

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

February 21, 2020

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.)

**B900, Babraham Research Campus**  
**Cambridge CB22 3AT**  
**United Kingdom**  
(Address of principal executive offices)

**Not Applicable**  
(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

On February 21, 2020, Bicycle Therapeutics plc (the “Company” or “Bicycle”) entered into a Discovery Collaboration and License Agreement (the “Genentech Collaboration Agreement”) with Genentech, a member of the Roche Group. The collaboration is focused on the discovery and development of *Bicycle* peptides directed to biological targets selected by Genentech and aimed at developing up to four potential development candidates against multiple immuno-oncology targets suitable for Genentech to advance into further development and commercialization. Bicycle will be responsible for discovery and lead optimization of such *Bicycle* peptides through specified phases of the collaboration, and following drug candidate selection Genentech will be responsible for all future research and development. The initial discovery and optimization activities will focus on two immuno-oncology targets, potentially with additional targeting elements, and Genentech has the option to nominate up to two additional immuno-oncology targets, potentially with additional targeting elements, to be the subject of additional collaboration programs during a specified period following completion of certain activities under an agreed research plan, in which case Genentech will pay to the Company an expansion fee of \$10.0 million per additional collaboration program. Genentech has the right, under certain limited circumstances, to select an alternative target to be the subject of a collaboration program, in some cases subject to payment of an additional target selection fee.

Under the Genentech Collaboration Agreement, Genentech will make an upfront payment to the Company of \$30.0 million. The Company will perform research activities for each target under the collaboration, under a mutually agreed upon research plan through specified collaboration phases, under the oversight of a joint research committee. For each collaboration program, Genentech may elect, at its sole discretion, to progress development candidates into further preclinical development and obtain exclusive worldwide development and commercialization rights for compounds directed to the target of such collaboration program in exchange for success-based milestone payments totaling \$10-12 million per collaboration program.

On a collaboration program-by-collaboration program basis, if Genentech elects to obtain exclusive development and commercialization rights and pays the applicable success-based milestone payments, Genentech will be required to make milestone payments to the Company upon the achievement of specified development, regulatory, and initial commercialization milestones for products arising from each collaboration program, totaling up to \$200.0 million. In addition, the Company is also eligible to receive up to \$200.0 million in sales milestone payments on a product-by-product basis. In addition, to the extent any of the product candidates covered by the licenses conveyed to Genentech are commercialized, the Company would be entitled to receive tiered royalty payments on net sales at percentages ranging from the mid-single to low double-digits, subject to certain standard reductions and offsets. Royalties will be payable, on a product-by-product and country-by-country basis, until the later of the expiration of specified licensed patents covering such product in such country, or ten years from first commercial sale of such product in such country.

Either party may terminate the Genentech Collaboration Agreement for the uncured material breach of the other party or in the case of insolvency. Genentech may terminate the Genentech Collaboration Agreement for convenience on specified notice periods depending on the development stage of the applicable program, either in its entirety or on a program-by-program basis or major market-by-major market basis.

The above description of the Genentech Collaboration Agreement does not purport to be complete and is qualified in its entirety by reference to the Genentech Collaboration Agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the period ending December 31, 2019.

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**Item 8.01 Other Events.**

On February 25, 2020, the Company issued a press release announcing the Company's entry into the Genentech Collaboration Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press release dated February 25, 2020</u>

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**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: February 25, 2020

**BICYCLE THERAPEUTICS PLC**

By: /s/ Lee Kalowski  
Name: Lee Kalowski  
Title: Chief Financial Officer

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**Bicycle Therapeutics Announces Exclusive Strategic Collaboration with Genentech to Develop and Commercialize *Bicycle*®-based Immuno-oncology Therapies**

*Bicycle will receive a \$30 million upfront payment; upfront payment and potential discovery, development, regulatory and commercial milestones could total up to \$1.7 billion*

**CAMBRIDGE, England & BOSTON, February 25, 2020** –[Bicycle Therapeutics plc](#) (NASDAQ: BCYC), a biotechnology company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (*Bicycle*®) technology, today announced that it has entered into a strategic collaboration agreement with Genentech, a member of the Roche Group, to discover, develop and commercialize novel *Bicycle*®-based immuno-oncology therapies.

By entering into this early discovery collaboration with Genentech, Bicycle will be exploring its technology on a wider range of immuno-oncology targets, combining the expertise of both companies. Bicycle brings its proprietary discovery platform, which allows rapid screening of novel targets to identify *Bicycles* and the ability to readily conjugate these together to create novel molecules that may overcome the potential limitations of other modalities. Genentech brings to the collaboration its knowledge of immuno-oncology drug discovery and emerging target biology, as well as its development and commercialization expertise.

“Our collaboration with Genentech recognizes the potential of Bicycle’s differentiated technology, which allows us to specifically direct immune cell stimulators and other payloads to tumors in a highly targeted manner,” said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. “In addition, the flexibility of the Bicycle platform enables rapid exploration of structure-activity relationships to fully optimize candidate molecules. We look forward to working closely with Genentech to pioneer the discovery and development of potential new cutting-edge cancer treatments based on *Bicycles*.”

“*Bicycles* represent a novel therapeutic modality and have shown promise as modulators of several types of tumor-killing immune cells,” said James Sabry, M.D., Ph.D., global head of Pharma Partnering, Roche. “By leveraging Genentech’s deep understanding of cancer immunology and Bicycle’s technological expertise, we hope to create a new wave of immunotherapy options to expand the population of patients who could potentially benefit from this powerful treatment paradigm.”

Under the terms of the agreement, Genentech and Bicycle will collaborate on the discovery and pre-clinical development of novel *Bicycle*-based immunotherapies against multiple targets. Bicycle will be responsible for discovery research and early pre-clinical development up to candidate selection, and Genentech will be responsible for further development and commercialization upon the selection of candidates. None of Bicycle’s wholly owned oncology pipeline, including its immuno-oncology candidates, are included in the collaboration.

Bicycle will receive a \$30 million upfront payment. The upfront payment and potential discovery, development, regulatory and commercial-based milestone payments could total up to \$1.7 billion.

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Bicycle will also be eligible to receive tiered royalties on *Bicycle*®-based medicines commercialized by Genentech.

### **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's lead product candidate, BT1718, a *Bicycle* Toxin Conjugate (BTC) that targets MT1-MMP, is being investigated in an ongoing Phase I/IIa clinical trial in collaboration with the Centre for Drug Development of Cancer Research UK. Bicycle is also evaluating BT5528, a second-generation BTC targeting EphA2, in a Company-sponsored Phase I/II study. Bicycle is headquartered in Cambridge, UK with many key functions and members of its leadership team located in Lexington, MA. For more information, visit [bicycletherapeutics.com](http://bicycletherapeutics.com).

### **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 Genentech; the discovery, development and potential commercialization of potential product candidates using Bicycle's technology and under the strategic collaboration agreement; the therapeutic potential for *Bicycles* in immuno-oncology 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 we may not realize the intended benefits of our technology or of the strategic collaboration agreement, including that we and Genentech may not identify, develop and commercialize additional product candidates; the risk that we may not be able to maintain our collaboration with Genentech and realize the benefits thereof; and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, are described in greater detail in the section entitled “Risk Factors” in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 7, 2019, 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 as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

### **Investor and Media Contact:**

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