

**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 3, 2023

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 3, 2023, Bicycle Therapeutics plc issued a press release announcing financial results for the fiscal quarter ended June 30, 2023 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 and is incorporated herein by reference.

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 August 3, 2023
104	Cover Page Interactive Data File (formatted in Inline XBRL)

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 3, 2023

BICYCLE THERAPEUTICS PLC

By: /s/ Alethia Young

Name: Alethia Young

Title: Chief Financial Officer



Bicycle Therapeutics Reports Second Quarter 2023 Financial Results and Provides Corporate Update

Continued progress across pipeline, including advancing BT8009, BT5528, and BT7480 in ongoing clinical trials; clinical and regulatory updates remain on track for BT8009 in 2H23

Entered into strategic collaborations with Novartis, Bayer, and broadened an ongoing collaboration with DKFZ in radiopharmaceuticals

Strengthened balance sheet with gross proceeds of approximately \$230M, from July 2023 public offering and \$45M Bayer upfront payment; pro-forma cash balance is over \$600M

Enhanced leadership team with new CFO hire, Alethia Young, who brings to Bicycle over 20 years of experience in the biopharma industry

CAMBRIDGE, England & BOSTON, August 3, 2023 – 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, 2023 and provided recent corporate updates.

“We have made significant progress in the first half of 2023 executing on our plan to become one of the world’s leading solid tumor medicines companies,” said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. “Not only have we continued to advance our three clinical trial candidates - BT5528, BT8009 and BT7480 – but we have also entered into multiple research and development collaborations with pioneers in the radiopharmaceutical space to develop *Bicycle*[®] radio-conjugates (BRCs). These collaborations enable us to advance a broad pipeline of partnered and wholly owned BRCs that represents the third pillar of our oncology strategy beyond our *Bicycle* toxin conjugate (BTC[™]) and *Bicycle* tumor-targeted immune cell agonist[®] (*Bicycle* TICA[™]) programs. Our clinical programs remain on track for us to provide updates in the second half of 2023. Additionally, we are excited to welcome Alethia Young, our new Chief Financial Officer, who brings over 20 years of experience in the healthcare and biotech industry to Bicycle. The advancement of our programs and platform in oncology and beyond are supported by a strong balance sheet that has been further enhanced by the recent proceeds from a public equity offering completed in July.”

Second Quarter 2023 and Recent Highlights

- **Raised Gross Proceeds of \$230.0 Million in Public Offering.** In July 2023, Bicycle announced the closing of an underwritten public offering resulting in gross proceeds of approximately \$230.0 million, including the full exercise of the underwriters’ option to purchase additional shares. Net proceeds were approximately \$215.5 million. In addition, the company also received gross proceeds from Bicycle’s at-the-market (ATM) offering program during the second quarter of 2023 totaling \$12.5 million.
 - **Continued Progress with Clinical and Regulatory Programs Including BT8009, BT5528, and BT7480.** Enrollment in the company’s clinical trial of BT8009, as well as discussions with the U.S. Food and Drug Administration (FDA) remain ongoing. The company expects to provide clinical and regulatory updates on BT8009 in the second half of 2023.
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Bicycle

- **Enhanced Leadership Team with Appointment of Alethia Young as Chief Financial Officer.** In June 2023, Bicycle announced the appointment of Alethia Young as its new Chief Financial Officer, effective July 17. Ms. Young brings to Bicycle more than 20 years of experience in the healthcare and biotech industry, most recently serving as the Chief Financial Officer at Graphite Bio. Prior to Graphite Bio, she served as a senior biotech analyst and head of research at Cantor Fitzgerald, and previously held senior biotech analyst positions at Credit Suisse and Deutsche Bank.
 - **Presented Potent Anti-Tumor Activity of a Lead-212 Labelled MT1-MMP Targeting *Bicycle Radionuclide Conjugate*[™] at TIDES 2023.** In May 2023, Bicycle presented preclinical results from a preclinical research collaboration with OranoMed. In these studies, Pb-BCY20603, a prototype BRC[™] that binds with high affinity to the tumor antigen MT1-MMP and carries a chelate of lead-212, showed potent anti-tumor activity in rodent tumor xenograft studies and achieved complete tumor regressions after 3 dosing cycles of 10 µCi, given two weeks apart. Median survival was increased for each dosing group with 90% survival observed for the 3 cycles of 10 µCi, treatment at the end of the 100-day study.
 - **Announced Multiple Strategic Collaborations for Developing BRCs for Potential Oncology Targets**
 - **Strategic Collaboration with Bayer.** In May 2023, Bicycle announced that it has entered into a strategic collaboration agreement with Bayer to discover, develop, manufacture, and commercialize BRCs for multiple agreed upon oncology targets. Bicycle will use its proprietary phage platform to develop bicyclic peptides, while Bayer will be responsible for, and fully fund, all further preclinical and clinical development, manufacturing, and commercialization activities. Bicycle received a \$45 million upfront payment in July 2023 and, with potential development and commercial-based milestone fees, payments under the collaboration to Bicycle could total up to \$1.7 billion. Bicycle will also be eligible to receive tiered royalties on *Bicycle*-based medicines commercialized by Bayer.
 - **Expanded Collaboration with the German Cancer Research Center.** In May 2023, Bicycle announced the extension of a collaboration with the German Cancer Research Center (DKFZ) to develop and discover BRCs for potential oncology targets. This enhanced relationship will provide a more continuous and purpose-driven commitment towards advancing Bicycle's wholly owned BRC candidates. Bicycle intends to commence initial testing of its wholly owned BRCs in patients during 2024.
 - **Strategic Collaboration with Novartis.** In March 2023, Bicycle announced a strategic collaboration with Novartis to collaborate on the discovery, development and commercialization of BRCs for multiple agreed upon oncology targets. Bicycle will utilize its proprietary phage platform to discover *Bicycles* to be developed into BRCs. Novartis will be responsible for and fund further development, manufacture and commercialization of the BRCs. Under the collaboration, Bicycle received a \$50 million upfront payment in April 2023 and is eligible for development and commercial-based milestone payments totaling up to \$1.7 billion. Bicycle will also be eligible to receive tiered royalties on *Bicycle*-based medicines commercialized by Novartis.
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Financial Results

