

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

May 4, 2023

Date of Report (Date of earliest event reported)

Bicycle Therapeutics plc

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction
of incorporation)

001-38916
(Commission
File Number)

Not applicable
(IRS Employer
Identification No.)

**Blocks A & B, Portway Building,
Granta Park Great Abington, Cambridge
United Kingdom**
(Address of principal executive offices)

CB21 6GS
(Zip Code)

Registrant's telephone number, including area code: **+44 1223 261503**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value £0.01 per share	n/a	The Nasdaq Stock Market LLC*
American Depositary Shares, each representing one ordinary share, nominal value £0.01 per share	BCYC	The Nasdaq Stock Market LLC

* Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Stock Market LLC.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

Collaboration and License Agreement

On May 4, 2023, BicycleTx Limited (the “Company”) and Bayer Consumer Care AG (“Bayer”) entered into a collaboration and license agreement (the “Collaboration Agreement”), pursuant to which the parties will perform research and discovery activities under a mutually agreed upon research plan during a research term of up to a specified number of years per target program to generate radiopharmaceutical compounds incorporating optimized *Bicycle* constructs directed to two specified targets, under the oversight of a joint steering committee. In addition, Bayer has a one-time right to expand the collaboration to include a third target program, and with respect to each of the up to three target programs, Bayer has an option, exercisable within a specified period of time following the effective date of the Collaboration Agreement, to generate, develop and commercialize non-radiopharmaceutical compounds directed to the applicable target, either itself or in collaboration with the Company.

For each collaboration program, Bayer may elect, at its sole discretion, to progress compounds arising from activities under the research programs into further preclinical development of potential products directed to the target of such collaboration program. On a target-by-target basis, if Bayer elects to progress development candidates directed to such target into further clinical development, Bayer will be required to use commercially reasonable efforts to develop and seek regulatory approval in certain major markets for products directed to the applicable target. During the term of the Collaboration Agreement, and until the expiration of all payment obligations with respect to a given target program, the Company will be exclusive to Bayer with respect to bicycles or macrocyclic peptides directed to targets included within the collaboration, and with respect to any compounds arising from the activities under the research program and directed to such selected targets.

Bayer will make an upfront payment to the Company of \$45 million. All other payments under the Collaboration Agreement will be made in British Pound Sterling and are described in this disclosure in such currency. If Bayer elects to expand the collaboration to include an additional target program, it will be required to make a one-time payment to the Company in connection with the selection of such target in the high single digit millions. In addition, on a target-by-target basis, if Bayer elects to exercise its option to expand its rights with respect to such target to develop and commercialize non-radiopharmaceutical compounds directed to such target, Bayer will be required to pay to the Company, for each such target program for which it exercises such option, either a one-time option fee payment, or quarterly payments of specified instalment amounts for a specified maximum time period during which the Company is performing research activities, with the aggregate amounts receivable by the Company ranging from the high single digit millions in the case of the option fee payment (where the Company is performing specified research activities following the exercise of the option), to the low single digit millions in the case of such instalment payments.

On a target-by-target basis for the up to three targets, if Bayer elects to progress one or more candidate compounds into further development, Bayer will be required to pay a candidate selection fee for the first such compound progressed by Bayer directed to such target that incorporates a radionuclide, and for the first such compound directed to such target that does not incorporate a radionuclide (and for which Bayer has not paid the option fee for non-radiopharmaceutical compounds), ranging from the high single-digit millions to the mid single-digit millions. On a target-by-target basis, if Bayer successfully conducts clinical development and achieves regulatory approval for compounds arising from the collaboration directed to such target in two indications, Bayer will be required to pay to the Company development and regulatory/first commercial sale milestones of up to £178 million for the first (whether radiopharmaceutical or non-radiopharmaceutical) product directed to the applicable target to achieve such milestones, or £534 million across all three potential target programs. In addition, if Bayer successfully commercializes products arising from the collaboration, Bayer will be required to pay to the Company, on a product-by-product basis, tiered royalties on net sales of products by Bayer, its affiliates or sublicensees at percentages ranging from the mid-single digits to the very low double digits, subject to standard reductions and offsets in certain circumstances, and a royalty floor. If Bayer commercializes diagnostic products directed to a target, royalties will be payable on such diagnostic products at a specified reduced percentage of the rates for therapeutic products. Royalties will be payable under the Collaboration Agreement on a product-by-product and country-by-country basis, commencing on the first commercial sale of each product, until the latest of (a) the expiration of the last valid claim of certain patents licensed by the Company to Bayer, (b) a specified number of years following first commercial sale of such product, and (c) expiration of all data and regulatory exclusivity for such product in the applicable country. On a target-by-target basis, Bayer will also owe the Company tiered sales milestones based on the achievement of specified levels of net sales of therapeutic products directed to such target totaling up to £194 million in the aggregate per target, or £582 million across all three potential target programs, and on diagnostic products directed to such target at a low double digit percentage of the therapeutic product milestones.

