

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

November 20, 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 November 20, 2020, Bicycle Therapeutics plc (the “Company”) and its three wholly-owned subsidiaries (collectively, “Bicycle”) entered into a Licence and Settlement Agreement (the “License Agreement”) and a Settlement Agreement (the “Settlement Agreement” and, together with the License Agreement, the “Pepscan Agreements”) with Pepscan Systems BV and certain affiliated companies (collectively, “Pepscan”), pursuant to which Bicycle and Pepscan settled all intellectual property disputes worldwide between Bicycle and Pepscan related to Pepscan’s CLIPS (Chemical Linkage of Peptides onto Scaffolds) peptide technology and certain Bicycle patents.

Under the terms of the License Agreement, Pepscan has granted to Bicycle an irrevocable, perpetual, sub-licensable, non-exclusive worldwide license under certain Pepscan patents and know-how relating to Pepscan’s CLIPS peptide technology to make, develop, use, manufacture, import, sell, dispose of, offer to sell, stock or otherwise supply Bicycle’s product candidates BT1718 and THR149. In consideration for this license, Bicycle will make an upfront payment of €2.0 million to Pepscan, will pay €1.0 million to Pepscan on November 20, 2021, and will make potential additional payments to Pepscan based on achievement of specified clinical, regulatory and commercial milestones. These potential additional payments are in the low single digit millions of euros, in the aggregate, for achievement of clinical and regulatory milestones. The potential commercial milestone payments are tiered based on sales for each of BT1718 and THR149 and will not exceed an aggregate amount in the mid double digit millions of euros. The License Agreement comprises full and final settlement both of the parties’ claims against each other relating to Pepscan’s applicable patents and know-how and of all other applicable contractual claims between Bicycle and Pepscan and includes a covenant not to sue in the future with respect to any such claims. Bicycle and Pepscan have also agreed to withdraw from any active proceedings relating to these claims.

Under the Settlement Agreement, Pepscan (i) will withdraw from any ongoing opposition proceedings relating to certain Bicycle patents, (ii) releases and forever discharges any and all of its claims relating to these Bicycle patents, and (iii) covenants not to commence or re-institute any proceedings or oppositions related to these patents. Bicycle also releases and forever discharges any and all of its claims relating to certain elements of these patents and covenants not to commence or re-institute any proceedings or oppositions against Pepscan, unless Pepscan is in breach of its obligations under the Settlement Agreement. In consideration for Pepscan’s withdrawal and release of claims, Bicycle will make an additional €1.0 million upfront payment to Pepscan.

The above description of the Pepscan Agreements does not purport to be complete and is qualified in its entirety by reference to the License Agreement and the Settlement Agreement, each of which will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the year ending December 31, 2020.

Item 8.01 Other Events.

On November 20, 2020, the Company issued a press release regarding the Pepscan Agreements. 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 November 20, 2020</u>

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: November 20, 2020

BICYCLE THERAPEUTICS PLC

By: /s/ Lee Kalowski

Name: Lee Kalowski

Title: Chief Financial Officer



Bicycle Therapeutics Announces Settlement of Patent Dispute with Pepsan Systems B.V.

CAMBRIDGE, England, & BOSTON – November 20, 2020 – [Bicycle Therapeutics plc](#) (NASDAQ:BCYC), a clinical-stage 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 settlement and license agreement with Pepsan Systems B.V. regarding Bicycle's use of Pepsan's CLIPS peptide technology.

The companies have agreed to settle all intellectual property disputes worldwide. Under the terms of the settlement, Bicycle has been granted a license to use CLIPS peptide technology in the development of its product candidates BT1718 and THR-149. Bicycle will pay €3 million upfront, will pay €1 million on the first anniversary of the date of settlement, and will make potential additional payments to Pepsan based on achievement of specified clinical, regulatory and commercial milestones.

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. BT8009 is a BTC targeting Nectin-4, a well-validated tumor antigen, and is also currently being evaluated a Company-sponsored Phase I/II trial. 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.

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 use of CLIPS peptide technology in the development of its product candidates BT1718 and THR-149, Bicycle's future payment obligations to Pepsan, and Bicycle's contemplated achievement of specified clinical, regulatory and commercial milestones. 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: risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as to Bicycle's abilities to meet other anticipated deadlines and milestones, presented by the ongoing COVID-19 pandemic; uncertainties inherent in the initiation and completion of clinical trials by Bicycle or its collaboration partners and in the clinical development of Bicycle's product candidates; availability and timing of results from clinical trials; expectations for regulatory approvals to conduct trials or to market product; 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 Bicycle's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 5, 2020, 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.

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