
Total non-current assets	**3,956.3**	**3,479.0**
Current assets		
Inventories	340.1	357.7
Trade and other receivables	75.8	2,155.7
Contract assets	3.9	4.9
Other financial assets	6,919.0	4,885.3
Other non-financial assets	359.3	280.9
Income tax assets	206.8	179.1
Cash and cash equivalents	10,376.7	11,663.7
Total current assets	**18,281.6**	**19,527.3**
Total assets	**22,237.9**	**23,006.3**
Equity and liabilities		
Equity		
Share capital	248.6	248.6
Capital reserve	1,232.3	1,229.4
Treasury shares	(10.8)	(10.8)
Retained earnings	18,640.4	19,763.3
Other reserves	(1,038.2)	(984.6)

Total equity	**19,072.3**	**20,245.9**
Non-current liabilities		
Lease liabilities, loans and borrowings	219.3	191.0
Other financial liabilities	42.1	38.8
Provisions	9.0	8.8
Contract liabilities	353.6	398.5
Other non-financial liabilities	77.9	13.1
Deferred tax liabilities	37.8	39.7
Total non-current liabilities	**739.7**	**689.9**
Current liabilities		
Lease liabilities, loans and borrowings	35.3	28.1
Trade payables and other payables	881.5	354.0
Other financial liabilities	146.0	415.2
Income tax liabilities	365.2	525.5
Provisions	363.9	269.3
Contract liabilities	474.3	353.3
Other non-financial liabilities	159.7	125.1
Total current liabilities	**2,425.9**	**2,070.5**
Total liabilities	**3,165.6**	**2,760.4**
Total equity and liabilities	**22,237.9**	**23,006.3**

Interim Consolidated Statements of Cash Flows

	Three months ended June 30,		Six months ended June 30,	
(in millions €)	**2024** *(unaudited)*	**2023** *(unaudited)*	**2024** *(unaudited)*	**2023** *(unaudited)*
Operating activities				
Profit / (Loss) for the period	(807.8)	(190.4)	(1,122.9)	311.8
Income taxes	2.0	(221.8)	(14.7)	(16.3)
Profit / (Loss) before tax	**(805.8)**	**(412.2)**	**(1,137.6)**	**295.5**
Adjustments to reconcile profit before tax to net cash flows:				
Depreciation and amortization of property, plant, equipment, intangible assets and right-of-use assets	49.9	31.9	88.2	63.3
Share-based payment expenses	20.2	13.1	36.5	21.7
Net foreign exchange differences	(13.2)	(397.0)	(41.9)	(343.9)
(Gain) / Loss on disposal of property, plant and equipment	(0.2)	0.1	(0.2)	0.3
Finance income excluding foreign exchange differences	(167.7)	(126.6)	(342.6)	(208.9)
Finance expense excluding foreign exchange differences	4.8	1.3	9.5	2.5
Government grants	(3.1)	—	(12.2)	(3.0)
Unrealized loss on derivative instruments at fair value through profit or loss[(1)]	5.0	124.0	6.7	200.2
Working capital adjustments:				
Decrease in trade and other receivables, contract assets and other assets[(1)]	1,599.6	4,137.0	2,097.8	5,030.8
Decrease / (Increase) in inventories	5.3	(24.8)	17.6	(9.3)
(Decrease) / Increase in trade payables, other financial liabilities, other liabilities, contract liabilities, refund liabilities and provisions	760.8	592.7	472.8	(268.9)
Interest received and realized gains from cash and cash equivalents	80.8	42.5	280.2	96.1
Interest paid and realized losses from cash and cash equivalents	(1.6)	(1.3)	(5.3)	(2.5)
Income tax received / (paid), net[(1)]	66.4	437.3	(192.4)	(407.6)

Share-based payments	(6.8)	(31.3)	(9.2)	(757.0)
Government grants received	32.8	—	42.0	—
Net cash flows from operating activities	**1,627.2**	**4,386.7**	**1,309.9**	**3,709.3**
Investing activities				
Purchase of property, plant and equipment	(88.6)	(67.2)	(147.1)	(112.4)
Proceeds from sale of property, plant and equipment	0.2	—	0.2	—
Purchase of intangible assets and right-of-use assets	(52.7)	(242.1)	(131.1)	(251.7)
Investment in other financial assets	(2,448.2)	(1,982.5)	(7,343.3)	(2,663.1)
Proceeds from maturity of other financial assets	2,347.9	—	5,075.5	—
Net cash flows used in investing activities	**(241.4)**	**(2,291.8)**	**(2,545.8)**	**(3,027.2)**
Financing activities				
Repayment of loans and borrowings	(2.3)	—	(2.3)	—
Payments related to lease liabilities	(20.6)	(9.4)	(28.4)	(18.7)
Share repurchase program	—	(154.0)	—	(436.0)
Net cash flows used in financing activities	**(22.9)**	**(163.4)**	**(30.7)**	**(454.7)**
Net increase / (decrease) in cash and cash equivalents	1,362.9	1,931.5	(1,266.6)	227.4
Change in cash and cash equivalents resulting from exchange rate differences	(3.3)	91.2	3.5	64.1
Change in cash and cash equivalents resulting from other valuation effects	40.5	—	(23.9)	—
Cash and cash equivalents at the beginning of the period	8,976.6	12,143.9	11,663.7	13,875.1
Cash and cash equivalents as of June 30	**10,376.7**	**14,166.6**	**10,376.7**	**14,166.6**

(1) Adjustments to prior-year figures relate to reclassifications within the cash flows from operating activities.