# Bicycle Therapeutics Reports First Quarter 2020 Financial Results and Provides Corporate Update

May 7, 2020

*- Significant recent progress achieved across pipeline of innovative* Bicycle®*-based therapies for oncology and beyond*

*- Dosing underway in Phase I dose escalation of BT5528 in combination with nivolumab*

*- Continued to strengthen corporate leadership with appointment of General Counsel*

*- Cash was $109.6 million at March 31, 2020*

CAMBRIDGE, England & BOSTON--(BUSINESS WIRE)--May 7, 2020-- Bicycle Therapeutics plc (NASDAQ:BCYC), a biotechnology company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (*Bicycles*®) technology, today reported financial results for the first quarter ended March 31, 2020 and discussed recent corporate updates.

"We are very proud of the tremendous progress we've made executing against our 2020 goals in the first few months of this year," said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. "Since January, we've entered two new immuno-oncology collaborations, including a partnership with Genentech worth up to $1.7 billion, and reached key milestones in the advancement of our clinical programs, such as establishing a recommended Phase II dose for our most advanced *Bicycle* Toxin Conjugate (BTC) BT1718 and advancing BT5528, our first second-generation BTC, through the Phase I dose escalation quickly. We also welcomed to Bicycle our General Counsel, Zafar Qadir, who brings extensive legal expertise and experience that will be integral to the achievement of our near- and long-term objectives. Despite uncertainties associated with the COVID-19 pandemic, we remain focused on achieving our stated goals for the year as planned. We look forward to providing updates on our progress as we advance our novel therapeutic candidates into and through the clinic."

**First Quarter 2020 and Recent Highlights**

- **Appointed Zafar Qadir as General Counsel.** Mr. Qadir joined Bicycle as head of the Company's legal function in April 2020.
- **Provided Comprehensive Pipeline Progress Update.** In April 2020, Bicycle announced updates across its wholly-owned and partnered programs in oncology and non-oncology indications:
  - The key objectives were met in the Phase I dose escalation portion of the Phase I/IIa study of **BT1718**, a BTC targeting MT1-MMP, in patients with solid tumors, sponsored by Cancer Research UK. A recommended Phase II dose was set at 20 mg/m$^2$ administered once weekly. With once-weekly dosing, BT1718 appeared tolerable, with manageable adverse events. Additionally, preliminary signs of anti-tumor activity were observed, including one partial response of a 68% reduction in a target lesion. The Company continues to expect that Cancer Research UK will initiate the Phase IIa portion of the Phase I/IIa study of BT1718 in 2020, although timing may be dependent on the impact of the COVID-19 pandemic. At present, enrollment of new patients into the Phase IIa portion of the trial at Cancer Research UK clinical sites in the UK has been paused due to the COVID-19 pandemic.
  - To date, administered doses of **BT5528**, a second-generation BTC targeting EphA2, appear well-tolerated with manageable adverse events in the ongoing Phase I/II trial in patients with advanced solid tumors associated with EphA2 expression. Dosing in both the monotherapy and nivolumab combination arms is underway. The combination arm opened in the second quarter of 2020, and the monotherapy escalation continues toward clinically relevant doses.
  - In 2020, Bicycle expects to initiate a Phase I/II trial of **BT8009**, a second-generation BTC targeting Nectin-4, in patients with advanced solid tumors, subject to potential timing and other impacts of the ongoing COVID-19 pandemic.
  - IND-enabling activities for **BT7480** are ongoing and on track to a potential initiation of clinical development in 2021, subject to potential timing and other impacts of the ongoing COVID-19 pandemic. BT7480 is a tumor-targeted immune cell agonist (TICA™) that targets Nectin-4 and agonizes CD137.
  - The Company expanded its immuno-oncology pipeline, selecting **BT7455** as a new TICA candidate. BT7455 targets EphA2 and agonizes CD137.
  - Cancer Research UK continues to advance preclinical development of **BT7401**, a systemic agonist of CD137.
  - Progress has also been made in the Company's partnered programs **beyond oncology:** preparations for Oxurion's Phase II trial of THR-149 are ongoing; three target programs in respiratory, cardiovascular, and metabolic diseases were transitioned to AstraZeneca for subsequent optimization towards potential candidate selection; and there has been early success in the collaboration with Dementia Discovery Fund (DDF) to develop *Bicycles* to modulate the activity of proteins implicated in the progression of dementia.
- **Entered into Strategic Collaboration with Genentech to Discover, Develop and Commercialize Novel *Bicycle*-based**

**Immuno-oncology Therapies.** In February 2020, Bicycle entered into a strategic collaboration agreement with Genentech. Under the terms of the agreement, Bicycle will be responsible for discovery research and early preclinical development up to candidate selection. Bicycle received a $30 million upfront payment. The upfront payment, an early milestone payment and potential future milestone payments could total up to $1.7 billion. Bicycle will also be eligible to receive tiered royalties. None of Bicycle's wholly-owned oncology assets, including its immuno-oncology candidates, are included in the collaboration.

