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 2021

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 \boxtimes Form 40-F \square

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 28, 2021, BioNTech SE (the "Company") was quoted in publications stating that fully vaccinated people could need a booster shoot of its COVID-19 vaccine with partner Pfizer Inc., 12 months and eventually a yearly booster shot. The Company also stated it has tested its COVID-19 vaccine against more than 30 variants, and it has had a promising responses against almost all the variants tested, including the so-called Indian variant, and "sufficient" against those it did not fight off as well. Additionally, the Company stated that it is discussing production sites in Africa. Lastly, the Company stated that it expects regulatory approval of its COVID-19 vaccine in China by July 2021. The publications are 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: <u>/s/ Dr. Sierk Poetting</u> Name: Dr. Sierk Poetting Title: Chief Financial Officer

Date: April 28, 2021

EXHIBIT INDEX

Exhibit Description of Exhibit

99.1 <u>April 28, 2021 Media Publications</u>

"Europe will reach herd immunity" this summer: BioNTech chief The Hill: Changing America By Adam Barnes April 28, 2021

Chief executive Ugur Sahin warned that initial herd immunity would not include children.

Ugur Sahin, Co-founder of Biontech SE, makes a speech after receiving the Federal Order Of Merit from President Frank-Walter Steinmeier at Schloss Bellevue on March 19, 2021 in Berlin, Germany. Pharmaceutical company BioNtech's chief executive said Wednesday that Europe could reach herd immunity in three to four months.

Exhibit 99.1

BIONTEC

Ugur Sahin, whose company partnered with Pfizer to create the most widely used COVID-19 vaccine in the U.S., told reporters that Europe could achieve herd immunity by "July, latest by August."

Sahin added that data has shown the immune response in inoculated people decreases over time and that a booster shot is likely, adding that the efficacy of his company's vaccine declines from 95 percent to 91 percent after six months.

Pharmaceutical company BioNtech's chief executive said Wednesday that Europe could reach herd immunity in three to four months.

Ugur Sahin, whose company partnered with Pfizer to create the most widely used COVID-19 vaccine in the U.S., told reporters that Europe could achieve herd immunity by "July, latest by August," The Associated Press (AP) reported.

But Sahin warned that initial herd immunity would not include children. The Pfizer BioNTech vaccine has yet to receive approval from the Food and Drug Administration (FDA) for use in children under the age of 16.

Sahin added that data has shown the immune response in inoculated people decreases over time and that a booster shot is likely, adding that the efficacy of his company's vaccine declines from 95 percent to 91 percent after six months. Pfizer CEO Albert Bourla said April 1 that a booster shot for the Pfizer BioNTech would be necessary after 12 months as variants emerge. A yearly vaccine similar to a flu shot could eventually be needed, Bourla said.

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Sahin echoed Bourla Wednesday, saying that fully vaccinated people could need a booster shot after 12 months and eventually a yearly shot.

"And then I expect it will probably be necessary to get another booster every year or perhaps every 18 months," Sahin said.

Sahin told reporters the company's vaccine has undergone testing against more than 30 COVID-19 variants and that it registers a good immune response against the variant first discovered in Britain, the AP reported. Sahin additionally explained that the vaccine is still being tested against the variant first discovered in India.

"But the Indian variant has mutations that we have previously investigated and against which our vaccine also works, so I am confident there, too," Sahin said.

White House chief medical advisor Anthony Fauci said Monday that herd immunity in the U.S. is a "moving target" and the focus should be on getting Americans vaccinated.

"We don't know what the durability of the infection-induced immunity is. We don't know if someone who got infected last winter or in the early part of 2020 is going to be safe from a protected standpoint now," Fauci said.

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CORRECTED-BioNTech CEO sees China approval for COVID shot by July

Reuters By Reuters stuff April 28, 2021

(Corrects expected approval timing to July)

BERLIN, April 28 (Reuters) - BioNTech expects that the COVID-19 vaccine it is making with Pfizer will win approval from the Chinese health authorities "by July at the latest", Chief Executive Ugur Sahin said on Wednesday.

This would mean that it would be possible to distribute the vaccine in China from July, the founder of the biotech startup told an online briefing with the German foreign correspondents' association.

"I am optimistic that we can help the people of China," said Sahin, adding that local partner Shanghai Fosun Pharmaceutical Group Co Ltd was "a great company". (Reporting by Douglas Busvine, editing by Kirsti Knolle)

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Pfizer COVID Vaccine Likely Will Need Third Booster Shot, BioNTech CEO Says Newsweek By Mary Ellen Cagnassola April 28, 2021

Ugur Sahin, BioNTech's chief executive and co-founder, told reporters on Wednesday that the vaccine his company created with Pfizer will likely require a third booster shot due to data showing a weaker immune response over time in people who received the vaccine, the Associated Press reported.

According to studies, the efficacy of the BioNTech-Pfizer vaccine drops from 95% to 91% after six months. Sahin said people who receive two doses of the vaccine should get the third dose nine to 12 months after the first shot.

