

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**

January 3, 2022

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.)

**B900, Babraham Research Campus**  
**Cambridge CB22 3AT**  
**United Kingdom**

(Address of principal executive offices)

**Not Applicable**  
(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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On January 5, 2022, Bicycle Therapeutics plc (the “Company”) announced the appointment of Alistair Milnes, age 48, as the Company’s Chief Operating Officer, effective as of January 3, 2022 (the “Effective Date”). Mr. Milnes assumes the role of Chief Operating Officer following the transition of Michael Skynner, Ph.D. to the newly-created role of Chief Technology Officer of the Company as of the Effective Date.

Mr. Milnes joined the Company in January 2021 as Vice President, Human Resources and Communications. Prior to joining the Company, Mr. Milnes provided independent human resources consulting services, including to the Company, from October 2020 to December 2020. He also previously served as Strategic Advisor, Transformation, People and Communications at Rio Tinto from January 2020 to December 2020, and in roles of increasing responsibility at Gazprom Marketing & Trading Ltd. from 2010 to October 2019, including serving as Director of Global Human Resources from December 2013 to November 2017, following which he became Director of Global Human Resources and Communications. Mr. Milnes received his B.A. from Edinburgh Napier University.

Mr. Milnes’ service as Chief Operating Officer of the Company is governed by a service agreement, effective as of the Effective Date, between BicycleTx Ltd. (“BicycleTx”) and Mr. Milnes (the “Service Agreement”). Pursuant to the terms of the Service Agreement, Mr. Milnes will receive an annual base salary of £365,000 and is eligible to earn an annual cash incentive award based on performance with a target value equal to 50% of his annual base salary. Mr. Milnes remains eligible to participate in BicycleTx’s employee benefit plans generally available to BicycleTx executive employees, subject to the terms of those plans.

In connection with his appointment and pursuant to the Service Agreement, the Compensation Committee of the Board of Directors of the Company (the “Compensation Committee”) approved a grant to Mr. Milnes on the Effective Date of an option (the “Option”) to purchase 70,000 of the Company’s ordinary shares, nominal value £0.01 per share (the “Ordinary Shares”), pursuant to the Company’s 2020 Equity Incentive Plan. Twenty-five percent of the Ordinary Shares underlying the Option will vest on the first anniversary of the Effective Date, and the remainder of the Ordinary Shares underlying the Option will vest in 36 equal installments monthly thereafter, subject to Mr. Milnes’ continued employment through each such vesting date. Mr. Milnes also received an annual equity incentive award grant commensurate with those received by the Company’s other executive officers on the Effective Date, pursuant to the Company’s standard equity compensation arrangements approved by the Compensation Committee.

Mr. Milnes’ employment has no specified term but can be terminated by either party in writing giving the other no less than six months’ notice. Mr. Milnes’ employment may be terminated, immediately and without notice, pursuant to the conditions specified in the Service Agreement, in which event Mr. Milnes would then be entitled to certain accrued obligations and may, depending on the circumstances, be entitled to receive payment in lieu of salary and benefits for all or any part of the notice period to which he would otherwise have been entitled. If Mr. Milnes’ employment is terminated as a result of his death, by BicycleTx without Cause (as defined in the Service Agreement) or by Mr. Milnes for Good Reason (as defined in the Service Agreement), BicycleTx will owe Mr. Milnes severance pay, the amount of which will depend on whether such termination occurs within the 12-month period following a Change of Control (as defined in the Service Agreement) of the Company. If such termination occurs within such 12-month period, Mr. Milnes would be entitled to receive a payment equal to 12 months of his then-annual salary, his target annual performance bonus for the year of termination, and benefits continuation (or cash in lieu thereof) for 12 months following his termination. Any equity awards held by Mr. Milnes subject to time-based vesting would also become fully vested. If such termination occurs other than within the 12-month period following a Change of Control (as defined in the Service Agreement) of the Company, Mr. Milnes would be entitled to receive a payment equal to nine months of his then annual salary, and benefits continuation (or cash in lieu thereof) for nine months following termination. The Service Agreement also binds Mr. Milnes to customary confidentiality, intellectual property and post-termination covenants.

