

**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 FEBRUARY 2024

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 February 8, 2024, BioNTech SE and Autolus Therapeutics plc announced a strategic collaboration aimed at advancing both companies' autologous CAR-T programs towards commercialization, pending regulatory authorizations. In connection with the strategic collaboration, the companies entered into a license and option agreement and a securities purchase agreement. 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: February 8, 2024

EXHIBIT INDEX

| <u>Exhibit</u> | <u>Description of Exhibit</u> |
|----------------|--|
| 99.1 | <u>BioNTech and Autolus Announce Strategic CAR-T Cell Therapy Collaboration to Advance Pipeline and Expand Late-Stage Programs</u> |

BioNTech and Autolus Announce Strategic CAR-T Cell Therapy Collaboration to Advance Pipeline and Expand Late-Stage Programs

- *Strategic alliance leverages manufacturing and commercial infrastructure as well as technology with the aim to advance both companies' autologous CAR-T programs towards market, pending market authorization*
- *BioNTech secures the right to utilize Autolus' manufacturing capacity in a cost-efficient set-up to accelerate the development of BNT211 into pivotal trials in CLDN6+ tumors*
- *BioNTech to support launch and expansion of development program of Autolus' lead cell therapy candidate obe-cel and will receive a royalty on net sales*
- *BioNTech has co-commercialization options for Autolus' AUTO1/22 and AUTO6NG programs*
- *BioNTech has the option to access a suite of Autolus target binders and cell programming technologies to support BioNTech's development of in vivo cell therapy and antibody-drug conjugate candidates*
- *BioNTech agrees to invest \$200 million in Autolus*

MAINZ, Germany and LONDON, United Kingdom, February 8, 2024 – BioNTech SE (Nasdaq: BNTX, “BioNTech”), a next-generation immunotherapy company pioneering novel therapies for cancer and other serious diseases, and Autolus Therapeutics plc (Nasdaq: AUTL, “Autolus”), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced a strategic collaboration aimed at advancing both companies' autologous CAR-T programs towards commercialization, pending regulatory authorizations. In connection with the strategic collaboration, the companies entered into a license and option agreement and a securities purchase agreement.

“The collaboration with Autolus enables us to expand our BNT211 program into trials for multiple cancer indications in a cost-efficient way. Autolus' state-of-the-art manufacturing facilities' set-up for clinical and commercial supply will enhance our own capacities in addition to our existing U.S. supply network and the ongoing expansion of our site in Gaithersburg, Maryland,” said **Prof. Ugur Sahin, M.D., CEO and Co-Founder of BioNTech**. “Furthermore, this collaboration grants us access to Autolus' precise cell targeting tools to further support BioNTech's development of *in vivo* cell therapy and antibody-drug conjugate candidates.”

“We see a remarkable opportunity to leverage our core capabilities, accelerate pipeline programs, realize cost-efficiencies and expand opportunities beyond autologous cell therapies,” said **Dr. Christian Itin, CEO of Autolus**. “We look forward to investing a portion of the capital raised on delivering on obe-cel's path in adult acute lymphoblastic leukaemia, potentially offering another treatment option for patients where there is still an unmet medical need. This collaboration creates a path for accelerating our respective oncology pipeline programs and broadening the use of Autolus' technology outside of autologous cell therapy applications.”

BioNTech has agreed to purchase \$200 million of Autolus' American Depositary Shares in a private placement. BioNTech will have a right to appoint a director to the Board of Autolus.

Under the terms of the license and option agreement, BioNTech will make a cash payment of \$50 million and is granted the following rights in exchange:

- BioNTech is eligible to receive an up to mid-single digit royalty on obe-cel net sales. Autolus will retain full rights to and control of the development and commercialization of obe-cel.
- BioNTech has the option to access Autolus' commercial and clinical site network, manufacturing capacities in the United Kingdom and commercial supply infrastructure in a cost-efficient set-up in order to accelerate the development of BNT211 in additional CLDN6+ tumor types. BioNTech plans to have 10 or more ongoing potentially registrational clinical trials in the pipeline by the end of 2024, including its fully owned CLDN6 CAR-T program BNT211 in relapsed or refractory germ cell tumors.

- Autolus will lead the development and commercialization for AUTO1/22 and AUTO6NG in any oncology indication with BioNTech having an option to support certain development activities and co-commercialize both candidates in certain territories. If BioNTech exercises an option, it will receive a profit share with respect to such exercised product candidate worldwide while Autolus will be eligible to receive an option exercise fee, milestone payments and co-funding of development expenses.
- Autolus granted BioNTech an exclusive license to develop and commercialize therapeutics incorporating certain of Autolus' proprietary binders along with options to license binders and cell programming technology for use in BioNTech's *in vivo* cell therapy development programs and investigational antibody-drug conjugates. If BioNTech exercises an option, Autolus will be eligible to receive exercise fees and milestones payments, with low-single digit royalties on net sales of the licensed products.

