

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

March 10, 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 March 10, 2020, Bicycle Therapeutics plc (the “Company”) issued a press release announcing financial results for the fiscal quarter and the year ended December 31, 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

Exhibit No.	Description
99.1	Press Release issued March 10, 2020

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: March 10, 2020

BICYCLE THERAPEUTICS PLC

By: /s/ Lee Kalowski

Name: Lee Kalowski

Title: Chief Financial Officer



Bicycle Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Corporate Updates

- *BT1718 on track for Phase IIa initiation in 2020; BT5528 Phase I dose escalation is ongoing; BT8009 on track for Phase I trial initiation in 2020*
- *IND-enabling activities for lead TICA™ BT7480 continue to progress*
- *Cash was \$92.1 million at December 31, 2019, which excludes \$30 million upfront payment from Q1 2020 strategic immuno-oncology collaboration with Genentech*

CAMBRIDGE, England, & BOSTON, March 10, 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 fourth quarter and full year ended December 31, 2019 and discussed recent corporate updates.

“Last year was transformational for Bicycle as the completion of our initial public offering and the strengthening of corporate leadership enabled successful execution against our pipeline development strategy,” said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. “This year is already off to a strong start, with two new immuno-oncology collaborations designed to expand upon our wholly owned portfolio of systemic immune cell agonists and tumor-targeted immune cell agonists (TICAs™). We look forward to the momentum continuing as we progress multiple *Bicycle* Toxin Conjugates through the clinic this year and prepare to begin clinical development of our first TICA. We believe our anticipated near-term milestones will further demonstrate the role *Bicycles* could play in creating a much-needed new treatment paradigm for people living with cancer and other serious diseases.”

Fourth Quarter 2019 and Recent Highlights

- **Entered into Strategic Collaboration with Genentech to Discover, Develop and Commercialize Novel *Bicycle*-based Immuno-oncology Therapies.** In February 2020, Bicycle entered into a strategic collaboration agreement with Genentech. Under the terms of the agreement, Bicycle will be responsible for discovery research and early preclinical development up to candidate selection. Bicycle will receive a \$30 million upfront payment. The upfront payment and potential milestone payments could total up to \$1.7 billion. Bicycle will also be eligible to receive tiered royalties. None of Bicycle’s wholly owned oncology assets, including its immuno-oncology candidates, are included in the collaboration.
 - **Announced Collaboration with Cancer Research UK to Develop New *Bicycle* Immuno-oncology Candidate, BT7401.** In January 2020, Bicycle announced a second collaboration with Cancer Research UK, the world’s largest independent funder of cancer research. Cancer Research UK will fund and sponsor development of BT7401, a multivalent *Bicycle* CD137 agonist, through a Phase I/IIa clinical study.
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- **Dosed First Patient in Phase I/II Trial of BT5528, a Second-generation Bicycle Toxin Conjugate (BTC) Targeting EphA2, in Patients with Advanced Solid Tumors.** In November 2019, Bicycle announced that the first patient had been dosed in the Phase I dose escalation portion of its Phase I/II trial of BT5528 in patients with advanced solid tumors associated with EphA2 expression. BT5528 is the first second-generation BTC to enter the clinic and has demonstrated promising anti-tumor activity and tolerability across a broad range of preclinical studies.
- **Presented New Preclinical Data for Novel, Fully Synthetic TICAs at the Society for Immunotherapy of Cancer's (SITC) 2019 Annual Meeting.** In an oral presentation at SITC, Bicycle presented 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.

Anticipated Key Events in 2020

- **Initiation of Phase IIa trial of BT1718**, a BTC targeting MT1-MMP, in patients with solid tumors expressing MT1 (trial sponsored by Cancer Research UK)
- **Interim BT5528 Phase I data readout** from the ongoing Phase I/II trial
- **Initiation of nivolumab arm in BT5528 Phase I** portion of the ongoing Phase I/II trial
- **Initiation of a Phase I/II trial of BT8009**, a second-generation BTC targeting Nectin-4, a tumor antigen shown to be overexpressed in tumor cells, in patients with solid tumors