The aggregate value of the potential non-royalty payments from Bayer to the Company, if Bayer successfully develops and commercializes both radiopharmaceutical and non-radiopharmaceutical products in all three potential target programs, in addition to exploiting diagnostic products for each such target, is \$1.7 Billion, based on a pound sterling to US dollar conversion as of the execution date of the agreement.

The Collaboration Agreement will remain in force on a product-by-product and country-by-country basis, unless earlier terminated by either party, until the expiration of the obligation for Bayer to make royalty payments to the Company for such product in such country, and will terminate in its entirety on the expiration of all such royalty terms in all countries. Either party may terminate the agreement upon 90 days' written notice for the other party's uncured material breach (or 20 business days in the case of non-payment by Bayer), subject to extension of such cure period in certain circumstances, or upon the other party's insolvency. In addition, the Company has the right to terminate in the case of a patent challenge by or on behalf of Bayer (or any of its affiliates or sublicensees). In addition, Bayer may terminate the Collaboration Agreement (i) in its entirety or with respect to any product, collaboration program or target for any reason upon 60 or 90 days' written notice to the Company (depending on whether such termination is prior to or following first commercial sale of a licensed product). The closing of the transaction is subject to clearance of the transaction under the U.K. National Security and Investment Act 2021.

On May 10, 2023, the Company and Bayer issued a joint press release announcing the transactions described above. A copy of the press release is attached to this report as Exhibit 99.1.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "potential" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this Current Report. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this Current Report include statements regarding the Company's collaboration with Bayer, potential future regulatory filings and approvals of product candidates developed pursuant to the Collaboration Agreement, and potential future payments that may be become payable to the Company pursuant to the Collaboration Agreement. Many factors may cause differences between current expectations and actual results, including risks to the Company's and its collaboration partners' abilities to meet anticipated deadlines and milestones; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of product candidates by the Company's collaboration partners; the risk that the Company or its collaboration partners may not realize the intended benefits of its technology; risks related to the Company's ability to maintain existing collaborations and realize the benefits thereof; expectations for regulatory approvals to conduct trials or to market products and other important factors. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this Current Report are discussed in the Company's filings with the Securities and Exchange Commission, including the sections titled "Risk Factors" contained therein. Except as required by law, the Company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 10, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 10, 2023

BICYCLE THERAPEUTICS PLC

By: /s/ Lee Kalowski

Name: Lee Kalowski

Title: Chief Financial Officer

Bicycle®



Bayer AG
 Communications
 51368 Leverkusen
 Germany
 Phone +49 214 30-1
www.bayer.com/en/media

News Release

Bayer and Bicycle Therapeutics Enter Strategic Collaboration for Development of Novel Targeted Radionuclide Therapies in Oncology

- Collaboration will leverage Bicycle Therapeutic's synthetic peptides for the discovery and development of multiple targeted radioconjugates of the company in oncology
 - Advancing the use of bicycle peptides as a novel targeting approach in radiopharmaceuticals
 - Bicycle Therapeutics to receive upfront payment of USD 45 million, and potential future development and commercial-based milestones, up to a total of USD 1.7 billion, plus tiered commercial royalties
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Berlin, Germany; Cambridge, UK and Boston, US May 10, 2023 – Bayer and Bicycle Therapeutics plc (NASDAQ: BCYC), a biotechnology company pioneering a new and differentiated class of therapeutics by utilizing proprietary bicyclic peptides technology (Bicycle®), today announced that they have entered into a strategic collaboration agreement to discover, develop, manufacture, and commercialize Bicycle radioconjugates for multiple agreed upon oncology targets.

