

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 5, 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 2.02. Results of Operations and Financial Condition

On November 5, 2020, Bicycle Therapeutics plc (the “Company”) issued a press release announcing financial results for the fiscal quarter ended September 30, 2020 and other business highlights. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release issued November 5, 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 5, 2020

BICYCLE THERAPEUTICS PLC

By: /s/ Lee Kalowski

Name: Lee Kalowski

Title: Chief Financial Officer



Bicycle Therapeutics Reports Third Quarter 2020 Financial Results and Provides Corporate Update

- Three clinical trials of novel Bicycles[®] initiated this quarter, including a Phase IIa for BT1718, a Phase I for BT8009, and a Phase II for THR-149
- Cash was \$149.8 million at September 30, 2020, which includes net proceeds received during Q3 from completion of \$50.0 million at-the-market (ATM) offering program and initial \$15.0 million drawn from debt financing
- Corporate leadership strengthened with key appointments to Scientific Advisory Board and senior management team

CAMBRIDGE, England, & BOSTON, November 5, 2020 – Bicycle Therapeutics plc (NASDAQ:BCYC), a biotechnology company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (*Bicycles*[®]) technology, today reported financial results for the third quarter ended September 30, 2020 and discussed recent corporate updates.

“Amidst the uncertainty brought on by the COVID-19 pandemic, Bicycle has made significant advances during the third quarter, including the initiation of dosing in a Phase IIa trial of BT1718, in a Phase I/II trial of BT8009, and in Oxurion’s Phase II study of THR-149,” said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. “As we advance and expand our clinical portfolio, with multiple potential inflection points in the coming year, we have thoughtfully bolstered our balance sheet through our ATM program and the closing of a non-dilutive debt financing. We have also enhanced Bicycle’s clinical leadership with the appointment of Dominic Smethurst as Chief Medical Officer and the addition of prominent scientists and clinicians to our Scientific Advisory Board, now chaired by renowned immunologist Sir Keith Peters. We believe we are well-positioned as we pursue our goal of realizing the full potential of our disruptive *Bicycle* technology.”

Third Quarter 2020 and Recent Highlights

- **Announced Expansion of the Scientific Advisory Board (SAB).** In October 2020, Bicycle announced that Drs. Garret FitzGerald, Jane Grogan, Caetano Reis e Sousa, and Charles Swanton have joined the Company’s SAB. The SAB works closely with Bicycle’s senior management team to advance the Company’s growing pipeline of potential *Bicycle*-based treatments for cancer and other difficult-to-treat diseases.
 - **Raised \$50 Million Through At-the-Market (ATM) Offering Program and Entered into Debt Financing from Hercules Capital.** Also in October, Bicycle announced that it had utilized its ATM offering program, initiated during the third quarter, generating gross proceeds of \$50.0 million. In addition, it closed a debt financing with Hercules Capital, Inc. for a term loan of up to \$40.0 million, \$15.0 million of which was drawn at closing.
 - **Presented Trials in Progress Poster for BT8009 at the European Society for Medical Oncology (ESMO) Virtual Congress 2020.** The poster describes the design of the ongoing Phase I/II trial of BT8009 in advanced solid tumors associated with Nectin-4 expression. BT8009 is a second-generation Nectin-4 targeting *Bicycle* Toxin Conjugate (BTC).
 - **Dosed First Patient in Phase I Dose Escalation Portion of Phase I/II Trial of BT8009 in Patients with Advanced Solid Tumor Malignancies.** In September 2020, Bicycle announced that the first patient had been dosed in the Phase I dose escalation portion of its Phase I/II trial of BT8009 in patients with advanced solid tumors associated with Nectin-4 expression.
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- **Dosed First Patient in Phase IIa Expansion Portion of Phase I/IIa Trial, Sponsored by Cancer Research UK, Evaluating BT1718 in Patients with MT1-MMP-Positive Tumors.** Also in September, Bicycle announced that the first patient had been dosed in the Phase IIa expansion portion of a Phase I/IIa trial of BT1718 in a cohort of patients with MT1-MMP-positive squamous non-small cell lung cancer (NSCLC) and in a basket cohort of patients with other MT1-MMP-positive solid tumors. BT1718 is a BTC targeting the tumor antigen MT1-MMP.
- **Announced First Patient Dosed in Oxurion’s Phase II Study of THR-149 in Patients with Diabetic Macular Edema (DME).** In September, Bicycle announced that the first patient had been dosed in Oxurion’s Phase II study of THR-149, a novel *Bicycle*-based plasma kallikrein (PKal) inhibitor, in patients with DME. The Phase II trial, named KALAHARI, is expected to include approximately 122 patients with central involved DME who do not respond adequately to anti-VEGF therapy.
- **Awarded Innovate UK Grant to Pursue Exploratory Research into Novel *Bicycle*-based Interventions for SARS-CoV-2.** In response to an invitation from the UK government, Bicycle applied for, and was awarded, \$2.8 million to explore the utility of *Bicycle* technology to generate binders to a range of SARS-CoV-2 targets. The application of the Bicycle platform to address the ongoing COVID-19 pandemic could enable the development of next-generation antivirals and diagnostics. Furthermore, this application of *Bicycles* offers a rapid and differentiated approach that can be swiftly deployed in response to current and future viral threats.
- **Appointed Dominic Smethurst as Chief Medical Officer.** The Company appointed Dominic Smethurst, MBChB, MRCP, MFPM as Chief Medical Officer in August 2020. Dr. Smethurst brings to Bicycle extensive expertise in developing bispecific immuno-oncology agents, as well as toxin conjugate therapeutics for cancer and other diseases where patients experience high unmet medical need.

