

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

August 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 August 5, 2020, Bicycle Therapeutics plc (the “Company”) issued a press release announcing financial results for the fiscal quarter ended June 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 August 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: August 5, 2020

BICYCLE THERAPEUTICS PLC

By: /s/ Lee Kalowski

Name: Lee Kalowski

Title: Chief Financial Officer



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

- Progress across pipeline continues with BT1718 Phase IIa and BT8009 Phase I/II trial initiations on-track for this year
- Cash was \$96.9 million at June 30, 2020, which excludes \$17.6 million net proceeds from ATM offering program and a \$6.7 million UK R&D tax credit, both received in July 2020

CAMBRIDGE, England, & BOSTON, August 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 second quarter ended June 30, 2020 and discussed recent corporate updates.

“Despite the challenges presented by the ongoing COVID-19 pandemic, we have made significant progress towards achieving our 2020 objectives,” said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. “In the coming months, we look forward to initiating the Phase IIa trial of BT1718 and the Phase I/II trial of BT8009. We are also continuing to advance BT5528 in the dose escalation portion of a Phase I/II trial, and we will be deploying our proprietary EphA2 immunohistochemistry, or IHC, assay to select and enroll EphA2-positive patients in the Phase I trial. We remain confident in our ability to achieve our near-term milestones, which should help enable our vision of pioneering the development of novel therapies for patients suffering from cancer and other serious diseases.”

Second Quarter 2020 and Recent Highlights

- **Appointed Sir Keith Peters FRS as Chairman of the Company’s Scientific Advisory Board (SAB).** Sir Keith Peters is a renowned expert in the field of clinical immunology and was appointed Chairman of Bicycle’s SAB in June 2020. He has worked closely with the Company’s leadership team as a member of the SAB since its inception in 2018.
- **Presented New Translational Data for BT5528 and Preclinical Data for Tumor-Targeted Immune Cell Agonists (TICAs™) at the American Association for Cancer Research (AACR) Virtual Annual Meeting II.** Translational data presented at AACR describe the development of Bicycle’s proprietary IHC assay for use in the Phase I/II trial of BT5528, a second-generation BTC that targets EphA2. This assay will be used to support patient selection and assess EphA2 expression levels in tumor samples collected in the ongoing Phase I/II trial. New

preclinical data presented for BT7480, a TICA targeting Nectin-4 and agonizing CD137, demonstrate that anti-tumor responses in a syngeneic mouse model can be achieved with an intermittent dosing regimen, indicating that continuous target coverage may be unnecessary for efficacy.

- **Presented Trials in Progress Poster for BT5528 at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program.** The poster describes the design of the ongoing Phase I/II trial of BT5528 in advanced solid tumors associated with EphA2 expression.
 - **Announced Publication of BT5528 Mechanism of Action in AACR Journal Molecular Cancer Therapeutics.** The manuscript, titled “MMAE delivery using the Bicycle toxin conjugate BT5528,” describes the physiochemical properties and preclinical profile of BT5528 that have enabled BT5528 to demonstrate a more favorable safety and efficacy profile than that of antibody drug conjugates (ADCs) with the same tumor antigen target and similar cytotoxic payload.
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Upcoming Investor Conferences

Bicycle will be participating in the following virtual investor conferences in the third quarter of 2020:

- Canaccord Genuity 40th Annual Growth Conference, August 11-13, 2020
- Citi 15th Annual BioPharma Conference, September 9-10, 2020
- Goldman Sachs 10th Annual Biotech Symposium, September 11, 2020
- H.C. Wainwright 22nd Annual Global Investment Conference, September 13-15, 2020
- Cantor Global Healthcare Conference, September 15-17, 2020
- Oppenheimer Fall Healthcare Life Sciences & MedTech Summit, September 21-23, 2020

Financial Results

- Cash and cash equivalents were \$96.9 million as of June 30, 2020, compared to \$92.1 million as of December 31, 2019. Cash at June 30, 2020 does not include \$17.6 million in net proceeds from the Company's "at the market" (ATM) offering program or \$6.7 million UK research and development tax credit reimbursement, both of which were received in July 2020.
- Research and development expenses totaled \$8.0 million for the three months ended June 30, 2020, compared to \$6.5 million for the three months ended June 30, 2019. The increase of \$1.4 million is primarily due to increased clinical and TICA program development expenses, partially offset by lower development expenses of other programs due to timing, and an increase in personnel related costs, including \$0.2 million of incremental non-cash share-based compensation expense.
- General and administrative expenses were \$6.2 million for the three months ended June 30, 2020, compared to \$3.0 million for the three months ended June 30, 2019. The increase of \$3.2 million is primarily due to an increase in professional fees and costs related to operations as a public company, an unfavorable effect of foreign exchange rates, and an increase in personnel related costs, including \$0.2 million of incremental non-cash share-based compensation expense.
- Net loss was \$12.1 million, or \$(0.67) basic and diluted net loss per share, for the three months ended June 30, 2020, compared to net loss of \$10.2 million, or \$(1.40) basic and diluted net loss per share, for the three months ended June 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. 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 the design and anticipated initiation or progression of Bicycle’s clinical trials; the therapeutic potential of Bicycle’s product candidates; 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; 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; 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 May 7, 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenues	\$ 1,571	\$ 1,522	\$ 2,700	\$ 7,906
Operating expenses:				
Research and development	7,958	6,537	15,728	12,813
General and administrative	6,196	2,973	11,197	6,375
Total operating expenses	14,154	9,510	26,925	19,188
Loss from operations	(12,583)	(7,988)	(24,225)	(11,282)
Other income (expense):				
Interest and other income, net	371	90	583	154
Other expense, net	—	(2,184)	—	(5,377)
Total other income (expense), net	371	(2,094)	583	(5,223)
Net loss before income tax provision	(12,212)	(10,082)	(23,642)	(16,505)
(Benefit from) provision for income taxes	(97)	135	(204)	215
Net loss	\$ (12,115)	\$ (10,217)	\$ (23,438)	\$ (16,720)
Net loss attributable to ordinary shareholders	\$ (12,115)	\$ (10,217)	\$ (23,438)	\$ (16,720)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (0.67)	\$ (1.40)	\$ (1.30)	\$ (4.08)
Weighted average ordinary shares outstanding, basic and diluted	18,077,770	7,298,139	18,024,314	4,101,564

Balance Sheets Data
(In thousands)
(Unaudited)

	June 30, 2020	December 31, 2019
Cash	\$ 96,910	\$ 92,117
Working capital	95,553	95,325
Total assets	118,602	110,194
Shareholders equity	71,026	93,198

Investor and Media Contact:

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