Bicycle Therapeutics Highlights 2025 Accomplishments and Strategic Priorities for 2026

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Dose selection from Phase 2/3 Duravelo-2 trial and update on potential approval pathway expected in 1Q 2026 as company seeks feedback from multiple regulatory agencies

Emerging radiopharmaceuticals pipeline progressing, with additional EphA2 human imaging data planned for the first half of 2026

Initial data for Phase 1/2 Duravelo-3 trial exploring zelenectide pevedotin in NECTIN4 amplified breast cancer expected in the second half of 2026

Expected financial runway into 2028 to support execution of clinical and strategic priorities

CAMBRIDGE, England & BOSTON--(BUSINESS WIRE)--Jan. 12, 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 highlights 2025 accomplishments and strategic priorities for 2026.

"In 2025, we remained steadfast in our goal of helping patients live longer and live well, making meaningful advancements to our pipeline and strengthening the operational capabilities that support our strategic priorities. In addition to the progress we continue to make with zelenectide pevedotin and BT5528, our recently announced collaborations with the United Kingdom Nuclear Decommissioning Authority, United Kingdom National Nuclear Laboratory and SpectronRx provide us with the potential for an end-to-end supply chain for ^{212}Pb, building on the existing supply chains we have established for ^{177}Lu and ^{68}Ga. In summary, by combining these supply collaborations with our proprietary Bicycle technology we have established a unique radiopharmaceutical capability from the identification of Bicycle targeting agents to the potential commercial supply of the radiotherapeutic across multiple radioisotopes," said Bicycle Therapeutics CEO Kevin Lee, Ph.D. "We look forward to providing updates on the potential approval pathway for zelenectide pevedotin and dose selection from the Phase 2/3 Durvelo-2 trial in the first quarter of 2026."

2025 Key Accomplishments

- Reported updated topline Phase 1 Duravelo-1 combination data for zelenectide pevedotin plus pembrolizumab in first-line cisplatin-ineligible patients with metastatic urothelial cancer (mUC). The data continue to show zelenectide pevedotin's promising anti-tumor activity and differentiated safety profile.
- Initiated Phase 1/2 Duravelo-3 trial for zelenectide pevedotin in NECTIN4-amplified breast cancer.
- Initiated Phase 1/2 Duravelo-4 trial for zelenectide pevedotin in NECTIN4-amplified non-small cell lung cancer.
- Reported first human imaging data for an early Bicycle® Radioconjugate (BRC®) molecule targeting EphA2 at the Targeted Radiopharmaceuticals Summit Europe. The data supports the potential of EphA2 as a novel cancer target and demonstrates the positive properties of BRC molecules for radiopharmaceutical use.
- Presented additional human imaging data for an early Bicycle® Radioconjugate (BRC®) molecule targeting MT1-MMP at the American Association for Cancer Research (AACR) Annual Meeting 2025. The company believes this data further supports the potential of MT1-MMP as a novel target in the treatment of cancer, demonstrates the translatability of BRC preclinical data and highlights the potential of Bicycle® molecules for targeted radionuclide therapies and radiopharmaceutical imaging.

2026 Strategic Priorities and Anticipated Milestones

Nectin-4 Pipeline (zelenectide, BT7480)

- Provide an update on dose selection for Phase 2/3 Duravelo-2 pivotal trial and zelenectide pevedotin's potential approval pathway in mUC following meetings with multiple regulatory agencies in the first quarter of 2026.
- Report dose selection data from Phase 2/3 Duravelo-2 pivotal trial evaluating zelenectide pevedotin in combination with pembrolizumab in patients with mUC at a scientific conference in the first half of 2026.
- Report additional Phase 1 Duravelo-1 combination data with pembrolizumab in first-line cisplatin-ineligible mUC at a scientific conference in the first half of 2026.
- Report longer-term follow-up Phase 1 Duravelo-1 monotherapy data in late-line mUC at a scientific conference in the first half of 2026.
- Report initial data for Phase 1/2 Duravelo-3 trial for zelenectide pevedotin in NECTIN4-amplified breast cancer at a scientific conference in the second half of 2026.
- Report Phase 1 BT7480 combination data with nivolumab at a scientific conference in the first half of 2026.

EphA2 Pipeline (BT5528, EphA2 imaging)

- Report Phase 1 BT5528 combination data with nivolumab in mUC patients at a scientific conference in the first half of 2026.
- Provide an update on future clinical development plans for BT5528 in the first half of 2026.
- Report additional EphA2 human imaging data in the first half of 2026.

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: Bicycle’s expectations with respect to the benefits of its agreements and collaborations with United Kingdom Nuclear Decommissioning Authority (NDA), United Kingdom National Nuclear Laboratory (UKNNL) and SpectronRx, respectively; Bicycle’s ability to leverage its agreements with NDA and SpectronRx and collaboration with UKNNL to create the world’s first end-to-end ^{212}Pb radiopharmaceutical ecosystem; the initiation of new clinical trials, the progress of Bicycle’s clinical trials, reporting data from Bicycle’s clinical trials, including for BT5528 and BT7480, the timing of EphA2 human imaging data and updates on future clinical development plans for BT5528 and dose selection in the Duravelo-2/3 clinical trial and approval pathway; the validation of MT1-MMP as a cancer target and BRC molecules having positive properties for radiopharmaceutical imaging; communications with and feedback from the FDA and other regulatory agencies; Bicycle’s expected financial runway; and the use of Bicycle’s technology through various partnerships to develop therapies for diseases beyond oncology. 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; 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’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-Q filed with the Securities and Exchange Commission (SEC) on October 30, 2025, 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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