

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

May 2, 2024

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 May 2, 2024, Bicycle Therapeutics plc issued a press release announcing financial results for the fiscal quarter ended March 31, 2024 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

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release issued May 2, 2024</a>
104	Cover Page Interactive Data File (formatted in Inline XBRL)

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**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: May 2, 2024

**BICYCLE THERAPEUTICS PLC**

By: /s/ Alethia Young

Name: Alethia Young

Title: Chief Financial Officer

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**Bicycle Therapeutics Reports Recent Business Progress and First Quarter 2024 Financial Results**

*Multiple preclinical and clinical abstracts accepted for presentation at 2024 ASCO Annual Meeting and AACR Annual Meeting underscore breadth of Bicycle<sup>®</sup> platform technology and pipeline*

*Continued progress across research and development (R&D) pipeline, with numerous clinical data readouts and updates expected in 2H 2024*

*Mike Hannay, D.Sc., FRPharmS, promoted to Chief Product and Supply Chain Officer*

*Cash and cash equivalents of \$457.0 million as of March 31, 2024, expected to provide financial runway into 2026*

CAMBRIDGE, England & BOSTON, May 2, 2024 – Bicycle Therapeutics plc (NASDAQ: BCYC), a biopharmaceutical company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (Bicycle<sup>®</sup>) technology, today reported recent business progress and financial results for the first quarter ended March 31, 2024.

“During the first quarter, we focused on execution across all aspects of our business. We were pleased to initiate our Phase 2/3 Duravelo-2 registrational trial for BT8009 in metastatic urothelial cancer, and we are actively working on patient enrollment and site activation. We continue to make progress across the rest of our pipeline of differentiated, precision-guided therapeutic candidates, and look forward to a catalyst-rich second half of the year,” said Kevin Lee, Ph.D., CEO of Bicycle Therapeutics. “Additionally, I am thrilled to congratulate Mike Hannay on his promotion to Chief Product and Supply Chain Officer. Since joining the company two years ago, he has significantly advanced our manufacturing capabilities and priorities, and I look forward to seeing him excel in this new position.”

**First Quarter 2024 and Recent Events**

- **Two abstracts accepted for poster presentation at the 2024 American Society for Clinical Oncology (ASCO) Annual Meeting.** Bicycle Therapeutics will present two abstracts highlighting the company’s clinical progress in developing Bicycle Toxin Conjugates<sup>®</sup> (BTC<sup>®</sup>) molecules as differentiated cancer therapies. The first abstract will examine the clinical pharmacokinetics and safety of BTC molecules, while the second abstract will outline the company’s ongoing Phase 2/3 clinical trial, called Duravelo-2, of BT8009 in metastatic urothelial cancer (mUC). ASCO is being held May 31-June 4 in Chicago.
  - **Three posters presented at the American Association for Cancer Research (AACR) Annual Meeting 2024.** Bicycle Therapeutics shared preclinical data showcasing the company’s work to develop BTC molecules for the treatment of solid tumors, Natural Killer Tumor-Targeted Immune Cell Agonist (NK-TICA<sup>®</sup>) molecules that can engage NK cells to directly kill malignant tumor cells and Bicycle Tumor-Targeted Immune Cell Agonist (Bicycle TICA<sup>®</sup>) molecules that can activate the body’s immune system to enable tumor rejection. Altogether, the posters underscore the breadth of the company’s platform technology and its capabilities to produce different modalities to target cancer.
  - **Continued progress across research and development (R&D) pipeline, with numerous clinical data readouts and program updates expected in 2H 2024.** Importantly, Bicycle Therapeutics initiated the Phase 2/3 Duravelo-2 registrational trial for BT8009 in mUC, and patient enrollment is ongoing. The company continues to assess BT8009, BT5528 and BT7480 in Phase 1/2 clinical trials across a variety of tumor types, and plans to provide updates from its wholly owned Bicycle<sup>®</sup> Radio Conjugate (BRC<sup>™</sup>) pipeline.
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- **Mike Hannay, D.Sc., FRPharmS, promoted to Chief Product and Supply Chain Officer.** Since joining Bicycle Therapeutics in April 2022, Professor Hannay has advanced the company's chemistry, manufacturing and controls (CMC) capabilities and drug manufacturing priorities, including preparations and buildout for the potential commercial launch of BT8009. Over the course of his career, through his work at Sanofi, Schwarz Pharma, Teva Pharmaceuticals and AstraZeneca, Professor Hannay has launched more than 40 medicines.

### **Participation in Upcoming Investor Conferences**

Bicycle Therapeutics management will participate in a fireside chat at the Citizens JMP Life Sciences Conference on May 13, 2024, at 9 a.m. ET.

