Bicycle Therapeutics Reports Second Quarter 2019 Financial Results and Provides Clinical Update

August 8, 2019

- Provides update on thePhase I/IIa trial evaluating lead asset BT1718 in patients with advanced solid tumors

- Successfully completed initial public offering (IPO) raising gross proceeds of $64.9 million

- Strengthened Board of Directors and clinical leadership team

CAMBRIDGE, England, & BOSTON--(BUSINESS WIRE)--Aug. 8, 2019-- Bicycle Therapeutics plc, a biotechnology company pioneering a new class of therapeutics based on its proprietary bicyclic peptide (*Bicycles*®) product platform, today reported financial results for the second quarter ended June 30, 2019 and provided a clinical update.

"The second quarter of this year was marked by the completion of our initial public offering, placing us in a solid financial position to advance our novel pipeline of *Bicycle* drug candidates through the clinic," said Kevin Lee, Ph.D., Chief Executive Officer of Bicycle Therapeutics. "We are pleased with the progress that our pipeline has made over the last quarter, including BT1718, which continues to progress in Phase I dose escalation. We believe that *Bicycles*, because of their low molecular weight and high affinity and selectivity, could provide meaningful efficacy to patients suffering from cancer and could avoid the toxicities associated with other classes of highly potent anti-cancer drugs, and we look forward to providing updates on our progress."

Second Quarter 2019 and Recent Highlights

- **Provided Update on the Phase I/IIa Trial Evaluating Lead Asset BT1718 in Patients with Advanced Solid Tumors.** Today, Bicycle announced that in the 25 mg/m^2 once weekly cohort, no dose limiting toxicities were observed, and the decision was made to continue with dose escalation.

- **Announced Changes to the Board of Directors.** In July 2019, Bicycle announced changes to the composition of its Board of Directors, including the appointment of pharmaceutical industry veteran Richard N. Kender and life sciences financing professional Janice Bourque, as well as an orderly transition for four board members to depart over the next twelve months, which will result in a reduction of the Company's board size while enhancing its scientific and U.S. public company board expertise.

- **Announced Positive Topline Results from Oxurion's Phase I Trial Using Novel *Bicycle*-based Plasma Kallikrein Inhibitor for the Treatment of Diabetic Macular Edema.** In July 2019, Bicycle announced the successful completion of Oxurion's Phase I clinical trial evaluating the safety and tolerability of a single intravitreal injection of THR-149, a novel *Bicycle*-based plasma kallikrein (PKal) inhibitor, in patients with diabetic macular edema (DME). No dose-limiting toxicities or drug-related adverse events were reported. A rapid onset of action was observed from Day 1, with an increasing average improvement in patients' best corrected visual acuity (BCVA) of up to 7.5 letters at Day 14. This activity was maintained with an average improvement in BCVA of 6.5 letters at Day 90 following the single injection.

- **Completed Initial Public Offering.** In May 2019, Bicycle completed its initial public offering (IPO) of 4,637,666 American Depositary Shares (ADSs), which included a partial exercise of the underwriters' option to purchase additional ADSs, at $14.00 per ADS, for gross proceeds of $64.9 million, before deducting underwriting discounts, commissions and offering expenses.

- **Entered Collaboration with Dementia Discovery Fund**. In May 2019, Bicycle announced its collaboration with the Dementia Discovery Fund (DDF), which allows the organization to use Bicycle technology for the development of novel therapeutics for neurodegenerative diseases. Under the terms of the agreement, Bicycle will identify *Bicycles* that bind to genetically-validated dementia targets. If promising lead compounds are identified, Bicycle will own the resulting IP and, with DDF, have the option to jointly establish a new company to develop those compounds.

- **Strengthened Clinical Team to Advance Expanding Pipeline.** In May 2019, Bicycle announced two senior appointments to help expand the Company's clinical pipeline. Lisa Mahnke, M.D., Ph.D., joined as Senior Vice President and Head of Clinical and Terrence West, MBA, joined as Vice President and Head of Program Management. Dr. Mahnke was recently VP, Head of Clinical Development at Syros Pharmaceuticals and previously served at EMD Serono. Mr. West was previously Executive Director, Project Management, at EMD Serono.

