

**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**

October 29, 2026
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 October 29, 2026, Bicycle Therapeutics plc issued a press release announcing financial results for the fiscal quarter ended September 30, 2026 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 October 29, 2026
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: October 29, 2026

BICYCLE THERAPEUTICS PLC

By: /s/ Travis Thompson

Name: Travis Thompson

Title: Chief Financial Officer

Bicycle Therapeutics Reports Recent Business Progress and Third Quarter 2026 Financial Results

Nuzefatide pevedotin granted FDA Orphan Drug Designation for the treatment of pancreatic cancer; further updates expected in 2027

Initiation of the first company-sponsored radioligand clinical trial for BT1702, an MT1-MMP- targeting Bicycle[®] Radioconjugate, expected in 2H 2027

Cash and cash equivalents of \$469.9 million as of September 30, 2026, with expected cash runway into 2030

CAMBRIDGE, England & BOSTON, October 29, 2026 - Bicycle Therapeutics plc (NASDAQ: BCYC), a pharmaceutical company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (Bicycle[®]) technology, today reported financial results for the third quarter ended September 30, 2026, and provided recent corporate updates.

“We are pleased with the continued progress made across our pipeline during the third quarter, as we advance nuzefatide pevedotin in the Phase 2 clinical trial in patients with recurrent pancreatic ductal adenocarcinoma and build our emerging pipeline of next-generation radioligands. We believe the FDA’s Orphan Drug Designation for nuzefatide in pancreatic cancer further supports our development strategy and underscores the significant unmet need in this patient population,” said Bicycle CEO Kevin Lee, Ph.D. “We remain focused on disciplined execution across our prioritized programs and believe our growing clinical data continue to demonstrate the potential of Bicycle[®] molecules to deliver highly targeted therapies with differentiated benefit/risk profiles. We look forward to advancing our pipeline and reaching important clinical milestones for nuzefatide and initiating our first company-sponsored radioligand clinical trial for BT1702 in the second half of 2027.”

Third Quarter 2026 and Recent Events

- **Nuzefatide pevedotin (nuzefatide), a potentially first-in-class EphA2 targeting Bicycle[®] Drug Conjugate (BDC[®]), was granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) for the treatment of pancreatic cancer.** In September 2026, the FDA granted nuzefatide ODD for the treatment of pancreatic cancer. The designation is granted to investigational therapies intended to treat rare diseases affecting fewer than 200,000 patients in the United States. The designation provides development incentives, including eligibility for tax credits on qualified clinical trial costs, exemption from certain FDA user fees, and the potential for seven years of market exclusivity upon regulatory approval.

Bicycle Therapeutics is actively enrolling patients in a Phase 2 clinical trial to evaluate efficacy, safety, and pharmacokinetics of nuzefatide in adult patients with recurrent pancreatic ductal adenocarcinoma (PDAC) and expects to provide further updates in 2027.

- **Bicycle Therapeutics continues to optimize its Bicycle[®] Radioconjugate (BRC[®]) molecules and advance its emerging radioligand pipeline, with initiation of the first company-sponsored radioligand clinical trial for BT1702, an MT1-MMP-targeting BRC[®], expected in the second half of 2027.**
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- **Zelenectide pevedotin is a BDC[®] molecule targeting Nectin-4, a well-validated tumor antigen.** Bicycle Therapeutics converted the Duravelo-2 trial to a randomized Phase 2 trial in May 2026 and deprioritized the program for internal development. The company expects to report Duravelo-2 survival data from the randomized Phase 2 trial in previously untreated patients with metastatic urothelial cancer (mUC) in the second half of 2027.

Third Quarter 2026 Financial Results

- Cash and cash equivalents were \$469.9 million as of September 30, 2026, compared to \$628.1 million as of December 31, 2025. The decrease in cash and cash equivalents is primarily due to cash used in operations, including cash payments for clinical program activities.
- Collaboration revenue was \$34.1 million for the three months ended September 30, 2026, compared to \$11.7 million for the three months ended September 30, 2025. The increase in collaboration revenue was primarily due to the recognition of all remaining revenue under Bicycle Therapeutics' collaboration with Bayer Consumer Care AG upon termination of the underlying collaboration agreement.
- Research and development (R&D) expenses were \$33.4 million for the three months ended September 30, 2026, compared to \$58.4 million for the three months ended September 30, 2025. The decrease in expense of \$25.0 million was primarily due to decreased clinical program expenses for zelenectide, decreased personnel-related costs and share-based compensation due to our workforce reductions announced in August 2025 and March 2026, as well as decreased discovery, platform and other expenses, offset by lower research and development incentives associated with the corresponding decrease in qualifying research and development expenses period over period.
- General and administrative (G&A) expenses were \$14.1 million for the three months ended September 30, 2026, compared to \$18.9 million for the three months ended September 30, 2025. The decrease in expense of \$4.8 million was primarily due to decreased personnel-related costs and share-based compensation due to our workforce reductions announced in August 2025 and March 2026.
- Net loss was \$10.5 million, or \$(0.15) basic and diluted net loss per share, for the three months ended September 30, 2026, compared to net loss of \$59.1 million, or \$(0.85) basic and diluted net loss per share, for the three months ended September 30, 2025.

