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 JUNE 2024

COMMISSION FILE NUMBER 001-39081

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

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

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

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

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

INFORMATION INCLUDED AS PART OF THIS FORM 6-K

BioNTech SE has been informed by its partner MediLink Therapeutics (Suzhou) Co., Ltd ("MediLink") that the U.S. Food and Drug Administration ("FDA") has placed a partial clinical hold on the multicenter, open-label, first-in-human Phase 1 clinical (NCT05653752) trial sponsored by MediLink that evaluates the early-stage antibody-drug conjugate ("ADC") product candidate BNT326/YL202 as a later-line treatment in heavily pre-treated patients with advanced or metastatic epidermal growth factor receptor ("EGFR")-mutated non-small cell lung cancer ("NSCLC") or HR+/HER2-negative breast cancer. The partial hold affects the enrollment of new patients in the trial in the U.S.

The FDA has shared with MediLink concerns that BNT326/YL202 may, at higher doses, expose human subjects to unreasonable and significant risk of illness or injuries. In order to address the FDA requests, certain steps need to be taken, including reviewing clinical and safety data, sharing available pharmacological data with the Agency and providing additional information in the investigators brochure regarding the safety findings including grade 5 adverse events observed in studies YL202-INT-101-01 and YL202-CN-201-01. MediLink has taken actions to pause enrollment of new patients in the U.S. and address the FDA requirements.

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

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

Date: June 17, 2024