"Accordingly, we need a third shot to get the vaccine protection back up to almost 100% again," Sahin said. "And then I expect it will probably be necessary to get another booster every year or perhaps every 18 months."

The emergence of new variants has created worry over the effectiveness of existing vaccines. Sahin said his company has tested its vaccine against more than 30 variants, including the prevailing strain originating from Britain. BioNTech found its vaccine encourages a promising response against almost all the variants tested and "sufficient" against those it did not fight off as well.

Concerns have been raised that existing vaccines might be less effective against new variants of the virus emerging in different parts of the world.

BioNTech Weighs Making Covid Shots in Africa to Expand Reach Bloomberg By Naomi Kresge and Antony Sguazzin April 28, 2021

(Bloomberg) -- BioNTech SE is discussing the possibility of Covid-19 vaccine production sites in Africa to expand the company's supply network in regions around the world, Chief Executive Officer Ugur Sahin said.

"I can imagine a production network in South America and for Africa," Sahin said at a briefing with members of Germany's foreign press association. "We are also talking about African production sites."

Though BioNTech and its U.S. partner Pfizer Inc. have committed to make 2.5 billion doses of their two-shot vaccine this year, the vast majority are tied up in lucrative contracts with the world's wealthiest countries. Africa trails the rest of the world in accessing the shots it needs to immunize its more than 1 billion residents. Globally, countries with the highest incomes are getting vaccinated about 25 times faster than those with the lowest, Bloomberg's Vaccine Tracker shows.

More Than 1.06 Billion Shots Given: Covid-19 Tracker Sahin said he had met with representatives from Gavi, the Vaccine Alliance, earlier on Wednesday about how to make more shots available in low-income countries.

Giving up patent rights on the vaccine isn't the solution, the CEO said, adding that BioNTech wants to avoid a proliferation of versions of its shot. One possibility instead would be a special license for competent manufacturers, though he said such production wouldn't be able to help with supply until the end of next year.

African Capacity

"We don't want to see a qualitatively inferior vaccine in Africa," Sahin said. "Everything has to be certified. This is why we're talking to organizations about giving a license for certified producers."

African epidemiologists and some politicians have said the continent needs to develop its own vaccine manufacturing.

Currently, the ability to make vaccines of any kind – and largely just packaging the shots rather than producing them -- is confined to South Africa, Senegal and Egypt on the continent.

South Africa's Aspen Pharmacare Holdings Ltd. has agreed to manufacture as many as 300 million Johnson & Johnson Covid shots annually at a plant it owns in the country. The country's partly state-owned Biovac Institute plans to build an active pharmaceutical ingredients plant at a cost of as much as 200 million euros (\$241 million) to make Covid shots in a partnership with ImmunityBio Inc.

"The greatest lesson that vaccine nationalism has taught us is the critical urgency for Africa to develop, manufacture and distribute its own biotechnology," South African Health Minister Zweli Mkhize said in an April 7 speech.

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BioNTech co-founder 'confident' vaccine works against Indian COVID-19 variant AFP

April 28, 2021 (taken up by Channel News Asia)

BERLIN: BioNTech co-founder Ugur Sahin on Wednesday (Apr 28) voiced confidence that the vaccine that his company jointly developed with Pfizer works against the Indian variant of the coronavirus.

"We are still testing the Indian variant, but the Indian variant has mutations that we have already tested for and which our vaccine works against, so I am confident," said Sahin.

"The vaccine is cleverly built and I'm convinced the bulwark will hold. And if we have to strengthen the bulwark again, then we will do it, that I'm not worried about," he added.

India is facing surging new cases and deaths in the COVID-19 pandemic, and fears are rising that the variant could be contributing to the unfolding catastrophe.

The World Health Organization (WHO) has said that the B1617 variant of COVID-19 first found in India had as of Tuesday been detected in "at least 17 countries".

The health agency recently listed B1617 - which counts several sub-lineages with slightly different mutations and characteristics - as a "variant of interest".

But so far it has stopped short of declaring it a "variant of concern", which would have indicated that it is more dangerous than the original version of the virus by, for instance, being more transmissible, deadly or able to dodge vaccine protections.

The Pfizer-BioNTech vaccine was the first to win authorisation in the West, and has since been deployed in dozens of countries worldwide.

Giving an update of the authorisation process in China, Sahin said approval was "very possible in July".

"We are almost through with all questions," he said.

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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 statement 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; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential second booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; BioNTech's plans for expansion of its manufacturing capacity and capabilities, facilities, and geographical presence; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimate for 2021 as well as the timing and expectations of manufacturing capacities of the manufacturing network. Any forward-looking statements in this statement 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: competition to create a vaccine for COVID-19; the ability to effectively scale our productions capabilities; and other potential difficulties.

Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events. The forwardlooking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forwardlooking 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. You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Annual Report on 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 <u>www.sec.gov</u>. 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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