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 MARCH 2022

COMMISSION FILE NUMBER 001-39081

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

An der Goldgrube 12
D-55131 Mainz
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): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On March 8, 2022, BioNTech SE (the "Company") announced the expansion of its strategic collaboration with Regeneron to advance the Company's FixVac candidate BNT116 in combination with Libtayo® (cemiplimab), a PD-1 inhibitor, in advanced non-small cell lung cancer (NSCLC). The press release 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/ Dr. Sierk Poetting

Name: Dr. Sierk Poetting

Title: Chief Operating Officer

Date: March 8, 2022

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech and Regeneron Expand Strategic Collaboration to Advance Clinical Development of FixVac and Libtayo® (cemiplimab) Combination in NSCLC

BioNTech and Regeneron Expand Strategic Collaboration to Advance Clinical Development of FixVac and Libtayo® (cemiplimab) Combination in NSCLC

- *BioNTech and Regeneron plan to jointly conduct clinical trials evaluating FixVac candidate BNT116 in combination with Libtayo for the treatment of advanced non-small cell lung cancer (NSCLC)*
- *The development costs for the trials will be equally shared between the parties*
- *The companies advance clinical development of FixVac and Libtayo combination to third tumor type building on their existing agreements in melanoma and prostate cancer by combining their complementary immunotherapies to pave the way for new treatment options in high medical need indications*

Mainz, Germany, March 8, 2022 — BioNTech SE (Nasdaq: BNTX, "BioNTech") today announced the expansion of its strategic collaboration with Regeneron to advance the Company's FixVac candidate BNT116 in combination with Libtayo® (cemiplimab), a PD-1 inhibitor, in advanced non-small cell lung cancer (NSCLC). Under the terms of the agreement the companies plan to jointly conduct clinical trials to evaluate their combination in different patient populations with advanced NSCLC. Lung cancer is worldwide one of the most common diagnosed malignant cancer types and the leading cause of cancer death.[1] NSCLC is the most common type of lung cancer, making up about 85% of all lung cancers.

"Advancing the sixth FixVac product candidate based on uridine mRNA into clinical development underlines the versatility and potential of this platform. Advanced NSCLC still has a five-year survival rate of only 25% leaving patients with very limited treatment options. We believe that a potent vaccine that induces strong T cell responses against shared tumor associated antigens combined with PD-1 blockade that further enables the activated T cell repertoire will help to address the high unmet medical need in this indication," said **Özlem Türeci, M.D., Co-Founder and Chief Medical Officer at BioNTech**. "We look forward to further building on our successful collaboration with Regeneron to accelerate the clinical development of BNT116 in our growing mRNA oncology pipeline."

The investigational mRNA-based cancer vaccine BNT116 is based on BioNTech's FixVac platform. It consists of a fixed combination of shared tumor-associated antigens that were identified to be frequently expressed in NSCLC. The companies plan to develop the collaboration beginning with Phase 1/2 clinical trials in the first-line treatment setting in advanced NSCLC. Under the terms of the agreement, BioNTech and Regeneron will equally share development costs for the trials. In addition, under a separate agreement, BioNTech plans to conduct and sponsor a Phase 1 clinical trial (LuCa-MERIT-1) evaluating the combination of BNT116 and Libtayo in further subpopulations with NSCLC.

"We are delighted to expand our collaboration with BioNTech to a third tumor type – advanced NSCLC – and investigate whether combining Libtayo with BNT116 will further enhance the efficacy and safety we've demonstrated with Libtayo in this cancer as both a monotherapy and in combination with chemotherapy," said **Israel Lowy, M.D., Ph.D., Senior Vice President, Clinical Development, Oncology, at Regeneron**. "Combining PD-1 inhibition with mRNA-based vaccines is an exciting, yet still emerging, approach in oncology. This collaboration provides an opportunity for us to conduct scientifically sophisticated and pioneering clinical research in this space and investigate whether this novel combination may help drive a multi-faceted activation of the immune system against advanced NSCLC."

The agreement follows the company's existing collaboration evaluating the combination of BioNTech's FixVac candidate BNT111 with Libtayo in advanced melanoma. BNT111 was granted U.S. FDA Fast Track Designation in November 2021 and is currently investigated in a randomized Phase 2 trial. The trial was initiated in June 2021, following encouraging data from an exploratory interim analysis of the ongoing Phase 1 Lipo-MERIT study with BNT111 as monotherapy and in combination with PD-1 blockade, which was published in *Nature*. In addition, BioNTech is investigating and sponsoring a Phase 1 clinical trial evaluating the combination of Libtayo with the Company's FixVac candidate BNT112 in prostate cancer.

Libtayo is being jointly developed by Regeneron and Sanofi.

About FixVac
BioNTech's FixVac platform candidates consist of a fixed combination of mRNA-encoded non-mutated antigens shared across patients with a defined cancer type. They feature the Company's proprietary RNA-lipoplex platform for intravenous administration that consists of mRNA optimized for translation efficiency and stability and a formulation that specifically targets dendritic cells. The vaccine antigens trigger a strong and precise innate and adaptive immune response against cancer cells overexpressing the respective antigens.

About BioNTech
Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company 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 T cells, bispecific checkpoint immuno-modulators, targeted cancer antibodies and 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 pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma and Pfizer.

For more information, please visit www.bioNTech.de

BioNTech Forward-Looking Statements
This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's FixVac program candidates BNT116, BNT111 and BNT112; BioNTech's collaboration with Regeneron; the ability to produce favorable clinical results in future clinical trials combining BNT116, BNT111 and BNT112 and Libtayo; timing for commencement of a Phase 1/2 trial in collaboration with Regeneron and any data readouts; timing for release of additional information relating to BNT116; 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 those a part of the FixVac platform, and specifically, including but not limited to statements regarding timing or plans for initiation of clinical trials, enrollment 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 our 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 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.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report as Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

[1] CA Cancer J Clin. 2021 May;71(3):209-249.

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