

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 4, 2022

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.)

**Blocks A & B, Portway Building,
Granta Park, Great Abington, Cambridge
United Kingdom**
(Address of principal executive offices)

CB21 6GS
(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 4, 2022, Bicycle Therapeutics plc (the “Company”) issued a press release announcing financial results for the fiscal quarter ended June 30, 2022 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 8.01 Other Events

Also on August 4, 2022, the Company posted an updated corporate presentation on the Company’s website. To access the presentation, investors should visit the “Presentation and Events” section of the Company’s website at investors.bicycletherapeutics.com.

The information furnished under this Item 8.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued August 4, 2022 regarding financial results and business highlights
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 4, 2022

BICYCLE THERAPEUTICS PLC

By: /s/ Lee Kalowski

Name: Lee Kalowski

Title: Chief Financial Officer



Bicycle Therapeutics Reports Second Quarter 2022 Financial Results and Provides Corporate Update

- Continued clinical progress across pipeline, including dosing of the first patient in expansion cohorts of Phase I/II study of BT5528
- Expansion of Genentech exclusive strategic collaboration, triggering a \$10 million payment to Bicycle in Q3
- Cash and cash equivalents of \$372.8 million as of June 30, 2022, excludes \$9.8 million UK R&D tax credit received in July and Genentech payment; expected financial runway into 2025

CAMBRIDGE, England, & BOSTON, August 4, 2022 – Bicycle Therapeutics plc (NASDAQ: BCYC), a biotechnology company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (*Bicycle*®) technology, today reported financial results for the second quarter ended June 30, 2022 and provided recent corporate updates.

“We are pleased with the progress of our wholly owned clinical oncology pipeline of *Bicycle* Toxin Conjugate, or BTC™, programs and *Bicycle* tumor-targeted immune cell agonist®, or *Bicycle* TICA™, programs,” said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. “In the second quarter, we initiated the expansion cohorts of our Phase I/II study of BT5528, and development of BT8009 and BT7480 remains on track as these programs advance in their respective clinical trials.”

“In addition, we were delighted to announce the second expansion of our immuno-oncology collaboration with Genentech last month, highlighting the potential of the platform beyond our BTCs and *Bicycle* TICAs,” Dr Lee continued. “We are pleased to have a strong balance sheet which helps support the advancement of our programs and which we anticipate provides a financial runway into 2025.”

Second Quarter 2022 and Recent Highlights

- **Announced First Patient Dosed in the Expansion Cohorts of Phase I/II Trial of BT5528.** In June 2022, Bicycle announced that the first patient was dosed in the expansion cohorts of the Phase I/II study of BT5528, Bicycle’s second-generation *Bicycle* Toxin Conjugate (BTC™) targeting EphA2. Up to 56 patients will be enrolled in the initial expansion cohorts, with the ability to further expand enrollment based on the results from these cohorts. Bicycle intends to provide completed results of the dose escalation portion of the clinical trial during the third quarter of 2022.
 - **Announced Expansion of Genentech Immuno-Oncology Collaboration.** In July 2022, Bicycle announced that Genentech exercised an option to initiate a new program, expanding the exclusive strategic collaboration agreement with Bicycle to discover, develop and commercialize novel *Bicycle*®-based immuno-oncology therapies. This expansion represented the second option exercised by Genentech under the terms of the original February 2020 agreement and triggered a \$10 million payment to Bicycle, which is expected to be received in the third quarter of 2022.
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- **Presented Trials in Progress Poster Featuring BT7480 Phase I/II Clinical Trial at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.** In June 2022, Bicycle presented a Trials in Progress poster highlighting the Phase I/II clinical trial of BT7480, a novel, fully synthetic *Bicycle* TICA™ targeting Nectin-4 and agonizing CD137.
- **Announced Interim BT8009 Phase I Clinical Trial Results at the 2022 American Association for Cancer Research (AACR) Annual Meeting.** In April 2022, Bicycle announced interim Phase I results from the Phase I/II trial of BT8009, a second-generation BTC™ targeting Nectin-4. As of March 7, 2022, 37 patients have been dosed in the Phase I/II trial of BT8009. A total of 12 response evaluable urothelial cancer (UC) patients have been dosed in monotherapy cohorts of 2.5mg/m² and 5.0mg/m² weekly in the ongoing trial. Four response evaluable UC patients were dosed at 2.5mg/m² weekly, with one patient observed to have tumor reductions constituting a confirmed partial response (PR) and two patients observed to have stable disease (SD). Eight response evaluable UC patients were dosed at 5.0mg/m² weekly, with four patients observed to have a confirmed complete response (CR) or PR, including one patient with a CR and three patients with a PR, and two patients with SD, reflecting a 50% overall response rate and 75% disease control rate. As of March 7, 2022, the median duration of response had not yet been reached in either the 2.5 mg/m² or 5.0mg/m² cohort, with four of the five responders in these cohorts still on therapy after at least 24 weeks.