About Bicycle Therapeutics

Bicycle Therapeutics is a clinical-stage pharmaceutical company developing a novel class of medicines, referred to as Bicycle[®] 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 nuzefatide pevedotin, formerly BT5528, a Bicycle[®] Drug Conjugate (BDC[®]) targeting EphA2, a historically undruggable target; a pipeline of other bicycle-based conjugate molecules, including Bicycle[®] Radioconjugates (BRC[®]) for radiopharmaceutical use; zelenectide pevedotin (formerly BT8009), a BDC[®] targeting Nectin-4, a well-validated tumor antigen; and, through various partnerships, is exploring the use of Bicycle[®] technology to develop therapies for diseases in additional therapeutic areas.

Bicycle Therapeutics is headquartered in Cambridge, UK, with many key functions and members of its leadership team located in Lexington, Mass. 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,” “promising,” “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 potential therapeutic benefit of nuzefatide pevedotin, including the reproducibility and durability of any favorable results initially seen in patients dosed to date in clinical trials, and the potential development of nuzefatide pevedotin in pancreatic cancer; the clinical and regulatory benefits anticipated from the Orphan Drug Designation granted to nuzefatide pevedotin, including the potential for seven years of market exclusivity upon regulatory approval, eligibility for tax credits and exemption from certain FDA user fees; the progress of Bicycle Therapeutics’ clinical trials, reporting data from Bicycle Therapeutics’ clinical trials, including for nuzefatide pevedotin, and updates on future clinical development plans for nuzefatide pevedotin; the potential of Bicycle molecules to deliver highly targeted therapies with differentiated benefit/risk profiles; the positive properties of Bicycle® radioligand molecules for radiopharmaceutical use; the development of the Bicycle® radioligands pipeline, including BRCs, and the expected initiation of the first company-sponsored radioligand clinical trial for BT1702 in the second half of 2027; communications with and feedback from the FDA and other regulatory agencies; Bicycle Therapeutics’ expected financial runway; and the use of Bicycle Therapeutics’ technology through various partnerships to develop therapies for diseases in additional therapeutic areas. Bicycle Therapeutics 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 related to the benefits and potential unintended consequences of the strategic reprioritization and recent workforce reductions; uncertainties inherent in research and development and in the initiation, progress and completion of clinical trials and clinical development of Bicycle Therapeutics’ product candidates; the risk that Bicycle Therapeutics may not realize the intended benefits of its technology or partnerships; the risk that Bicycle Therapeutics may not achieve any of its clinical development strategies; timing of results from clinical trials; whether the outcomes of preclinical studies and prior clinical trials will be predictive of future clinical trial results; the risk that trials may have unsatisfactory outcomes; potential adverse effects arising from the testing or use of Bicycle Therapeutics’ product candidates; the risk that Bicycle Therapeutics’ 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 Therapeutics’ 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 Therapeutics’ Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on July 30, 2026, as well as in other filings Bicycle Therapeutics 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 Therapeutics 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
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Collaboration revenue	\$ 34,057	\$ 11,734	\$ 35,573	\$ 24,631
Operating expenses:				
Research and development	33,422	58,426	123,483	188,513
General and administrative	14,112	18,859	45,608	58,475
Total operating expenses	47,534	77,285	169,091	246,988
Loss from operations	(13,477)	(65,551)	(133,518)	(222,357)
Other income (expense):				
Interest and other income	4,213	6,700	13,450	22,587
Interest expense	(45)	(44)	(137)	(149)
Total other income, net	4,168	6,656	13,313	22,438
Net loss before income tax provision	(9,309)	(58,895)	(120,205)	(199,919)
Provision for (benefit from) income taxes	1,169	205	1,431	(1,113)
Net loss	\$ (10,478)	\$ (59,100)	\$ (121,636)	\$ (198,806)
Net loss per share, basic and diluted	\$ (0.15)	\$ (0.85)	\$ (1.74)	\$ (2.87)
Weighted average ordinary shares outstanding, basic and diluted	69,979,934	69,303,746	69,823,830	69,251,291

Balance Sheets Data
(In thousands)
(Unaudited)

	September 30, 2026	December 31, 2025
Cash and cash equivalents	\$ 469,928	\$ 628,110
Working capital	493,097	625,901
Total assets	567,179	717,597
Total shareholders' equity	505,277	609,977

Investors:

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