

**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 MARCH 2023

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 March 20, 2023, BioNTech SE (the “Company”) and OncoC4, Inc. (“OncoC4”) announced that they have entered into an exclusive worldwide license and collaboration agreement to develop and commercialize OncoC4’s next-generation anti-CTLA-4 monoclonal antibody candidate, ONC-392, as monotherapy or combination therapy in various cancer indications. 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: March 20, 2023

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	<u>BioNTech and OncoC4 Announce Strategic Collaboration to Co-Develop and Commercialize Novel Checkpoint Antibody in Multiple Solid Tumor Indications</u>



BioNTech and OncoC4 Announce Strategic Collaboration to Co-Develop and Commercialize Novel Checkpoint Antibody in Multiple Solid Tumor Indications

- *BioNTech to receive exclusive worldwide license from OncoC4 to develop and commercialize its anti-CTLA-4 monoclonal antibody candidate, ONC-392*
- *BioNTech and OncoC4 will co-develop ONC-392 as monotherapy or in combination with anti-PD1 in various solid tumor indications, with a randomized Phase 3 trial planned to start in 2023*
- *BioNTech also plans to combine ONC-392 with its proprietary oncology product candidates to evaluate complementary modes of action with the aim to increase therapeutic effect and unlock larger patient populations*
- *OncoC4 will receive \$200 million upfront and is eligible to receive development, regulatory and commercial milestone payments and double-digit tiered royalties*

MAINZ, Germany and ROCKVILLE, Maryland, USA, March 20, 2023 – [BioNTech SE](#) (Nasdaq: BNTX, “BioNTech”) and OncoC4, Inc. (“OncoC4”), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel biologicals for cancer treatment, today announced that they have entered into an exclusive worldwide license and collaboration agreement to develop and commercialize OncoC4’s next-generation anti-CTLA-4 monoclonal antibody candidate, ONC-392, as monotherapy or combination therapy in various cancer indications. The transaction is expected to close in the first half of 2023, subject to customary closing conditions and regulatory clearances.

CTLA-4 is a molecule that inhibits the activity of immune cells via various mechanisms. OncoC4’s CTLA-4 antibody candidate ONC-392 aims to delete immunosuppressive T cells (regulatory T cells, “Tregs”) in the tumor microenvironment, but spare Tregs in healthy tissues. With a potentially differentiated safety profile, ONC-392 may be able to achieve a more effective dosing regimen in the clinic and more successful tumor killing. Data from the ongoing Phase 1/2 trial ([NCT04140526](#)) in patients with advanced solid tumors were presented at SITC in [2022](#) and [2021](#), where ONC-392 showed encouraging clinical activity, either as single agent or in combination with pembrolizumab in patients with metastases, particularly those who progressed on immunotherapies targeting PD-1 and CTLA-4.

ONC-392 received Fast Track designation from the U.S. Food and Drug Administration (“FDA”) as a monotherapy for immunotherapy-resistant non-small cell lung cancer (“NSCLC”). The data in monotherapy of PD-1-resistant NSCLC support the initiation of a randomized Phase 3 trial which will evaluate ONC-392 as monotherapy against the current standard of care in that indication ([NCT05671510](#)). The candidate is currently also being evaluated in an additional Phase 2 trial as a combination therapy with pembrolizumab in platinum-resistant ovarian cancer ([NCT05446298](#)).

“Despite being a prime target for more than a decade, we believe that targeting CTLA-4 has not reached its full potential in cancer immunotherapy,” said **Prof. Ugur Sahin, M.D., Chief Executive Officer and Co-Founder of BioNTech**. “The data presented by OncoC4 on their ONC-392 antibody indicate a differentiated safety profile and encouraging clinical activity in various types of tumors. We believe that this antibody is a valuable addition to our immuno-oncology portfolio, whether used alone or in combination with our personalized immunotherapies.”

“Because of its specific mechanism of action, we believe ONC-392 has the potential to broaden the reach of CTLA-4-targeting immunotherapy,” said **Yang Liu, PhD, Co-Founder, CEO and Chief Scientific Officer of OncoC4**. “We very much look forward to working hand-in-hand with BioNTech in developing ONC-392 for cancer indications with unmet medical needs.”

Under the terms of the agreement, OncoC4 will receive a \$200 million upfront payment and is eligible to receive development, regulatory and commercial milestone payments as well as double-digit tiered royalties. BioNTech and OncoC4 will jointly develop ONC-392 as monotherapy and in combination with anti-PD-(L)-1 antibodies in a range of solid tumor indications, including NSCLC, until approval, with the parties equally sharing development costs for such studies. All combinations outside of PD-1 inhibition, in particular all combinations with a compound in BioNTech's pipeline, will be solely developed by BioNTech. BioNTech will hold the exclusive worldwide commercialization rights for any of these products with participation of OncoC4 in certain markets to be negotiated in the future.

About ONC-392 and CTLA-4

ONC-392 is OncoC4's next-generation anti-CTLA-4 antibody candidate. The immune checkpoint receptor CTLA-4 inhibits T cell immune response and reduces the activity of T cells in recognizing and eliminating cancer cells. Blocking CTLA-4 preserves T cell activity and enhances anti-tumor activity. OncoC4's next-generation anti-CTLA-4 antibody candidate ONC-392 was designed to preserve CTLA-4 recycling and thus Treg function in the peripheral tissues. This aims to give rise to fewer immune-related adverse effects and a positive safety profile.

About OncoC4, Inc.

Based in Rockville, Maryland, OncoC4 is a privately held, late clinical-stage biopharmaceutical company that is actively engaged in the discovery and development of novel biologicals for cancer treatment. Its lead clinical candidate is ONC-392, a next generation anti-CTLA-4 antibody that allows CTLA-4 to recycle and maintain its protective function against autoimmune diseases while enhancing anti-tumor activity at the same time. In addition, OncoC4 has a pipeline of first-in-class preclinical product candidates focusing on the CD24-Siglecs cancer immune evasion pathway. More information: www.oncoc4.com.

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, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, 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. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's collaboration with OncoC4, Inc., including the timing of the closing of the proposed transaction; the ability of OncoC4's anti-CTLA-4 monoclonal antibody (ONC-392) to eliminate immunosuppressive regulatory T cells and enhance anti-tumor activity in various cancer indications; the development of ONC-392 as a monotherapy or combination therapy in various cancer indications; the timing and success of a Phase 3 study evaluating ONC-392 as a monotherapy against the current standard of care in PD-1-resistant NSCLC; the timing and success of a Phase 2 trial of ONC-392

as a combination therapy with pembrolizumab in platinum-resistant ovarian cancer; and OncoC4's ability to receive development, regulatory and commercial milestone payments and potential tiered royalties. 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. These risks and uncertainties include, but are not limited to: the possibility that the proposed transaction may not close; and the ability of BioNTech to develop and, if approved, commercialize these potential immunotherapies.

For a discussion of these and other risks and uncertainties, see BioNTech's Quarterly Report on Form 6-K for the quarter ended September 30, 2022, filed with the SEC on November 7, 2022, 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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