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 JULY 2020

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): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On July 31, 2020, BioNTech SE (the "Company"), issued a press release announcing a strategic collaboration with Regeneron for a clinical trial combining BioNTech's BNT111 FixVac product candidate and Libtayo® (cemiplimab), a fully human anti-PD-1 therapy, for the treatment of melanoma. The press release is attached hereto as Exhibit 99.1.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, 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 Financial Officer

Date: July 31, 2020

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Press Release dated July 31, 2020 - BioNTech Announces Strategic Collaboration with Regeneron to Advance FixVac and Libtayo® (cemiplimab) Combination in Melanoma.

BioNTech Announces Strategic Collaboration with Regeneron to Advance FixVac and Libtayo® (cemiplimab) Combination in Melanoma

- *BioNTech and Regeneron plan to jointly conduct a randomized Phase 2 study combining BNT111 FixVac and Libtayo for the treatment of melanoma that has progressed after prior PD-1 blockade*
- *Combines two immunotherapies with complementary mechanisms of action with the aim to accelerate the path to market approval in melanoma if the trial is successful*
- *Development costs for the clinical trial to be shared equally with each company retaining full commercial rights to their respective product candidates*

MAINZ, Germany, July 31, 2020 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today announced a strategic collaboration with Regeneron for a clinical trial combining BioNTech's BNT111 FixVac product candidate and Libtayo® (cemiplimab), a fully human anti-PD-1 therapy, for the treatment of melanoma. The companies plan to jointly conduct a randomized Phase 2 study in patients with anti-PD1-refractory/relapsed, unresectable Stage III or IV cutaneous melanoma. Melanoma is the deadliest skin cancer and estimated to kill more than 63,000 people around the world this year.[1]

BNT111 is the most advanced of five clinical stage FixVac product candidates within BioNTech's broader development pipeline. It is an mRNA cancer immunotherapy targeting four antigens frequently expressed in the tumors of patients with melanoma – NY-ESO-1, MAGE-A3, tyrosinase, and TPTE. BNT111 has demonstrated clinical anti-tumor activity as a monotherapy and in combination with checkpoint inhibitors in an ongoing Phase 1 trial in patients with advanced melanoma after prior checkpoint blockade.

"We believe our FixVac platform represents a powerful new drug class of mRNA immunotherapies against cancer. We look forward to working together with Regeneron to advance this product candidate into potentially registrational clinical trials," said **Ugur Sahin, CEO and Co-founder of BioNTech**.

The two companies plan to pursue a clinical trial for the combination in the second-line treatment setting for advanced melanoma. The companies plan to disclose more details related to the planned Phase 2 study in the third quarter of 2020, with the goal of initiating the trial in the fourth quarter of 2020.

"Despite recent treatment advances with anti-PD-1 therapies for patients with melanoma, most patients fail to obtain a durable benefit. The combination of Libtayo and BNT111 FixVac has the potential to augment the immune system's ability to effectively recognize melanoma in multiple ways and hopefully improve immune targeting to control the cancer," said **Israel Lowy, M.D., Ph.D., Senior Vice President, Translational Science and Oncology, at Regeneron**.

Under the terms of the agreement, development costs for the clinical trial will be shared equally and both companies will contribute their products for the trial. Each party will retain full commercial rights for its respective product and record revenues related to its own product.

Libtayo is being jointly developed by Regeneron and Sanofi.

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1 WHO International Agency for Research on Cancer (2020): https://gco.iarc.fr/tomorrow/graphic-isotype?type=1&type_sex=0&mode=population&sex=0&populations=900&cancers=16&age_group=value&apc_male=0&apc_female=0&single_unit=10000&print=0

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, bi-specific 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, 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 candidate BNT111; BioNTech’s collaboration with Regeneron; timing for commencement of a Phase 2 trial in collaboration with Regeneron; timing for release of additional information relating to this trial; and the registrational potential of any Phase 2 trial we may initiate. 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. 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 favorable clinical results in future clinical trials combining BNT111 and Libtayo. For a discussion of these and other risks and uncertainties, see BioNTech’s Annual Report on Form 20-F filed with the SEC on March 31, 2020, which has been filed with the SEC and 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.

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