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 APRIL 2026

COMMISSION FILE NUMBER 001-39081

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

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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 April 11, 2026, BioNTech SE announced positive results from the primary analysis of a Phase 2 cohort evaluating trastuzumab pamirtecan (BNT323/DB-1303) in patients with HER2-expressing, advanced endometrial cancer whose disease progressed on or after first-line chemotherapy with or without prior checkpoint inhibitor treatment. The press release is attached 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/ Ramon Zapata-Gomez
Name: Ramon Zapata-Gomez
Title: Chief Financial Officer

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

Date: April 13, 2026

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech and DualityBio's Antibody-Drug Conjugate Trastuzumab Pamirtecan Demonstrated Clinically Meaningful Efficacy in Patients with HER2-Expressing, Recurrent Endometrial Cancer

BioNTech and DualityBio's Antibody-Drug Conjugate Trastuzumab Pamirtecan Demonstrated Clinically Meaningful Efficacy in Patients with HER2-Expressing, Recurrent Endometrial Cancer

- *Trastuzumab pamirtecan, an investigational HER2-targeted antibody-drug conjugate, met the primary efficacy endpoint in a Phase 2 cohort of heavily pre-treated patients with HER2-expressing, recurrent endometrial cancer, an area of high unmet medical need*
- *Data demonstrated clinically meaningful antitumor activity across all HER2 expression levels and a manageable safety profile, with centrally[i] HER2-tested patients showing a confirmed objective response rate of 47.9% in all evaluable patients, 49.3% in patients with prior immune checkpoint inhibitor treatment, and a median progression-free survival of 8.1 months*
- *Largest trial to date to report results for a HER2-targeted antibody-drug conjugate in this indication supports potential of trastuzumab pamirtecan in real-world patient populations, including patients with lower HER2 expression levels and prior checkpoint inhibitor treatment*

MAINZ, Germany, April 11, 2026 – BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today announced positive results from the primary analysis of a Phase 2 cohort evaluating trastuzumab pamirtecan (BNT323/DB-1303) in patients with HER2-expressing, advanced endometrial cancer whose disease progressed on or after first-line chemotherapy with or without prior checkpoint inhibitor treatment. This cohort is part of a global Phase 1/2a clinical trial (NCT05150691) investigating the HER2-targeted antibody-drug conjugate ("ADC") candidate trastuzumab pamirtecan in multiple solid tumors.

The data demonstrated clinically meaningful efficacy and a manageable safety profile for trastuzumab pamirtecan monotherapy across all HER2 immunohistochemistry ("IHC") expression levels (IHC1+, IHC2+, IHC3+)[ii]. Outcomes were consistent among patients regardless of prior checkpoint inhibitor treatment. The data will be presented today in an oral session at the 2026 Society of Gynecologic Oncology ("SGO") Annual Meeting on Women's Cancers in San Juan, Puerto Rico.

“Endometrial cancer is one of the few cancers with an increasing mortality rate,[1] and there is an urgent need for new treatment options, especially for patients with recurrent disease with lower HER2 expression levels where current standard-of-care chemotherapy offers only a 15 % response rate[2],” said **Bhavana Pothuri, M.D., Medical Director of the Clinical Trials Office (CTO) and Director of Gynecologic Oncology Research at the NYU Langone Perlmutter Cancer Center**. “We are encouraged by these results for trastuzumab pamirtecan, which showed clinically meaningful responses across all HER2 levels. Importantly, these results were seen in a broad patient population that reflects real-world clinical practice, including patients who have received prior immune checkpoint inhibitor treatment and those with visceral metastases.”

