

**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 7, 2019

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 7, 2019, Bicycle Therapeutics plc (the “Company”) issued a press release announcing financial results for the fiscal quarter ended September 30, 2019 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>
99.1	Press Release issued November 7, 2019

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 7, 2019

BICYCLE THERAPEUTICS PLC

By: /s/ Lee Kalowski

Name: Lee Kalowski

Title: Chief Financial Officer



Bicycle Therapeutics Reports Third Quarter 2019 Financial Results and Corporate Update

- *BT7480 selected as lead immuno-oncology candidate to advance into IND-enabling studies*
- *Preclinical data on Bicycle® tumor-targeted immune cell agonists to be presented at SITC Annual Meeting on November 9, 2019*
- *Cash was \$96.0 million at September 30, 2019, which excludes \$6.0 million UK R&D incentive received in Q4 2019*
- *Continued to enhance corporate leadership through key appointments to management team and Board of Directors*

CAMBRIDGE, England & BOSTON, November 7, 2019 — Bicycle Therapeutics plc (NASDAQ:BCYC), a clinical-stage 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, 2019 and discussed recent corporate updates.

“The significant progress we have made in the past few months is instrumental to our goal of advancing our novel pipeline of *Bicycle* drug candidates through the clinic,” said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. “We’ve bolstered all three areas of the pipeline, namely, our wholly-owned *Bicycle* Toxin Conjugate and immuno-oncology programs, as well as our collaborations to develop new *Bicycle*-based therapies for indications beyond oncology. We have also continued to strengthen our leadership team both at the corporate and Board levels. These efforts further position the Company to evaluate the potential of *Bicycles* to enable possible first-in-class medicines that transform the treatment paradigm for people living with a broad range of serious diseases, in ways that existing modalities cannot.”

Third Quarter 2019 and Recent Highlights

- **Presenting New Preclinical Data for Novel, Fully Synthetic *Bicycle* Tumor-targeted Immune Cell Agonists (TICAs) at the Society for Immunotherapy of Cancer’s (SITC) 2019 Annual Meeting.** This week, Bicycle is presenting new data showing that its lead immuno-oncology candidate, BT7480, a TICA targeting Nectin-4 and agonizing CD137, rapidly penetrates tumors and effects powerful anti-tumor activity in preclinical models. In addition to data on BT7480, the Company will present preclinical research at SITC on other emergent *Bicycle* TICA strategies. Details of the Company’s poster presentations on Saturday, November 9, 2019 can be found in the News section of bicycletherapeutics.com.

- **Enhanced Executive Team and Board of Directors.** In October 2019, Bicycle announced the appointment of Nigel Crockett, Ph.D., as Chief Business Officer and of Veronica Jordan, Ph.D., to the Company's Board of Directors.
- **Expanded Neuroscience Collaborations to Include Oxford University's Oxford Drug Discovery Institute (ODDI).** Bicycle announced that it will collaborate with ODDI to use *Bicycle* technology for the development of novel therapeutics for dementia. This expands upon the collaboration announced in May 2019 between Bicycle and the Dementia Discovery Fund (DDF), a specialized venture capital fund focused on discovering and developing novel therapies for dementia. If promising lead compounds are identified, Bicycle will have rights to the development of the resulting intellectual property and, with DDF, will have the option to jointly establish a new company to develop those compounds.
- **Presented New Translational Data for Lead Asset BT1718 and Preclinical Data for Other *Bicycle* Toxin Conjugates at AACR-NCI-EORTC 2019.** Bicycle presented new translational data for BT1718 and preclinical data for BT5528 and BT8009 during poster sessions at the 2019 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. The translational data for BT1718 characterize enrollment criteria for identifying expansion cohorts in the Phase IIa part of the ongoing Phase I/IIa trial.
- **Presented Updated Data from Phase I/IIa Trial Evaluating BT1718 in Patients with Advanced Solid Tumors at ESMO 2019 Annual Congress.** Bicycle and Cancer Research UK presented updated data from the ongoing Phase I portion of the Phase I/IIa trial evaluating BT1718 in patients with advanced solid tumors. As of August 7, 2019, 54% of evaluable patients dosed had stable disease at the eight-week timepoint, including a patient who experienced a 45% reduction in a target lesion, and BT1718 appeared tolerable with once-weekly dosing.