Upcoming Investor Presentations

Bicycle will present at the following investor conferences in the fourth quarter of 2020. The conferences will be held in a virtual meeting format:

- Jefferies Global Healthcare Conference on Thursday, November 19, 2020 at 1:10 p.m. ET
- Piper Sandler 32nd Annual Healthcare Conference, December 1-3, 2020

A live webcast of each presentation will be accessible in the Investors & Media section of Bicycle’s website at bicycletherapeutics.com. Archived replays of the webcasts will be available for 90 days following the presentation dates.

Financial Results

- Cash and cash equivalents were \$149.8 million as of September 30, 2020, compared to \$92.1 million as of December 31, 2019. The increase in cash is primarily due to net proceeds of \$46.4 million from the ATM offering and net proceeds of \$14.6 million from a Loan Agreement with Hercules, offset by cash used in operating activities. Cash at September 30, 2020 does not include net proceeds of \$1.8 million from the ATM offering received in October 2020.
 - Research and development expenses totaled \$7.4 million for the three months ended September 30, 2020, compared to \$6.1 million for the three months ended September 30, 2019. The increase of \$1.3 million was primarily due to increased clinical program expenses for BT5528 and BT8009, partially offset by lower development expenses of other programs due to timing, and an increase in personnel related costs, including \$0.3 million of incremental non-cash share-based compensation expense.
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- General and administrative expenses were \$7.2 million for the three months ended September 30, 2020, compared to \$4.8 million for the three months ended September 30, 2019. The increase of \$2.4 million was primarily due to an increase in professional fees and costs related to operations as a public company, offset by favorable effect of foreign exchange rates, and an increase in personnel related costs, including \$0.4 million of incremental non-cash share-based compensation expense.
- Net loss was \$10.1 million, or \$(0.52) basic and diluted net loss per share, for the three months ended September 30, 2020, compared to net loss of \$9.5 million, or \$(0.53) basic and diluted net loss per share, for the three months ended September 30, 2019.

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 in 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 anticipated advancement and expansion of its clinical pipeline, the application of the Bicycle platform to address the ongoing COVID-19 pandemic or other viral threats, anticipated enrollment in and progression of Bicycle's and its collaborator's clinical trials, the therapeutic potential of Bicycle's product candidates; the availability of future funding under Bicycle's debt facility with Hercules Capital, Inc., and Bicycle's ability to achieve planned 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 and its collaboration partners' abilities to meet other anticipated deadlines and milestones, presented by the ongoing COVID-19 pandemic; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of Bicycle's product candidates by Bicycle or its collaboration partners; the risk that Bicycle may not realize the intended benefits of its technology; availability and timing of results from preclinical studies and clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial results; the risk that trials and studies may be delayed and may not have satisfactory outcomes; expectations for regulatory approvals to conduct trials or to market product; the risk that Bicycle may not satisfy certain conditions precedent to the availability of additional borrowings under its debt facility with Hercules Capital; and other important factors, any of which could cause Bicycle's 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 August 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.

Bicycle Therapeutics plc

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenues	\$ 3,842	\$ 614	\$ 6,542	\$ 8,520
Operating expenses:				
Research and development	7,363	6,078	23,091	18,891
General and administrative	7,154	4,789	18,351	11,164
Total operating expenses	14,517	10,867	41,442	30,055
Loss from operations	(10,675)	(10,253)	(34,900)	(21,535)
Other income (expense):				
Interest and other income, net	72	440	655	594
Other expense, net	—	—	—	(5,377)
Total other expense, net	72	440	655	(4,783)
Net loss before income tax provision	(10,603)	(9,813)	(34,245)	(26,318)
Benefit from income taxes	(465)	(331)	(668)	(116)
Net loss	\$ (10,138)	\$ (9,482)	\$ (33,577)	\$ (26,202)
Net loss attributable to ordinary shareholders	\$ (10,138)	\$ (9,482)	\$ (33,577)	\$ (26,202)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (0.52)	\$ (0.53)	\$ (1.81)	\$ (3.00)
Weighted average ordinary shares outstanding, basic and diluted	19,426,833	17,900,978	18,504,013	8,734,943

Balance Sheets Data
(In thousands)
(Unaudited)

	September 30, 2020	December 31, 2019
Cash	\$ 149,842	\$ 92,117
Working capital	147,111	95,325
Total assets	170,059	110,194
Shareholders equity	109,551	93,198

Investor and Media Contact:

Bicycle Therapeutics
Maren Killackey
maren.killackey@bicycletx.com
+1-617-203-8300