The analysis of the Phase 2 cohort included 145 patients with advanced or metastatic HER2-expressing endometrial cancer whose disease had progressed following first- or later lines of therapy. This cohort met its primary efficacy endpoint of objective response rate (“ORR”) evaluated in 73 patients previously treated with checkpoint inhibitor therapy and confirmed HER2 status by central testing, showing a confirmed ORR of 49.3% (95% CI: 37.4, 61.3). In all centrally tested patients (n=96) the confirmed ORR was 47.9% (95% CI: 37.6, 58.4) with a median progression-free survival (“mPFS”) of 8.1 months (95% CI: 5.5, 11.8).

Among the 143 efficacy-evaluable patients by local[i] HER2 status testing, the confirmed ORR was 44.1% (95% CI: 35.8, 52.6). Trastuzumab pamirtecan consistently demonstrated encouraging antitumor activity across all HER2 expression levels, with comparable results whether HER2 testing was conducted locally or centrally. Among patients with local HER2 testing, the confirmed ORR was 33.9% (IHC1+) and 40.4% (IHC2+) in patients with lower levels of HER2 expression, and 73.1% (IHC3+) in patients with higher HER2 expression levels. The median duration of response (“mDoR”) was 10.3 months. mPFS for all evaluable patients (n=145), whether they had received prior checkpoint inhibitor treatment or not, was 8.0 months (95% CI: 5.6, 8.3).

The safety profile was manageable and as expected for HER2-targeted ADCs. The most common treatment-related adverse events (TRAEs) were low-grade nausea, anemia, platelet count decrease, and low-grade fatigue. Grade ≥3 treatment-related adverse events (TRAEs) were reported in 68 of 145 (46.9%) patients. Adjudicated cases of interstitial lung disease (“ILD”) or pneumonitis of grade ≥3 occurred in 4.8% of patients and were consistent with the known safety profile of HER2-targeted ADC therapies. The majority of events grade 3 or higher were efficiently manageable with appropriate medical interventions.

“These positive results in patients with endometrial cancer including those with lower HER2 expression levels support the potential of trastuzumab pamirtecan,” said **Prof. Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. “HER2 remains an important therapeutic target, particularly in gynecologic cancers and breast cancer. We are continuing to advance trastuzumab pamirtecan, both as a monotherapy and in novel-novel treatment combination approaches, with the aim to address the significant unmet medical needs in the treatment of patients with HER2-driven tumors.”

Trastuzumab pamirtecan received Fast Track and Breakthrough Therapy designations from the U.S. Food and Drug Administration (“FDA”) for the treatment of endometrial cancer in 2023. A global confirmatory Phase 3 clinical trial Fern-EC-01 (NCT06340568) evaluating trastuzumab pamirtecan monotherapy compared to chemotherapy in previously treated patients with HER2-expressing, recurrent endometrial

cancer is ongoing. BioNTech and DualityBio plan to file a biologics license application (“BLA”) in 2026, subject to regulatory feedback from the FDA.

About trastuzumab pamirtecan

Trastuzumab pamirtecan (BNT323/DB-1303) is a third-generation topoisomerase-1 inhibitor-based ADC targeting HER2 and is being developed by BioNTech and Duality Biologics. Trastuzumab pamirtecan was built from DualityBio’s proprietary Duality Immune Toxin Antibody Conjugates (“DITAC”) platform. HER2 is a surface-expressed protein on solid tumors and has been linked to the aggressive growth and spread of cancer cells. Preclinical data and preliminary clinical data for trastuzumab pamirtecan indicate its potential to target HER2 receptors on solid tumors irrespective of expression level with a manageable safety profile and a potentially expanded therapeutic window.

Trastuzumab pamirtecan is being evaluated in an ongoing Phase 1/2 trial (NCT05150691) in patients with advanced/metastatic solid tumors, and in two global Phase 3 clinical trials. Fern-EC-01, a randomized Phase 3 clinical trial (NCT06340568) evaluating trastuzumab pamirtecan compared with investigator's choice of single agent chemotherapy in previously treated patients with HER2-expressing advanced recurrent endometrial cancer, is currently enrolling patients. DYNASTY-Breast02, a Phase 3 clinical trial (NCT06018337) evaluating trastuzumab pamirtecan in patients with Hormone Receptor-positive (“HR+”) and Human Epidermal Growth Factor Receptor 2 (“HER2”)-low, metastatic breast cancer that have progressed on hormone and/or cyclin-dependent kinase 4/6 (“CDK4/6”) therapy, is fully enrolled and expected to read out this year.