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In connection with his appointment as Chief Operating Officer, Mr. Milnes will also execute the Company's standard form of deed of indemnity, the form of which was filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") on November 12, 2019.

Mr. Milnes was not selected as an officer of the Company pursuant to any understanding or arrangement between him and any other person, he has no family relationships with any of the Company's directors or executive officers, and he has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

The foregoing description of the Service Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Service Agreement, which will be filed as an exhibit to a subsequent filing with the SEC.

**Item 7.01 Regulation FD Disclosure.**

On January 5, 2022, the Company posted an updated corporate presentation on the Company's website. To access the presentation, investors should visit the "Investor Events and Presentations" section of the Company's website at [investors.bicycletherapeutics.com](http://investors.bicycletherapeutics.com).

The information furnished under this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the SEC made by the Company, regardless of any general incorporation language in such filing.

**Item 8.01 Other Events.**

On January 5, 2022, the Company issued a press release announcing continued clinical progress in its ongoing Phase I/II clinical trials of BT8009, BT5528, and BT7480, as well as the management transitions described in Item 5.02 of this Current Report on Form 8-K. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

**Item 9.01 Financial Statements and Exhibits**

(a) Exhibits

[99.1](#) [Press Release issued January 5, 2022](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: January 5, 2022

**BICYCLE THERAPEUTICS PLC**

By: /s/ Lee Kalowski

Name: Lee Kalowski

Title: Chief Financial Officer

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### **Bicycle Therapeutics Announces Continued Clinical Progress and Updates to Management Team**

**CAMBRIDGE, England, & BOSTON, January 5, 2022** – Bicycle Therapeutics plc (NASDAQ: BCYC), a biotechnology company pioneering a new and differentiated class of therapeutics based on its proprietary bicyclic peptide (*Bicycle*®) technology, today announced continued progress in its ongoing Phase I/II clinical trials of BT8009, BT5528 and BT7480.

“Last quarter, we reported interim clinical results from ongoing trials of two of our *Bicycle* toxin conjugates, BT8009 and BT5528, demonstrating preliminary anti-tumor activity in two tumor types, and announced the first patient dosed in the Phase I clinical trial of BT7480, our first tumor-targeted immune cell agonist to enter the clinic. In our trial of BT8009, we are pleased to confirm the preliminary activity and see that these patients remain on trial. We look forward to presenting interim BT8009 Phase I results at a medical meeting and initiating the BT5528 expansion cohorts this year,” said Kevin Lee, Ph.D., Chief Executive Officer. “We are also pleased with our progress advancing BT7480 in the ongoing Phase I clinical trial and look forward to sharing additional details regarding the potential for *Bicycles* beyond our toxin conjugates as we strive to become a leader in the development of targeted oncology therapeutics.”

#### ***Bicycle* Toxin Conjugates® (BTCs) BT8009 and BT5528**

In the ongoing Phase I portion of the Phase I/II clinical trial of BT8009, a second-generation BTC<sup>TM</sup> targeting Nectin-4, four out of 11 patients were previously reported to have a partial response under Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, including one out of four (25%) in the 2.5mg/m<sup>2</sup> dose and three out of seven (43%) at the 5.0 mg/m<sup>2</sup> cohorts. All four patients previously reported as responders have since received at least one subsequent scan, and all have been confirmed as ongoing RECIST 1.1 responses. One patient in the 5.0 mg/m<sup>2</sup> cohort, who previously was reported to have a partial response with an 89% tumor reduction, has now received two subsequent scans, which each showed that total tumor volume has been reduced by 100%, constituting a confirmed complete response. All four patients previously reported to have a RECIST 1.1 clinical response remain on therapy. The tolerability profile of the 2.5mg/m<sup>2</sup> and 5.0 mg/m<sup>2</sup> cohorts remains consistent with that previously reported.

