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 JANUARY 2021

COMMISSION FILE NUMBER 001-39081

BioNTech SE

(Translation of registrant's name into English)

An der Goldgrube 12
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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): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On January 7, 2021, BioNTech SE (the "Company") announced the publication of preclinical data on its novel mRNA vaccine approach against autoimmune diseases in the peer-reviewed journal *Science*. The publication titled "A non-inflammatory mRNA vaccine for treatment of experimental autoimmune encephalomyelitis" summarizes the findings on the disease-suppressing effects of a non-inflammatory, nucleoside-modified mRNA vaccine in several clinically relevant mouse models of multiple sclerosis (MS). 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 Financial Officer

Date: January 7, 2021

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Press Release dated January 7, 2021 – BioNTech Publishes Data on Novel mRNA Vaccine Approach to Treat Autoimmune Diseases in *Science*.

BioNTech Publishes Data on Novel mRNA Vaccine Approach to Treat Autoimmune Diseases in *Science*

- *Collaborative study of BioNTech with TRON and the University Medical Center and Research Center for Immunotherapy at Johannes Gutenberg University of Mainz introduces novel non-inflammatory mRNA vaccine encoding disease-related autoantigens that suppressed disease activity in several complex mouse models of multiple sclerosis*
- *Approach addresses key pitfalls in the treatment of autoimmune diseases such as the induction of systemic immune suppression*
- *Approach can easily be tailored to individual disease-causing antigens of patients and confers bystander tolerance to address highly complex, polyclonal and rare autoimmune disease types*
- *Represents the first application of BioNTech's mRNA technology for the purpose of antigen-specific immune-modulation of autoimmune diseases, which further expands BioNTech's diversified immunology pipeline into another category of disease relevant targets*

MAINZ, GERMANY, January 7, 2021 (GLOBE NEWSWIRE) — BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") announced today the publication of preclinical data on its novel mRNA vaccine approach against autoimmune diseases in the peer-reviewed journal *Science*. The publication titled "A non-inflammatory mRNA vaccine for treatment of experimental autoimmune encephalomyelitis" summarizes the findings on the disease-suppressing effects of a non-inflammatory, nucleoside-modified mRNA vaccine in several clinically relevant mouse models of multiple sclerosis (MS).

Autoimmune diseases like MS represent conditions in which the immune system malfunctions and attacks healthy tissue or cells of the body. In MS, the inflammation causes the destruction of the protective myelin sheath that covers the nerve fibers. This damage disrupts the ability to transmit signals between nerve cells and the target tissue resulting in a range of neurological, sensory and motor symptoms that may differ greatly between individuals.

This first application of BioNTech's mRNA technology in MSs represents a new modality in this indication and underlines BioNTech's potential to leverage its proprietary mRNA platform.

In the study, a non-inflammatory nanoparticulate mRNA vaccine candidate encoding a MS-associated antigen was systemically applied to mice with experimental autoimmune encephalomyelitis (EAE), which represent clinically relevant mouse models of human MS. The mRNA vaccine candidate was designed to deliver the encoded autoimmune disease target antigen into antigen-presenting cells in the lymph nodes body-wide in a non-inflammatory context to enable systemic, immune tolerance-inducing antigen presentation in lymphoid tissues.

In all investigated EAE mouse models, the vaccine was able to prevent symptomatic disease or, in mice with early-stage disease, reduced further disease progression and restored motor functions. Pro-inflammatory effector T (T_{eff}) cell infiltration in the brain and spinal cord and demyelination of the spinal cord was considerably reduced. These effects were achieved via development of disease-suppressing regulatory T (T_{reg}) cells directed exquisitely against the antigen encoded by the mRNA vaccine. The T_{reg} cells also executed a strong immunosuppressive bystander effect in the different MS mouse models, demonstrating that the T_{reg} cells, once activated by their target antigen, can also suppress T_{eff} cells against other antigens in the inflamed tissue in a complex disease setting. This is a crucial factor to also address polyclonal diseases based on multiple, partly unknown antigens, as well as inter-individual heterogeneity between patients.

Importantly, the preclinical vaccine candidate did not suppress functional immune responses against other, non-myelin antigens (e.g. influenza vaccine antigens), therefore addressing one of the key challenges in autoimmune treatment in the preclinical studies, the induction of an unspecific, systemic immune suppression. In addition, the vaccine candidate, even after repetitive application, did not induce formation of autoantibodies against the targeted antigen, another potential pitfall in current autoimmune therapies that could exacerbate disease. Overall, these initial results regarding the immune response together with the flexibility of the mRNA approach to target individual patient antigens indicate the potential of mRNA therapeutics to address highly complex and rare autoimmune disease indications.

The publication represents results of a collaborative study of scientists from BioNTech, TRON – Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz, the Institute for Molecular Medicine at the University Medical Center of the Johannes Gutenberg University Mainz and the Research Center for Immunotherapy (FZI) at the Johannes Gutenberg University Mainz.

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, 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, as amended, including, but not limited to: statements concerning the applicability of BioNTech’s mRNA technology in autoimmune diseases. 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. 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. 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.

For a discussion of these risks and uncertainties, see BioNTech’s Quarterly Report for the Three and Nine Months Ended September 30, 2020, filed as Exhibit 99.2 to its Current Report on Form 6-K filed with the SEC on November 10, 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.

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