Bicyclic peptides are peptides consisting of 9-20 amino acids that can be synthetically manufactured and bind to targets with high affinity and selectivity, affording high tumor penetration and fast excretion from healthy organs. They are chemically synthesizable, featuring a low molecular weight and tunable pharmacokinetics, with a large surface-area for molecular interactions that allows protein-protein interactions to be targeted. The two companies will jointly use Bicycle's peptide technology to develop bicyclic peptides for several undisclosed oncology targets. Targeted radiotherapies are an innovative class of cancer therapies. Due to their unique mode of action, they have the potential to unlock a broad opportunity space and serve patients in high-unmet medical need indications.

“At Bayer, we enter strategic collaborations to expand our access to innovation,” said Christian Rommel, Ph.D., Global Head of Research and Development and Member of the Executive Committee, Pharmaceuticals Division, Bayer. “With Bicycle's proprietary peptide-based technology, we continue to strengthen our oncology development pipeline by adding next-generation targeted radiotherapeutics to address high unmet medical needs of cancer patients.”

“Bayer is a pioneer in the radiopharmaceuticals space and provides new and additional validation of our unique technology,” said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. “We believe our bicyclic peptide platform, coupled with Bayer’s scale and expertise in developing radiopharmaceuticals, has the potential to deliver improved clinical outcomes for patients with cancer. We look forward to collaborating with Bayer to bring forth new potential first-in-class radiopharmaceutical treatments based on Bicycles.”

Under the terms of the agreement, Bayer and Bicycle will collaborate on the development of bicyclic peptides for multiple oncology targets. Bicycle will utilize its proprietary phage platform to discover and develop bicyclic peptides and Bayer will be responsible for, and fully fund, all further preclinical and clinical development, manufacturing, and commercialization activities. Bicycle will receive a \$45 million upfront payment and with potential development and commercial-based milestone fees, payments to Bicycle could total up to \$1.7 billion. Bicycle will also be eligible to receive mid-single to double-digit tiered royalties on Bicycle-based medicines commercialized by Bayer. The closing of the transaction is subject to clearance of the transaction under the U.K. National Security and Investment Act 2021.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to www.bayer.com.

About Bicycle Therapeutics

Bicycle Therapeutics (NASDAQ: BCYC) is a clinical-stage biopharmaceutical company developing a novel class of medicines, referred to as Bicycles, for diseases that are underserved by existing therapeutics. Bicycles are fully synthetic short peptides constrained with small molecule scaffolds to form two loops that stabilize their structural geometry. This constraint facilitates target binding with high affinity and selectivity, making Bicycles attractive candidates for drug development. Bicycle is evaluating BT5528, a second-generation Bicycle Toxin Conjugate (BTC™) targeting EphA2; BT8009, a second-generation BTC targeting Nectin-4, a well-validated tumor antigen; and BT7480, a Bicycle TICA™ targeting Nectin-4 and agonizing CD137, in company-sponsored Phase I/II trials. In addition, BT1718, a BTC that targets MT1-MMP, is being investigated in an ongoing Phase I/IIa clinical trial sponsored by the Cancer Research UK Centre for Drug Development. Bicycle is headquartered in Cambridge, UK, with many key functions and members of its leadership team located in Cambridge, MA. For more information, visit bicycletherapeutics.com.

Contact for media inquiries Bayer:

Lisa Hennig, +49 172 8693420

E-Mail: lisa.hennig@bayer.com

Find more information at www.bayer.com.

Follow us on twitter.com/bayer

Contact for media inquiries Bicycle:

Argot Partners

Sarah Sutton, +1 212-600-1902

Email: bicycle@argotpartners.com

Contact for investor inquiries Bicycle:

SVP, Capital Markets & Corporate Communications

David Borah, CFA, phone +1 617-203-8300

Email: david.borah@bicycletx.com

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Forward Looking Statements

This press release may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will” and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding Bicycle’s collaboration with Bayer; the discovery, development, manufacture and potential commercialization of potential product candidates using Bicycle’s technology and under the strategic collaboration agreement; the therapeutic potential for Bicycles in oncology and other applications; and the potential to receive milestone payments and royalties under the strategic collaboration agreement. Bicycle may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: the risk that Bicycle may not realize the intended benefits of its technology or of the collaboration agreement with Bayer, including that Bicycle and Bayer may not successfully identify, develop, manufacture and commercialize any product candidates; and other important factors, any of which could cause Bicycle’s actual results to differ from those contained in the forward-looking statements and which are described in greater detail in the section entitled “Risk Factors” in Bicycle’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 28, 2023, as well as in other filings Bicycle may make with the SEC in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and Bicycle expressly disclaims any obligation to update any forward-looking statements contained herein, whether because of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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