About BioNTech's cell and gene therapy portfolio

BioNTech has been active in the development of cell and gene therapies since 2009. Today, it is a core platform technology in BioNTech's pipeline. BioNTech is investing in multiple platform technologies with the aim to lead in the field. BioNTech's engineered cell therapy portfolio features both chimeric antigen receptor (CAR) and T cell receptor (TCRs) or individualized T cell receptor therapeutic drug candidates.

BNT211 is BioNTech's most advanced cell therapy development program. BNT211 is an autologous Claudin-6 (CLDN6)-targeting CAR-T cell therapy candidate that is being tested alone and in combination with a CAR-T cell Amplifying RNA Vaccine ("CARVac"), encoding CLDN6. The CAR-T cells are equipped with a second-generation CAR of high sensitivity and specificity. CARVac is intended to support *in vivo* expansion of CAR-T cells to increase their persistence and efficacy. CLDN6 is expressed on multiple solid tumors such as ovarian cancer, sarcoma, testicular cancer, endometrial cancer and gastric cancer. BioNTech plans to initiate its first pivotal Phase 2 trial evaluating BNT211 in 2L+ germ cell tumors in 2024 and is continuing to assess additional indications for further development.

About BioNTech

BioNTech is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech 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 (CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapeutics, as well as 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 Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, OncoC4, Regeneron and Pfizer.

For more information, please visit www.BioNTech.com.

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. These forward-looking statements include, but are not limited to, statements concerning: the collaboration between BioNTech and Autolus to advance both companies' autologous CAR-T programs towards commercialization, pending regulatory authorizations, including BNT211 in CLDN6+ tumors, obe-cel in adult acute lymphoblastic leukemia, and AUTO1/22 and AUTO6NG in any oncology indication; the expected impact of the collaboration on BioNTech's business, including any potential benefits to BioNTech and Autolus resulting from the collaboration; BioNTech's access to or option to access Autolus' target binders and cell programming technologies to support development of *in vivo* cell therapy and ADC candidates;

BioNTech's co-commercialization options for Autolus' AUTO1/22 and AUTO6NG programs; BioNTech's option to enter into a future agreement to access Autolus' commercial and clinical site network, manufacturing capacities and commercial supply infrastructure; BioNTech's plans regarding the timing, characterization and number of potentially registrational trials, including BNT211 in relapsed or refractory germ cell tumors; BioNTech's agreement to make an equity investment in Autolus, including BioNTech's director appointment right; the parties' ability to receive certain milestone, royalty, revenue sharing, and/or profit-sharing payments; the planned next steps in BioNTech's pipeline programs, including, but not limited to, statements regarding timing or plans for initiation or enrollment of clinical trials, 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 BioNTech's 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'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. 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. These risks and uncertainties include, but are not limited to: the risk that the proposed transactions may not close, in whole or in part; the compliance of the proposed transactions with applicable securities laws with respect to the purchase and sale of Autolus securities, including the availability of exemptions from registration and/or the future registration of purchased securities; the reaction of third parties, including competitors, to the transactions, including BioNTech's planned equity investment in Autolus; each party's ability to protect and maintain its intellectual property position; Autolus' ability to maintain its manufacturing and supply infrastructure; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; BioNTech's and its counterparties' ability to manage and source necessary energy resources, capital requirements, the use of capital and unexpected expenditures; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators to continue research and development activities relating to BioNTech's development candidates and investigational medicines; unforeseen safety issues and potential claims that are alleged to arise from the use of products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market, if approved, its product candidates; BioNTech's ability to manage its development and expansion; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and product candidates; risks relating to the global financial system and markets; BioNTech's ability to create long-term value for its shareholders; and other factors not known to BioNTech at this time.

You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended September 30, 2023, and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech's current expectations and speak only as of the date hereof.

About Autolus

Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer and autoimmune disease. Using a broad suite of proprietary and modular T cell programming technologies, Autolus is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize target cells, break down their defense mechanisms and eliminate these cells. Autolus has a pipeline of product candidates in development for the treatment of hematological malignancies, solid tumors and autoimmune diseases. For more information, please visit www.autolus.com.

Autolus Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding Autolus' development of its product candidates, including the obe-cel program; the profile and potential application of obe-cel in additional disease settings; the future clinical development, efficacy, safety and therapeutic potential of Autolus' product candidates, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical and preclinical activity and milestones; expectations regarding the initiation, design and reporting of data from clinical trials and preclinical studies; expectations regarding the regulatory approval process for any product candidates; the benefits of the collaboration between Autolus and BioNTech, including the potential and timing to receive equity investments, milestone payments, profit share payments, and/or royalties under the terms of the strategic collaboration; Autolus' current and future manufacturing capabilities; and the completion and timing of the proposed private placement. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, but are not limited to, the risks that Autolus' preclinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; the results of early clinical trials are not always being predictive of future results; the cost, timing and results of clinical trials; that many product candidates do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; and possible safety and efficacy concerns. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Autolus' actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Autolus' Annual Report on Form 20-F filed with the Securities and Exchange Commission, or the SEC, on March 7, 2023 and in Autolus' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Autolus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing Autolus' views as of any date subsequent to the date of this press release.

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