Upcoming Investor Presentations

Bicycle will present at the following investor conferences in the fourth quarter of 2019:

- Jefferies London Healthcare Conference on Wednesday, November 20, 2019 at 2:40 p.m. GMT (9:40 a.m. ET) in London, England
- Piper Jaffray 31st Annual Healthcare Conference on Tuesday, December 3, 2019 at 3:30 p.m. ET in New York, NY

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 was \$96.0 million as of September 30, 2019, compared with \$63.4 million as of December 31, 2018. The September 30, 2019 cash balance excludes a UK research and development incentive payment of approximately \$6.0 million received in October 2019.
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- Research and development expenses were \$6.1 million for the three months ended September 30, 2019, compared to \$5.6 million for the three months ended September 30, 2018. The increase of \$0.4 million is primarily due to \$0.3 million of incremental non-cash share-based compensation expense, as well as other personnel related costs.
- General and administrative expenses were \$4.8 million for the three months ended September 30, 2019, compared to \$2.3 million for the three months ended September 30, 2018. The increase of \$2.5 million is primarily due to a \$0.9 million unfavorable effect of foreign exchange rates, \$0.7 million in personnel related costs, including \$0.3 million of incremental non-cash share-based compensation expense, as well as increased professional fees related to operations as a public company.
- Net loss was \$9.5 million, or \$(0.53) basic and diluted net loss per share, for the three months ended September 30, 2019, compared to net loss of \$7.7 million, or \$(17.73) basic and diluted net loss per share, for the quarter ended September 30, 2018.

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, is a *Bicycle*[®] Toxin Conjugate being investigated in an ongoing Phase I/IIa clinical trial in collaboration with the Centre for Drug Development of Cancer Research UK. 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 the clinical development of BT1718, BT7480 or any of Bicycle's other product candidates or programs; statements regarding the potential results of Bicycle's collaboration with Oxford University's Oxford Drug Discovery Institute and the Dementia Discovery Fund; and statements regarding the potential impact of new directors and employees on Bicycle's development. 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: uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of Bicycle's product candidates; availability and timing of results from preclinical studies and clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; our ability to maintain existing collaborations and realize the benefits thereof and develop new

relationships; 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 the final prospectus for our initial public offering, filed with the Securities and Exchange Commission (SEC) on May 23, 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.

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,	
	2019	2018	2019	2018
Collaboration revenues	\$ 614	\$ 1,610	\$ 8,520	\$ 6,079
Operating expenses:				
Research and development	6,078	5,642	18,891	14,268
General and administrative	4,789	2,325	11,164	6,015
Total operating expenses	10,867	7,967	30,555	20,283
Loss from operations	(10,253)	(6,357)	(21,535)	(14,204)
Other income (expense):				
Interest and other income	440	26	594	75
Other expense, net	—	(1,361)	(5,377)	(1,472)
Total other income (expense), net	440	(1,335)	(4,783)	(1,397)
Net loss before income tax provision	(9,813)	(7,692)	(26,318)	(15,601)
Benefit from income taxes	(331)	—	(116)	(396)
Net loss	\$ (9,482)	\$ (7,692)	\$ (26,202)	\$ (15,205)
Net loss attributable to ordinary shareholders	\$ (9,482)	\$ (7,692)	\$ (26,202)	\$ (15,205)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (0.53)	\$ (17.73)	\$ (3.00)	\$ (36.44)
Weighted average ordinary shares outstanding, basic and diluted	17,900,978	433,795	8,734,943	417,223

Balance Sheets Data
(In thousands)
(Unaudited)

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Cash	\$ 95,954	\$ 63,380
Working capital	101,415	67,840
Total assets	116,060	81,626
Total shareholders' equity (deficit)	95,325	(69,826)

Investor and Media Contact:

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