Exploration of additional doses and frequencies continues, and Bicycle intends to provide further updates this year.

Financial Results

- Cash and cash equivalents were \$372.8 million as of June 30, 2022, compared to \$438.7 million as of December 31, 2021. The decrease in cash is primarily due to cash used in operating activities.
 - Research and development expenses were \$19.9 million for the three months ended June 30, 2022, compared to \$11.7 million for the three months ended June 30, 2021. The increase in expense of \$8.2 million was primarily due to increased clinical program expenses for BT5528 and BT8009, *Bicycle* TICA program development expenses, as well as increased personnel-related expenses, including \$1.6 million of incremental non-cash share-based compensation expenses, and increased facilities-related expenses.
 - General and administrative expenses were \$11.8 million for the three months ended June 30, 2022, compared to \$7.3 million for the three months ended June 30, 2021. The increase of \$4.5 million for the three months ended June 30, 2022 as compared to the same period in the prior year was primarily due to an increase in personnel-related expenses, including \$1.5 million of incremental non-cash share-based compensation expense, and an unfavorable effect of foreign exchange rates.
 - Net loss was \$26.8 million, or \$(0.90) basic and diluted net loss per share, for the three months ended June 30, 2022, compared to net loss of \$17.9 million, or \$(0.74) basic and diluted net loss per share, for the three months ended June 30, 2021.
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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 is evaluating BT5528, a second-generation *Bicycle* Toxin Conjugate (BTC™) targeting EphA2; BT8009, a second-generation BTC targeting Nectin-4, a well-validated tumor antigen; and BT7480, a *Bicycle* TICA™ targeting Nectin-4 and agonizing CD137, in company-sponsored Phase I/II trials. In addition, BT1718, a BTC that targets MT1- MMP, is being investigated in an ongoing Phase I/IIa clinical trial sponsored by the Cancer Research UK Centre for Drug Development. Bicycle is headquartered in Cambridge, UK, with many key functions and members of its leadership team located in Lexington, Massachusetts. 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 of its product candidates, including BT5528, BT8009 and BT7480; the anticipated dosing in and progression of Bicycle’s clinical trials; the availability of data from clinical trials; the therapeutic potential for *Bicycles* in oncology and other applications; Bicycle’s plans to expand its discovery efforts and early development pipeline; and Bicycle’s expected financial runway. 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 clinical trial site initiation, 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 and clinical development of Bicycle’s product candidates; the risk that Bicycle may not realize the intended benefits of its technology; availability and timing of results from clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial results; whether initial or interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that trials may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of Bicycle’s product candidates; the risk that Bicycle’s projections regarding its expected financial runway are inaccurate or that its conduct of its business requires more cash than anticipated; 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 5, 2022, 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 because 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,	
	2022	2021	2022	2021
Collaboration revenues	\$ 4,378	\$ 1,785	\$ 8,238	\$ 3,593
Operating expenses:				
Research and development	19,854	11,722	34,138	21,415
General and administrative	11,824	7,340	28,783	15,479
Total operating expenses	31,678	19,062	62,921	36,894
Loss from operations	(27,300)	(17,277)	(54,683)	(33,301)
Other income (expense):				
Interest income	908	23	1,126	38
Interest expense	(883)	(819)	(1,701)	(1,341)
Total other income (expense), net	25	(796)	(575)	(1,303)
Net loss before income tax provision	(27,275)	(18,073)	(55,258)	(34,604)
Benefit from income taxes	(447)	(160)	(866)	(500)
Net loss	\$ (26,828)	\$ (17,913)	\$ (54,392)	\$ (34,104)
Net loss per share, basic and diluted	\$ (0.90)	\$ (0.74)	\$ (1.84)	\$ (1.48)
Weighted average ordinary shares outstanding, basic and diluted	29,648,564	24,052,168	29,626,974	23,047,745

Balance Sheets Data
(In thousands)
(Unaudited)

	June 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 372,769	\$ 438,680
Working capital	367,152	422,317
Total assets	445,482	479,792
Total shareholders' equity	311,392	346,254

Investors:

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