A live webcast of the fireside chat will be accessible from the Investor section of the company's website at [www.bicycletherapeutics.com](http://www.bicycletherapeutics.com). A replay of the webcast will be archived and available following the event.

### **First Quarter 2024 Financial Results**

- Cash and cash equivalents were \$457.0 million as of March 31, 2024, compared to \$526.4 million as of December 31, 2023. The decrease in cash and cash equivalents is primarily due to cash used in operating activities, including upfront payments associated with the initiation of our Phase 2/3 Duravelo-2 registrational trial.
  - R&D expenses were \$34.9 million for the three months ended March 31, 2024, compared to \$32.2 million for the three months ended March 31, 2023. The increase in expense of \$2.7 million was primarily due to increased clinical program expenses for BT8009 development and increased personnel-related expenses. These expenses were offset by decreased clinical program expenses for Bicycle TICA<sup>®</sup> molecule development and BT5528 development, as well as \$8.2 million of one-time, incremental retroactive U.K. R&D tax credits.
  - General and administrative expenses were \$16.4 million for the three months ended March 31, 2024, compared to \$14.5 million for the three months ended March 31, 2023. The increase of \$1.9 million was primarily due to an increase in personnel-related costs.
  - Net loss was \$26.6 million, or \$(0.62) basic and diluted net loss per share, for the three months ended March 31, 2024, compared to net loss of \$39.1 million or \$(1.30) basic and diluted net loss per share, for three months ended March 31, 2023.
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## About Bicycle Therapeutics

Bicycle Therapeutics is a clinical-stage biopharmaceutical company developing a novel class of medicines, referred to as Bicycle<sup>®</sup> molecules, for diseases that are underserved by existing therapeutics. Bicycle molecules 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 Bicycle molecules attractive candidates for drug development. The company is evaluating BT8009, a Bicycle<sup>®</sup> Toxin Conjugate (BTC<sup>®</sup>) targeting Nectin-4, a well-validated tumor antigen; BT5528, a BTC targeting EphA2, a historically undruggable target; and BT7480, a Bicycle Tumor-Targeted Immune Cell Agonist<sup>®</sup> (Bicycle TICA<sup>®</sup>) targeting Nectin-4 and agonizing CD137, in company-sponsored clinical trials. Additionally, the company is developing Bicycle<sup>®</sup> Radio Conjugates (BRC<sup>™</sup>) for radiopharmaceutical use and, through various partnerships, is exploring the use of Bicycle<sup>®</sup> technology to develop therapies for diseases beyond oncology.

Bicycle Therapeutics is headquartered in Cambridge, UK, with many key functions and members of its leadership team located in Cambridge, Mass. For more information, visit [bicycletherapeutics.com](http://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 progress across its R&D pipeline and the advancement of its product candidates, including BT8009, BT5528 and BT7480; the anticipated progression of Bicycle’s clinical trials and the availability of and timing of announcement of data from clinical trials and program updates for clinical candidates; the development of potential radiopharmaceutical or other product candidates using Bicycle’s technology through various partnerships; the therapeutic potential for Bicycles in oncology and other applications; 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: uncertainties inherent in research and development and 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 partnerships; availability and timing of results from clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial results; the risk that trials may have unsatisfactory outcomes; potential adverse effects arising from the testing or use of Bicycle’s product candidates; the risk that Bicycle’s projections regarding its expected cash 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 20, 2024, 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.

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2024</b>	<b>2023</b>
Collaboration revenues	\$ 19,530	\$ 4,896
Operating expenses:		
Research and development	34,864	32,211
General and administrative	16,382	14,488
Total operating expenses	51,246	46,699
Loss from operations	(31,716)	(41,803)
Other income (expense):		
Interest income	5,624	2,929
Interest expense	(821)	(808)
Total other income (expense), net	4,803	2,121
Net loss before income tax provision	(26,913)	(39,682)
Benefit from income taxes	(350)	(618)
Net loss	\$ (26,563)	\$ (39,064)
Net loss per share, basic and diluted	\$ (0.62)	\$ (1.30)
Weighted average ordinary shares outstanding, basic and diluted	42,560,091	30,001,725

**Balance Sheets Data**  
**(In thousands)**  
**(Unaudited)**

	<b>March 31,</b> <b>2024</b>	<b>December 31,</b> <b>2023</b>
Cash and cash equivalents	\$ 456,997	\$ 526,423
Working capital	466,452	492,331
Total assets	547,143	595,344
Total shareholders' equity	356,048	370,932

**Investors:**

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