# Bicycle Therapeutics Reports Recent Business Progress and First Quarter 2025 Financial Results

May 1, 2025

*Multiple abstracts accepted for presentation at 2025 ASCO and AACR annual meetings underscore breadth of Bicycle® technology and potential of oncology pipeline*

*Phase 1/2 Duravelo-3 trial for zelenectide pevedotin in NECTIN4-amplified breast cancer open and actively recruiting patients*

*Bolstered business and clinical expertise with appointments to Board of Directors, Clinical Advisory Board and company management team*

*Cash and cash equivalents of $793.0 million as of March 31, 2025, with expected financial runway into 2H 2027*

CAMBRIDGE, England & BOSTON--(BUSINESS WIRE)--May 1, 2025-- 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 recent business progress and financial results for the first quarter ended March 31, 2025.

"In the first quarter, we continued to advance our business priorities and our pipeline of oncology therapeutics. We were pleased to share additional human imaging data that continue to validate the potential of MT1-MMP as a novel cancer target and demonstrate the positive properties of our Bicycle Radioconjugate molecules for radiopharmaceutical use," said Bicycle Therapeutics CEO Kevin Lee, Ph.D. "Our work to develop zelenectide pevedotin for various Nectin-4 associated cancers continues to progress, as we recently initiated our Phase 1/2 Duravelo-3 trial for NECTIN4 gene-amplified breast cancer and remain on track for dose selection in our Phase 2/3 Duravelo-2 trial for metastatic urothelial cancer in the second half of this year. Additionally, with new members on our leadership team, Board of Directors and Clinical Advisory Board, and expected financial runaway extending to the second half of 2027, we remain focused on continuing to execute our strategy and make meaningful advances for patients."

**First Quarter 2025 and Recent Events**

- **Additional human imaging data for an early Bicycle® Radioconjugate (BRC®) molecule targeting MT1-MMP presented at the American Association for Cancer Research (AACR) Annual Meeting 2025.** A poster presentation included new data from a second patient who underwent MT1-MMP-PET/CT imaging that build on previously announced data. Altogether, the data continue to validate the potential of MT1-MMP as a novel cancer target and demonstrate the positive properties of BRC molecules for radiopharmaceutical use. Importantly, the imaging data from these two patients are representative of the data generated to date in 12 out of 14 patients with various solid tumors. Bicycle Therapeutics continues to advance its emerging BRC pipeline, with initial EphA2 human imaging data expected in 2H 2025 and company-sponsored clinical trials planned for 2026.

- **Two abstracts accepted for poster presentation at the 2025 American Society for Clinical Oncology (ASCO) Annual Meeting.** Bicycle Therapeutics will present two abstracts highlighting the development of zelenectide pevedotin for metastatic urothelial cancer (mUC). The first abstract outlines previously disclosed topline combination data for zelenectide pevedotin plus pembrolizumab in first-line mUC from the Phase 1 Duravelo-1 trial, while the second abstract provides an overview of the ongoing Phase 2/3 Duravelo-2 registrational trial for zelenectide pevedotin in mUC. Dose selection in Duravelo-2 remains on track for the second half of the year.

- **Phase 1/2 Duravelo-3 trial for zelenectide pevedotin in NECTIN4-amplified breast cancer open and actively recruiting patients.** Bicycle Therapeutics previously announced a development strategy leveraging NECTIN4 amplification for zelenectide pevedotin in breast cancer, lung cancer and multiple tumor types. The strategy is based on the company's discovery that the NECTIN4 gene sits on a commonly amplified chromosomal site in cancer, creating more copies of the gene and often translating to more protein expression. Data from post-hoc analyses of late-line breast cancer and lung cancer patients enrolled in Duravelo-1 showed enhanced anti-tumor activity of zelenectide pevedotin in patients with NECTIN4 amplification and/or polysomy. Based on these data, the U.S. Food and Drug Administration granted Fast Track designation to zelenectide pevedotin for the treatment of adult patients with previously treated, NECTIN4-amplified, advanced or metastatic triple-negative breast cancer and non-small cell lung cancer. The Duravelo-3 breast cancer trial is the first of several planned trials to expand the development of zelenectide pevedotin for additional solid tumors.