Financial Results

- Cash and cash equivalents were $108.5 million as of June 30, 2019, compared with $63.4 million as of December 31, 2018. In the second quarter of 2019, Bicycle completed its IPO for gross proceeds of $64.9 million, before deducting underwriting discounts, commissions and offering expenses.

- Collaboration revenues were $1.5 million for the three months ended June 30, 2019 compared to $1.7 million for the three months ended June 30, 2018. The change in revenue includes $1.1 million of revenue recognized from new collaboration activities in Q2 2019, offset by a decrease in Sanofi revenue.

- Research and development expenses totaled $6.5 million for the three months ended June 30, 2019, compared to $4.9 million for the three months ended June 30, 2018. The increase of $1.6 million is primarily due to a $2.5 million increase in direct program related spending and personnel related expenses, offset by an increase in research and development tax credit reimbursement of $0.9 million.

- General and administrative expenses were $3.0 million for the three months ended June 30, 2019, compared to $1.7 million for the three months ended June 30, 2018. The increase was largely due to increased personnel costs associated with the growth of the Company and professional fees related to operations as a public company.

- Net loss was $10.2 million, or $(1.40) basic and diluted net loss per share, for the three months ended June 30, 2019, compared to net loss of $5.0 million, or $(11.85) basic diluted net income per share, for the three months ended June 30, 2018.

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, is a *Bicycle* Toxin Conjugate being investigated in an ongoing Phase I/IIa clinical trial in collaboration with the Centre for Drug Development of Cancer Research UK. Bicycle is headquartered in Cambridge, U.K. 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 the clinical development of BT1718 or any of Bicycle's other product candidates or programs; statements regarding the potential results of Bicycle's collaboration with the Dementia Discovery Fund; and statements regarding the potential impact of new directors and employees on Bicycle's development. 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 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 interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; our ability to maintain existing collaborations and realize the benefits thereof and develop new relationships; expectations for regulatory approvals to conduct trials or to market product; 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 the final prospectus for our initial public offering, filed with the Securities and Exchange Commission (SEC) on May 23, 2019, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenues	$1,522	$1,661	$7,906	$4,469
Operating expenses:				
Research and development	6,537	4,917	12,813	8,626
General and administrative	2,973	1,702	6,375	3,690

Total operating expenses	9,510	6,619	19,188	12,316
Loss from operations	(7,988)	(4,958)	(11,282)	(7,847)
Other income (expense):				
Interest and other income	90	52	154	49
Other expense, net	(2,184)	(73)	(5,377)	(111)
Total other expense, net	(2,094)	(21)	(5,223)	(62)
Net loss before income tax provision	(10,082)	(4,979)	(16,505)	(7,909)
Provision for (benefit from) income taxes	135	—	215	(396)
Net loss	$(10,217)	$(4,979)	$(16,720)	$(7,513)
Net loss attributable to ordinary shareholders	$(10,217)	$(4,979)	$(16,720)	$(7,513)
Net loss per share attributable to ordinary shareholders, basic and diluted	$(1.40)	$(11.85)	$(4.08)	$(18.38)
Weighted average ordinary shares outstanding, basic and diluted	7,298,139	420,063	4,101,564	408,807

Balance Sheets Data
(In thousands)
(Unaudited)

	June 30, 2019	December 31, 2018
Cash	$108,536	$63,380
Working capital	111,012	67,840
Total assets	126,246	81,626
Shareholders equity (deficit)	104,559	(69,826)

View source version on businesswire.com: https://www.businesswire.com/news/home/20190808005162/en/

Source: Bicycle Therapeutics

Media:
Ten Bridge Communications
Sara Green
sgreen@tenbridgecommunications.com
+1-617-233-1714

Investors:
Argot Partners
Maeve Conneighton
maeve@argotpartners.com
+1-212-600-1902