

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 2022

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):

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On January 11, 2022, BioNTech SE (the “Company”) and [InstaDeep Ltd](#) (“InstaDeep”) today announced the development of a new computational method that analyses worldwide available sequencing data and predicts high-risk variants of SARS-CoV-2. 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: January 11, 2022

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<u>BioNTech and InstaDeep Developed and Successfully Tested Early Warning System to Detect Potential High-Risk SARS-CoV-2 Variants</u>



BioNTech and InstaDeep Developed and Successfully Tested Early Warning System to Detect Potential High-Risk SARS-CoV-2 Variants

- *Early Warning System combines Spike protein structural modeling with artificial intelligence (AI) to detect and monitor high-risk SARS-CoV-2 variants, identifying >90% of WHO-designated variants on average two months prior to officially receiving the designation*
- *Study introduces a new method of combining publicly available SARS-CoV-2 sequence information with predictive analytics to effectively detect and monitor potential high-risk variants which could help increase preparedness against future variants of concern*
- *Early Warning System is fully scalable as new variant data become available*
- *Study is available on the pre-print server BioRxiv and has been submitted to a peer-reviewed journal*

NEW YORK, USA and LONDON, UNITED KINGDOM, January 11, 2022 — BioNTech SE (Nasdaq: BNTX, “BioNTech”) and [InstaDeep Ltd](#) (“InstaDeep”) today announced the development of a new computational method that analyses worldwide available sequencing data and predicts high-risk variants of SARS-CoV-2. The Early Warning System (EWS) developed in collaboration by BioNTech and InstaDeep is based on artificial intelligence (AI) calculated immune escape and fitness metrics.

The new method combines structural modeling of the viral Spike protein and AI algorithms to quickly flag potential high-risk variants entered into SARS-CoV-2 sequence data repositories within less than a day based on metrics scoring their fitness (e.g. ACE2 and variant Spike protein interaction) as well as their immune escape properties. The companies validated these predictions using experimental data generated in-house and publicly available data.

During the trial period, the system has identified >90% of the World Health Organization (WHO)-designated variants (Variants of Concern, VOC; Variants of Interest, VOI; Variants Under Monitoring, VUM) on average two months in advance. WHO-designated variants Alpha, Beta, Gamma, Theta, Eta and Omicron were detected by the EWS in the same week its sequence was first uploaded. The Omicron variant was ranked as a high-risk variant the same day its sequence became available. The IHU variant observed in France has also been evaluated by the EWS, which highlighted immune escape properties that are relatively similar to Omicron but with significantly lower fitness, making it less of a concern given current data.

The results from the study underline that the EWS is capable of evaluating new variants in minutes and risk monitoring variant lineages nearly in real-time. It is also fully scalable as new variant data becomes available.

“With the advanced computational methods we have been developing over the past months we can analyse sequence information of the Spike protein and rank new variants according to their predicted immune escape and ACE2 binding score,” said **Ugur Sahin, M.D., Chief Executive Officer and Co-Founder of BioNTech**. “Early flagging of potential high-risk variants could be an effective tool to alert researchers, vaccine developers, health authorities and policy makers, thereby providing more time to respond to new variants of concern.” “More than 10,000 novel variant sequences are currently discovered every week and human experts simply cannot cope with complex data at this scale. We’ve addressed this challenge by deploying the powerful AI capabilities of InstaDeep’s DeepChain platform combined with BioNTech’s SARS-CoV-2 know-how and technology. For the first time, high-risk variants could be detected on the spot, potentially saving months of precious time. We are happy to make our research work publicly available and, most importantly, look forward to its continued real-world impact,” added **Karim Beguir, Co-Founder and CEO of InstaDeep**.