Financial Results

- Cash was \$92.1 million as of December 31, 2019, compared with \$63.4 million as of December 31, 2018. Cash at December 31, 2019 does not include the \$30 million upfront payment from Genentech.
 - Research and development expenses were \$6.6 million for the three months ended December 31, 2019 and \$25.5 million for the year ended December 31, 2019, compared to \$6.5 million for the three months ended December 31, 2018 and \$20.8 million for the year ended December 31, 2018. The increase of \$0.1 million for the three months ended December 31, 2019 as compared to the same period in the prior year was primarily due to an increase in personnel-related expenses, including \$0.4 million of incremental non-cash share-based compensation expense, offset by a decrease of \$0.9 million in direct program spending. The increase of \$4.8 million for the year ended December 31, 2019 as compared to the same period in the prior year was primarily due to an increase of \$2.1 million in direct program spending as well as an increase in personnel-related expenses, including \$0.8 million of incremental non-cash share-based compensation expense.
 - General and administrative expenses were \$3.4 million for of the three months ended December 31, 2019 and \$14.6 million for the year ended December 31, 2019, compared to \$2.1 million for of the three months ended December 31, 2018 and \$8.1 million for the year ended December 31, 2018. The increase of \$1.3 million for the three months ended December 31, 2019 as compared to the same period in the prior year is primarily due \$0.9 million in personnel-related costs, including \$0.4 million of incremental non-cash share-based compensation expense, as well as \$1.6 million in professional fees and costs related to operations as a public company, offset by a \$1.2 million favorable effect of foreign exchange rates. The increase of \$6.4 million for the year ended December 31, 2019 as compared to the same period in the prior year was primarily due to an increase in personnel-related expenses, including \$1.2 million of incremental non-cash share-based compensation expense, as well as an increase in professional fees and costs related to operations as a public company, offset by a \$0.6 million favorable effect of foreign exchange rates.
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Net loss was \$4.4 million, or \$(0.25) basic and diluted net loss per share, for the three months ended December 31, 2019 and net loss was \$30.6 million, or \$(2.77) basic and diluted net loss per share for the year ended December 31, 2019, compared to net loss of \$6.6 million, or \$(13.19) basic and diluted net loss per share for the three months ended December 31, 2018, and net loss of \$21.8 million, or \$(49.78) basic and diluted net loss per share for the year ended December 31, 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, 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 regarding our collaborations with Cancer Research UK and Genentech; the possible discovery, development and commercialization of product candidates, including with our collaboration partners; potential payments that may be made pursuant to the strategic collaboration with Genentech; our intentions to initiate and advance clinical trials; the possible results of clinical trials; the therapeutic potential of our product candidates; and our 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: the risk that we may not realize the intended benefits of our technology, including that we or our collaboration partners may not identify, develop and commercialize additional product candidates; the risk that we may not be able to maintain existing collaborations and realize the benefits thereof or develop new relationships; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of Bicycle's product candidates by Bicycle or our 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 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Collaboration revenues	\$ 5,281	\$ 1,057	\$ 13,801	\$ 7,136
Operating expenses:				
Research and development	6,649	6,493	25,540	20,761
General and administrative	3,396	2,106	14,560	8,121
Total operating expenses	10,045	8,599	40,100	28,882
Loss from operations	(4,764)	(7,542)	(26,299)	(21,746)
Other income (expense):				
Interest and other income	220	94	814	169
Other expense, net	—	807	(5,377)	(665)
Total other income (expense), net	220	901	(4,563)	(496)
Net loss before income tax provision	(4,544)	(6,641)	(30,862)	(22,242)
Benefit from income taxes	(138)	—	(254)	(396)
Net loss	\$ (4,406)	\$ (6,641)	\$ (30,608)	\$ (21,846)
Net loss attributable to ordinary shareholders	\$ (4,406)	\$ (6,641)	\$ (30,608)	\$ (21,846)
Net loss per share attributable to ordinary shareholders, basic and diluted	\$ (0.25)	\$ (13.19)	\$ (2.77)	\$ (49.78)
Weighted average ordinary shares outstanding, basic and diluted	17,926,165	503,309	11,045,370	438,862

Balance Sheets Data
(In thousands)
(Unaudited)

	December 31,	
	2019	2018
Cash	\$ 92,117	\$ 63,380
Working capital	95,325	67,840
Total assets	110,194	81,626
Shareholders equity (deficit)	93,198	(69,826)

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