- Cash and cash equivalents were \$340.4 million as of June 30, 2023, compared to \$339.2 million as of December 31, 2022. The increase in cash and cash equivalents is primarily due to \$50.0 million received from our collaboration agreement with Novartis and \$14.8 million of net proceeds from our ATM offering program, offset by cash used in operating activities. Our cash and cash equivalents at June 30, 2023 do not include the upfront payment from Bayer or proceeds from our public offering received in July 2023. Additionally in July, the company strengthened its balance sheet with gross proceeds of \$230.0 million, or net proceeds of approximately \$215.5 million, from the July 2023 public offering.
- Research and development expenses were \$39.7 million for the three months ended June 30, 2023, compared to \$19.9 million for the three months ended June 30, 2022. The increase in expense of \$19.9 million was primarily due to increased clinical program expenses for BT8009, BT7480 development expenses, and other discovery and platform related expenses, as well as increased personnel-related expenses, including incremental non-cash share-based compensation expense of \$1.3 million, offset by incremental UK research and development incentives.
- General and administrative expenses were \$14.8 million for the three months ended June 30, 2023, compared to \$11.8 million for the three months ended June 30, 2022. The increase of \$3.0 million for the three months ended June 30, 2023 as compared to the same period in the prior year was primarily due to an increase in professional and consulting fees, as well as an increase in personnel-related expenses, including incremental non-cash share-based compensation expense of \$1.2 million, offset by a favorable impact of foreign exchange rates.
- Net loss was \$42.6 million, or \$(1.41) basic and diluted net loss per share, for the three months ended June 30, 2023, compared to net loss of \$26.8 million, or \$(0.90) basic and diluted net loss per share, for three months ended June 30, 2022.

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 Cambridge, 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 of its product candidates, including BT8009, BT5528 and BT7480; the anticipated progression of Bicycle’s clinical trials; the availability of and timing of announcement of data from clinical trials and regulatory updates for clinical candidates; statements regarding Bicycle’s collaborations with Bayer, Novartis and DKFZ; the discovery, development and potential commercialization of potential radiopharmaceutical or other product candidates using Bicycle’s technology under the strategic collaboration agreements; Bicycle’s intent to commence initial testing of its wholly owned BRCs in patients by the end of 2024; and the therapeutic potential for *Bicycles* in oncology and other applications. 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, progress 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 or strategic collaborations; 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 have unsatisfactory outcomes; potential adverse effects arising from the testing or use of Bicycle’s product candidates; 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 4, 2023, 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		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Collaboration revenues	\$ 11,397	\$ 4,378	\$ 16,293	\$ 8,238
Operating expenses:				
Research and development	39,720	19,854	71,931	34,138
General and administrative	14,788	11,824	29,276	28,783
Total operating expenses	54,508	31,678	101,207	62,921
Loss from operations	(43,111)	(27,300)	(84,914)	(54,683)
Other income (expense):				
Interest income	812	908	3,741	1,126
Interest expense	(821)	(883)	(1,629)	(1,701)
Total other income (expense), net	(9)	25	2,112	(575)
Net loss before income tax provision	(43,120)	(27,275)	(82,802)	(55,258)
Benefit from income taxes	(517)	(447)	(1,135)	(866)
Net loss	\$ (42,603)	\$ (26,828)	\$ (81,667)	\$ (54,392)
Net loss per share, basic and diluted	\$ (1.41)	\$ (0.90)	\$ (2.71)	\$ (1.84)
Weighted average ordinary shares outstanding, basic and diluted	30,191,693	29,648,564	30,097,234	29,626,974

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Balance Sheets Data
(In thousands)
(Unaudited)

	June 30,	December 31,
	2023	2022
Cash and cash equivalents	\$ 340,433	\$ 339,154
Working capital	336,164	316,041
Total assets	454,170	410,609
Total shareholders' equity	220,097	270,783

Investors:

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