The Early Warning System (EWS) relies on two approaches: (1) structural modeling of the interaction of the viral Spike protein receptor-binding domain (RBD) with the host cell receptor and scoring the

impact of the virus variant in escaping the immune response, and (2) AI-based predictive modeling to extract information from hundreds of thousands of registered virus variants from global sequence repositories. The EWS computes an immune escape score and a fitness (transmissibility potential) prior score. While the immune escape score alone was already highly predictive of the risk, combining these two metrics into a Pareto score provided the best assessment of the risk posed by a given virus variant. The higher the score, the higher the risk of the variant impacting global health. The EWS approach ranks SARS-CoV-2 variants for immune escape and fitness potential based solely on existing data, and therefore is not dependent on a “wait-and-watch” approach.

The EWS was able to distinguish the WHO-designated variants from those that had no designation during a 11-month period, underlining the viable computational model ability to determine variant lineage. An analysis conducted every week between September 16th, 2020 and November 23rd, 2021 flagged 12 out of 13 WHO-designated variants with an average of 58 days of lead time (i.e. two months) before the variants were given their designation. For variants Alpha to Mu, only around 25 cases on average were recorded at the time of them being flagged by the EWS. This is in contrast with the WHO announcements that happened on average when more than 1,500 cases were recorded. The EWS detected Omicron on the day its sequence was first uploaded as the highest immune escaping variant from over more than 70,000 variants that were discovered between early October 2021 and late November 2021 while also assigning it a high fitness score.

The data published as a pre-print is the result of a collaboration established between BioNTech and InstaDeep in November 2020 to coalesce AI and immunology. As part of the collaboration, the companies formed a joint AI Innovation Lab in London, UK, and Mainz, Germany, to advance novel drug discovery and design, protein engineering, manufacturing and supply chain optimization.

About SARS-CoV-2 Mutations

The last two years have demonstrated how the frequent and wide circulation of the SARS-CoV-2 virus increases its likelihood to mutate in parts of its genetic make-up with the potential to change its features. Current known variants harbor mutations that distinguish them from the original strain identified in early 2020. Over 13,400 individual missense mutations have been observed in the Spike protein alone. Available data show that thousands of new variants are emerging every week at an increasing rate, with a weekly average of registered variants of about 300 in September 2020, 7,000 in August 2021 and 12,000 in December 2021.

While most mutations either reduce the overall fitness of the virus, or bear no consequences to its features, some individual or combinations of mutations lead to high-risk variants (HRVs) with modified immune evasion capabilities and/or improved transmissibility. A variant that can bypass neutralization by antibodies is of particular importance and poses a risk to individuals who previously had COVID-19 and those that are fully vaccinated.

As new sequences continue to be detected in infected individuals, foreseeing variants that have the potential to become HRVs is critical for pandemic preparedness. Identifying these variants creates a significant challenge for public health authorities as detection by varied tests in the lab is very time consuming. The EWS allows for early detection of these variants and shortens the time that health authorities need to assess their impact and respond in a timely manner.

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. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech’s efforts to combat COVID-19; its collaboration with InstaDeep; capabilities of the Early Warning System (EWS) to predict potential High-Risk Variants (HRV) and to save time in HRV identification; and uncertainties regarding the impact of COVID-19 on BioNTech’s trials, business and general operations. 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: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see the section entitled “Risk Factors” 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.

About InstaDeep

Founded in 2014, InstaDeep is today an EMEA leader in decision-making AI products for the Enterprise, with headquarters in London and offices in Paris, Tunis, Lagos, Dubai and Cape Town. With expertise in both machine intelligence research and concrete business deployments, the Company provides a competitive advantage to its partners in an AI-first world. Leveraging its extensive know-how in GPU-accelerated computing, deep learning and reinforcement learning, InstaDeep has built products, such as its novel DeepChain™ protein design platform, that tackle the most complex challenges across a range of industries. InstaDeep has also developed collaborations with global leaders in the Artificial intelligence ecosystem, such as Google DeepMind, Nvidia and Intel. The Company is part of Intel’s AI Builders program and was named an Elite Partner by Nvidia. InstaDeep was recently selected by CB Insights as one of the 100 most promising AI start-ups in the world for the second year running. To learn more, please visit www.instadeep.com.

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