- **Announced new Board of Directors and key clinical leadership appointments.** Felix J. Baker, Ph.D., will succeed Pierre Legault, MBA, CPA, as chairman of the Bicycle Therapeutics Board of Directors as Mr. Legault and Richard Kender, MBA, will retire from the Board following the company's Annual General Meeting on June 17, 2025. In addition, world-renowned oncology experts Alessandro Riva, M.D., and Fabrice André, M.D., Ph.D., have joined the company's Board of Directors and Clinical Advisory Board, respectively. Furthermore, Eric Westin, M.D., has been promoted to chief medical

officer and Jim MacDonald-Clink has been promoted to senior vice president, head of business development, following the transitions of Santiago Arroyo, M.D., Ph.D., chief development officer, and Nigel Crockett, Ph.D., chief business officer, to advisor roles as distinguished fellows.

**Participation in Upcoming Investor Conferences**

Bicycle Therapeutics management will participate in a fireside chat at the 2025 RBC Capital Markets Global Healthcare Conference on Tuesday, May 20, at 2:05 p.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. A replay of the webcast will be archived and available following the event.

**First Quarter 2025 Financial Results**

- Cash and cash equivalents were $793.0 million as of March 31, 2025, compared to $879.5 million as of December 31, 2024. The decrease in cash and cash equivalents is primarily due to cash used in operations, including increased cash payments for clinical program activities.
- Research and development (R&D) expenses were $59.1 million for the three months ended March 31, 2025, compared to $34.9 million for the three months ended March 31, 2024. The increase in expense of $24.2 million was primarily due to increased clinical program expenses for zelenectide pevedotin development, increased personnel-related expenses and lower U.K. R&D tax credits period over period.
- General and administrative expenses were $21.1 million for the three months ended March 31, 2025, compared to $16.4 million for the three months ended March 31, 2024. The increase in expense of $4.7 million was primarily due to increased professional and consulting fees as well as increased personnel-related costs, including incremental share-based compensation expense of $0.5 million for the three months ended March 31, 2025.
- Net loss was $60.8 million, or $(0.88) basic and diluted net loss per share, for the three months ended March 31, 2025, compared to net loss of $26.6 million or $(0.62) basic and diluted net loss per share, for three months ended March 31, 2024.

**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 zelenectide pevedotin (formerly BT8009), a Bicycle® Drug Conjugate (BDC™) targeting Nectin-4, a well-validated tumor antigen; BT5528, a BDC molecule targeting EphA2, a historically undruggable target; and BT7480, a Bicycle Tumor-Targeted Immune Cell Agonist® (Bicycle TICA®) targeting Nectin-4 and agonizing CD137, in company-sponsored clinical trials. Additionally, the company is developing Bicycle® Radioconjugates (BRC®) for radiopharmaceutical use and, through various partnerships, is exploring the use of Bicycle® 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.

**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 the validation of MT1-MMP as a cancer target and BRCs having positive properties for radiopharmaceutical use; the initiation of new clinical trials, the progress of Bicycle's ongoing clinical trials and the timing of dose selection in the Duravelo-2 clinical trial; Bicycle's expected financial runway; and the use of Bicycle Therapeutics' technology through various partnerships to develop therapies for diseases beyond oncology. 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 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 partnerships; the risk that Bicycle Therapeutics may 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 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' Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 25, 2025, 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 and Comprehensive Loss**
**(In thousands, except share and per share data)**
**(Unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2025 | 2024 |
| Collaboration revenue | $ 9,977 | $ 19,530 |
| Operating expenses: | | |
| Research and development | 59,058 | 34,864 |
| General and administrative | 21,123 | 16,382 |
| Total operating expenses | 80,181 | 51,246 |
| Loss from operations | (70,204) | (31,716) |
| Other income (expense): | | |
| Interest and other income | 8,414 | 5,624 |
| Interest expense | (51) | (821) |
| Total other income, net | 8,363 | 4,803 |
| Net loss before income tax provision | (61,841) | (26,913) |
| Benefit from income taxes | (1,087) | (350) |
| Net loss | $ (60,754) | $ (26,563) |
| Net loss per share, basic and diluted | $ (0.88) | $ (0.62) |
| Weighted average ordinary shares outstanding, basic and diluted | 69,196,945 | 42,560,091 |

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

| | March 31, 2025 | December 31, 2024 |
|---|---|---|
| Cash and cash equivalents | $ 792,973 | $ 879,520 |
| Working capital | 798,463 | 861,375 |
| Total assets | 883,894 | 956,868 |
| Total shareholders' equity | 740,333 | 793,060 |

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