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

FORM 6-K

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

FOR THE MONTH OF AUGUST 2024

COMMISSION FILE NUMBER 001-39081

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

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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 August 19, 2024, BioNTech SE issued a website statement announcing that the U.S. Food and Drug Administration has lifted the partial clinical hold that was placed on the MediLink Therapeutics (Suzhou) Co., Ltd. Phase I trial evaluating BNT326/YL202 (NCT05653752). The statement is attached hereto as Exhibit 99.1.

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	By: /s/ Dr. Sierk Poetting
Name: Jens Holstein	Name: Dr. Sierk Poetting
Title: Chief Financial Officer	Title: Chief Operating Officer

Date: August 19, 2024

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Lift of Partial Clinical Hold for BNT326/YL202

Lift of Partial Clinical Hold for BNT326/YL202

On August 15, 2024, the U.S. Food and Drug Administration ("FDA") lifted the partial clinical hold that was placed on MediLink Therapeutics' (Suzhou) Co., Ltd. ("MediLink") Phase I trial evaluating BNT326/YL202 (NCT05653752), which was announced on June 17, 2024. The complete response including data analysis, updated investigator brochure and informed consent for patients, and amended clinical trial protocol meets the FDA's requirements by incorporating additional risk mitigation measures. BNT326/YL202 is a Human Epidermal Growth Factor Receptor 3 ("HER3")-targeting antibody-drug conjugate ("ADC") candidate that is being developed in collaboration between BioNTech SE ("BioNTech") and MediLink. The trial recruitment will be re-initiated. Clinical development will focus on dose levels no higher than 3 mg/kg, where the safety profile was manageable and encouraging clinical activity was observed.

The study sponsor MediLink had observed a dose level-dependent trend of treatment-related adverse events ("TRAEs") of BNT326/YL202, in particular neutrophil count decrease ("neutropenia") and an increasing rate of mucositis events. These events are common TRAEs of established chemotherapies and increase a person's risk for developing serious infections.[1, 2] Neutropenia is usually managed by dose reduction, dose interruption, and/or administration of primary prophylaxis, such as recombinant granulocyte colony-stimulating factors ("G-CSFs") in appropriate patients based on individualized febrile neutropenia risk assessment of the patient and of the chemotherapy regimen.

Based on emerging safety data from the ongoing trial evaluating BNT326/YL202, the companies swiftly and proactively took precautionary measures, including not enrolling additional patients in dose cohorts higher than 3 mg/kg, and reducing dose levels for participants already enrolled at higher dose levels in the trial. In parallel, MediLink has notified the FDA and worked with BioNTech on analyzing the emerging data and implementing further risk mitigation measures. These include updates to the investigator brochure, the informed consent for patients, and the clinical trial protocol with amended guidance on dose delay, reduction and modification, and prophylactic medications addressing TRAEs.

BioNTech and MediLink are committed to patient safety and will continue to develop BNT326/YL202 in solid tumors with high unmet medical need.

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.

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[1] Naidu MU et al. Chemotherapy-induced and/or radiation therapy-induced oral mucositis--complicating the treatment of cancer. Neoplasia. 2004 Sep-Oct;6(5):423-31. doi: 10.1593/neo.04169. PMID: 15548350; PMCID: PMC1531648.

[2] Ba Y, Shi Y, Jiang W, Feng J, Cheng Y, Xiao L, Zhang Q, Qiu W, Xu B, Xu R, Shen B, Luo Z, Xie X, Chang J, Wang M, Li Y, Shuang Y, Niu Z, Liu B, Zhang J, Zhang L, Yao H, Xie C, Huang H, Liao W, Chen G, Zhang X, An H, Deng Y, Gong P, Xiong J, Yao Q, An X, Chen C, Shi Y, Wang J, Wang X, Wang Z, Xing P, Yang S, Zhou C. Current management of chemotherapy-induced neutropenia in adults: key points and new challenges: Committee of Neoplastic Supportive-Care (CONS), China Anti-Cancer Association Committee of Clinical Chemotherapy, China Anti-Cancer Association. Cancer Biol Med. 2020 Nov 15;17(4):896-909. doi: 10.20892/j.issn.2095-3941.2020.0069. Epub 2020 Dec 15. PMID: 33299642; PMCID: PMC7721096.

For more information, please visit www.BioNTech.com.

Forward-Looking Statements
This statement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. 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 statement are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech’s control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading “Risk Factors” in BioNTech's Quarterly Report on Form 6-K for the period ended June 30, 2024 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC’s website at https://www.sec.gov/. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this statement in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech’s current expectations and speak only as of the date hereof.

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