**Upcoming Investor Presentation**

Bicycle will present at the Bank of America 2020 Health Care Conference on Thursday, May 14, 2020 at 3:00 p.m. ET. The conference will be held in a virtual meeting format.

A live webcast of the presentation will be accessible in the Investors & Media section of Bicycle's website at bicycletherapeutics.com. An archived replay of the webcast will be available for 60 days following the presentation date.

**Financial Results**

- Cash and cash equivalents were $109.6 million as of March 31, 2020, compared with $92.1 million as of December 31, 2019. Cash at March 31, 2020 includes the $30 million upfront payment from Genentech.
- Research and development expenses totaled $7.8 million for the three months ended March 31, 2020, compared to $6.3 million for the three months ended March 31, 2019. The increase of $1.5 million is primarily due to increased clinical and TICA program development expenses, partially offset by lower development expenses of other programs due to timing and an increase in personnel related costs, including $0.6 million of incremental non-cash share-based compensation expense.
- General and administrative expenses were $5.0 million for the three months ended March 31, 2020, compared to $3.4 million for the three months ended March 31, 2019. The increase of $1.6 million is primarily due to an increase in personnel related costs, including $1.3 million of incremental non-cash share-based compensation expense as well as professional fees and costs related to operations as a public company, partially offset by a favorable effect of foreign exchange rates.
- Net loss was $11.3 million, or $(0.63) basic and diluted net loss per share, for the three months ended March 31, 2020, compared to net loss of $6.5 million, or $(7.80) basic and diluted net loss per share, for the quarter ended March 31, 2019.

**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's lead product candidate, BT1718, a *Bicycle* Toxin Conjugate (BTC) that targets MT1-MMP, is being investigated in an ongoing Phase I/IIa clinical trial in collaboration with the Centre for Drug Development of Cancer Research UK. Bicycle is also evaluating BT5528, a second-generation BTC targeting EphA2, in a Company-sponsored Phase I/II study. Bicycle is headquartered in Cambridge, UK with many key functions and members of its leadership team located in Lexington, 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 collaborations with multiple third parties; the discovery, development and potential commercialization of product candidates using Bicycle's technology and under collaboration agreements with third parties; anticipated advancement of preclinical development efforts and initiation and progression of clinical trials; the therapeutic potential for *Bicycles* in various disease applications; the potential impacts of the ongoing COVID-19 pandemic on site initiation, patient enrollment and treatment; Bicycle's ability to achieve planned milestones; and the potential to receive milestone payments and royalties under our collaboration agreements. 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: the risk that Bicycle may not realize the intended benefits of its technology, including that Bicycle or its collaboration partners may not identify, develop and commercialize additional product candidates; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of Bicycle's product candidates; availability and timing of results from preclinical studies and clinical trials; 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 and studies may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of Bicycle's product candidates; risks related to Bicycle's ability to maintain existing collaborations and realize the benefits thereof; expectations for regulatory approvals to conduct trials or to market products; risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as to Bicycle's and its collaboration partners' abilities to meet other anticipated deadlines and milestones, presented by the ongoing COVID-19 pandemic; and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, are described in greater detail in the section entitled "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 10, 2020, 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 as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Collaboration revenues | $ 1,129 | $ 6,384 |
| Operating expenses: | | |
| Research and development | 7,774 | 6,276 |
| General and administrative | 4,998 | 3,402 |
| Total operating expenses | 12,772 | 9,678 |
| Loss from operations | (11,643) | (3,294) |
| Other income (expense): | | |
| Interest and other income | 212 | 64 |
| Other expense, net | — | (3,193) |
| Total other income (expense), net | 212 | (3,129) |
| Net loss before income tax provision | (11,431) | (6,423) |
| (Benefit from) provision for income taxes | (107) | 80 |
| Net loss | $ (11,324) | $ (6,503) |
| Net loss attributable to ordinary shareholders | $ (11,324) | $ (6,503) |
| Net loss per share attributable to ordinary shareholders, basic and diluted | $ (0.63) | $ (7.80) |
| Weighted average ordinary shares outstanding, basic and diluted | 17,997,929 | 834,043 |

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

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Cash | $ 109,637 | $ 92,117 |
| Working capital | 107,193 | 95,325 |
| Total assets | 129,282 | 110,194 |
| Shareholders' equity | 81,813 | 93,198 |

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