About the Phase 1/2a trial

The global, multi-cohort Phase 1/2a clinical trial (NCT05150691) evaluated the safety and tolerability of trastuzumab pamirtecan in patients with advanced solid tumors that express HER2. Cohort 2b is a Phase 2 expansion cohort which enrolled 145 patients with advanced/metastatic HER2-expressing endometrial cancer whose disease had progressed after first- and later lines of therapy. The HER2 status was determined for all patients through local testing and, where possible, confirmed via central testing. The primary endpoints were objective response rate in patients with prior checkpoint inhibitor treatment with HER2 expression, confirmed by retrospective central testing, and safety. Secondary endpoints included ORR, DoR, DCR, PFS and OS.

About BioNTech

Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel investigative therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery and therapeutic modalities with the intent of rapid development of novel biopharmaceuticals. Its diversified portfolio of oncology product candidates aiming to address the full continuum of cancer includes mRNA cancer immunotherapies, next-generation immunomodulators and targeted therapies such as antibody-drug conjugates (ADCs) and innovative chimeric antigen receptor (CAR) T cell therapies. Based on its deep expertise in mRNA development and in-house manufacturing capabilities, BioNTech and its collaborators are researching and 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 Bristol Myers Squibb, Duality Biologics, Genentech, a member of the Roche Group, Genmab, MediLink, OncoC4, Pfizer and Regeneron.

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

BioNTech 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 be limited to, statements concerning: the collaboration between BioNTech and DualityBio to jointly clinically develop antibody-drug conjugates (ADCs) including trastuzumab pamirtecan (BNT323/DB-1303); timing of the Phase 1/2a trial for trastuzumab pamirtecan in advanced/metastatic solid tumors and the global Phase 3 trials as well as any subsequent data readouts; the registrational potential of any trial we may initiate for trastuzumab pamirtecan; the timing of any planned BLA submissions for trastuzumab pamirtecan in any indication; the nature and characterization of and timing for release of clinical data across BioNTech's platforms, which is subject to peer review, regulatory review and market interpretation; the planned next steps in BioNTech's pipeline programs, including, but not limited to, statements regarding timing or plans for initiation or enrollment of clinical trials, or submission for and receipt of product approvals with respect to BioNTech's product candidates; the ability of BioNTech's mRNA technology to demonstrate clinical efficacy outside of BioNTech's infectious disease platform; the potential safety and efficacy of BioNTech's other product candidates; and BioNTech's anticipated market opportunity and size for its product candidates. Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include but are not limited to discussions with regulatory agencies regarding timing and requirements for additional clinical trials; and the ability to produce comparable clinical results in future clinical trials. 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 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. 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; the timing of and BioNTech's ability to obtain and maintain regulatory approval for BioNTech's product candidates; 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; 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, 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 BioNTech's production capabilities and manufacture BioNTech's products and BioNTech's 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 20-F for the period ended December 31, 2025 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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[i] Central testing refers to HER2 expression level analysis performed at a single, designated laboratory, whereas local testing refers to analysis performed at a patient’s individual trial site or local laboratory.
[ii] HER2 immunohistochemistry (“IHC”) expression levels: IHC1+ = low expression, IHC2+ = moderate expression, IHC3+ = high expression

[1] National Cancer Institute. Cancer Stat Facts: Uterine Cancer. https://seer.cancer.gov/statfacts/html/corp.html. Accessed March 17, 2026.
[2] Makker V, et al. J Clin Oncol. 2023 Apr 14;41(16):2904–2910