Dose escalation in the BT8009 Phase I trial remains ongoing, with patients currently being dosed at 7.5mg/m<sup>2</sup> weekly or every-other-week. Bicycle intends to present interim Phase I results from the ongoing clinical trial at a medical meeting this year.

The Phase I/II trial of BT5528, Bicycle’s second-generation BTC targeting EphA2, is also ongoing, with plans remaining on track to initiate the expansion cohorts this year, with an expected recommended Phase II dose of 6.5mg/m<sup>2</sup> every-other-week.

#### ***Bicycle* tumor-targeted immune cell agonist<sup>TM</sup> (*Bicycle* TICA<sup>TM</sup>) BT7480**

Bicycle also initiated a Phase I clinical trial of BT7480, a novel, fully synthetic *Bicycle* TICA targeting Nectin-4 and agonizing CD137, in the fourth quarter of 2021, and dose escalation in that trial remains ongoing. BT7480 and other *Bicycle* TICAs, including a novel NK-cell-engaging molecule, were the subjects of four posters at SITC in November 2021.

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## Management Team Updates

Bicycle is also announcing the expansion of and transition in its management team. Michael Skynner, Ph.D., the company's Chief Operating Officer (COO), has been appointed to the newly created position of Chief Technology Officer, effective January 3, 2022, to focus on leading and overseeing the growth of Bicycle's proprietary phage display discovery platform in oncology, as well as on creating innovative opportunities for the platform outside of oncology. Dr. Skynner joined the company in January 2016 as Vice President, Operations and Discovery and had served as COO since March 2018. Alistair Milnes, who has served as the company's Vice President, Human Resources and Communications since January 2021, has assumed the COO role. Mr. Milnes previously led human resources and communications at multinational energy and mineral companies. Both Dr. Skynner and Mr. Milnes are based in the United Kingdom.

"We are delighted to announce our recent management team appointments, with Mike Skynner becoming our new CTO and Alistair Milnes moving to the COO role. Mike has been an invaluable contributor to Bicycle's success to date and has led our platform discovery efforts since joining in early 2016. Following recent promising clinical progress, we believe it is time to focus on accelerating the growth of our proprietary oncology pipeline and on identifying innovative ways to potentially capitalize on our unique technology beyond our current therapeutic focus. I am confident that Mike can help us achieve these objectives." Dr. Lee added, "I am similarly enthusiastic about Alistair's appointment as COO and believe his operational experience and track record of successfully identifying, recruiting, and retaining key talent at large, multinational companies will be instrumental in helping guide Bicycle through our next phase of growth."

## 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 is evaluating BT5528, a second-generation *Bicycle* Toxin Conjugate (BTC™) targeting EphA2; BT8009, a second-generation BTC targeting Nectin-4, a well-validated tumor antigen; and BT7480, a *Bicycle* TICA™ targeting Nectin-4 and agonizing CD137, in company-sponsored Phase I/II trials. In addition, BT1718, a BTC that targets MT1-MMP, is being investigated in an ongoing Phase I/IIa clinical trial sponsored by the Cancer Research UK Centre for Drug Development. 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](http://bicycletherapeutics.com).

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## 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 discovery, development and potential commercialization of potential product candidates using Bicycle’s technology; Bicycle’s anticipated advancement of its product candidates, including BT5528, BT8009 and BT7480; the advancement of Bicycle’s product candidate pipeline; anticipated design of, initiation of expansion cohorts in and progression of Bicycle’s clinical trials; the availability of data from clinical trials; the therapeutic potential for *Bicycles* in oncology and other applications; and Bicycle’s ability to accelerate its product pipeline and identify potentially innovative applications of its technology 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: risks to clinical trial site initiation, patient enrollment and follow-up, as well as to Bicycle’s abilities to meet other anticipated deadlines and milestones, presented by the ongoing COVID-19 pandemic; uncertainties inherent in the initiation 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; availability and timing of results from clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial results; 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 may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of Bicycle’s product candidates; the risk that Bicycle may not be able to identify additional product candidates or additional applications of its technology; 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 4, 2021, 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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