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 OCTOBER 2024

COMMISSION FILE NUMBER 001-39081

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

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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): ☐

INFORMATION INCLUDED AS PART OF THIS FORM 6-K

BioNTech SE ("BioNTech") has been informed by its partner OncoC4, Inc. ("OncoC4") that the U.S. Food and Drug Administration ("FDA") has placed a partial clinical hold on the companies' two-stage, open-label, randomized Phase 3 trial, PRESERVE-003 (NCT05671510). BioNTech and OncoC4 understand that the partial clinical hold in the ongoing Phase 3 trial with BNT316/ONC-392 (gotistobart) in non-small cell lung cancer ("NSCLC") is due to varying results between the squamous and non-squamous NSCLC patient populations.

The trial evaluates the efficacy and safety of the antibody candidate BNT316/ONC-392 as monotherapy in patients with metastatic NSCLC that progressed under previous PD-(L)1-inhibitor treatment. A recent assessment of the trial data by the independent data monitoring committee identified a possible variance in population results. Consequently, OncoC4 and BioNTech decided to proactively pause enrollment of new patients and informed the FDA of the possible variance for further alignment.

While the companies are assessing next steps for the ongoing trial with BNT316/ONC-392 in NSCLC, patients already enrolled in the trial will continue to receive treatment. Trials evaluating BNT316/ONC-392 in other indications remain unaffected.

About BNT316/ONC-392 (gotistobart)

BNT316/ONC-392 (gotistobart) is a next-generation anti-CTLA-4 antibody candidate jointly being developed by BioNTech and OncoC4. BNT316/ONC-392 is currently in late-stage clinical development as monotherapy or combination therapy in various cancer indications. The immune checkpoint receptor CTLA-4 inhibits T cell immune response and reduces the activity of T cells in recognizing and eliminating cancer cells. This mechanism is also exploited by cancer cells to prevent them from being eliminated by T cells. Blocking CTLA-4 may help to preserve T cell activity and enhance anti-tumor activity. BNT316/ONC-392 was designed with the aim to address this mechanism while preserving CTLA-4 recycling and thus the immunosuppressive T cell (regulatory T cells, or "Tregs") function in the peripheral tissues. This approach aims to give rise to fewer immune-related adverse effects and a more favorable safety profile. The PRESERVE-003 trial (NCT05671510), which is the subject of the partial clinical hold, is a registrational Phase 3 trial to evaluate the candidate as monotherapy in patients with metastatic non-small cell lung cancer (NSCLC). In addition, the candidate is being evaluated in a Phase 2 trial as a combination therapy with pembrolizumab in platinum-resistant ovarian cancer (NCT05446298), in a Phase 1/2 trial in metastatic castration-resistant prostate cancer (NCT05682443) as well as in a Phase 1/2 trial in multiple solid tumors (NCT04140526).

Forward-Looking Statements

This statement 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: the next steps in the PRESERVE-003 trial and other clinical trials of BNT316/ONC-392, the potential that BNT316/ONC-392 may help to preserve T cell activity and enhance anti-tumor activity, and the potential efficacy and safety of BNT316/ONC-392. 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.

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: October 18, 2024