

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

Date of Report (Date of earliest event reported): May 29, 2024

Iterum Therapeutics plc

(Exact name of Registrant as Specified in Its Charter)

Ireland
(State or Other Jurisdiction
of Incorporation)

001-38503
(Commission File Number)

Not applicable
(IRS Employer
Identification No.)

Fitzwilliam Court
1st Floor
Leeson Close
Dublin 2, , Ireland
(Address of Principal Executive Offices)

Not applicable
(Zip Code)

Registrant’s Telephone Number, Including Area Code: +353 1 6694820

(Former Name or Former Address, if Changed Since Last Report)

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, par value \$0.01 per share	ITRM	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 May 29, 2024, Iterum Therapeutics International Limited (“ITIL”), a subsidiary of Iterum Therapeutics plc (the “Company”), entered into a consulting agreement with Sailaja Puttagunta M.D., the Company’s Chief Medical Officer (“CMO”), with an effective date of June 1, 2024 (the “Consulting Agreement”).

The Consulting Agreement provides that Dr. Puttagunta, whose previously announced resignation as CMO is effective as of May 31, 2024, will serve as a consultant to ITIL providing general support and advice throughout the regulatory review period of the Company’s recently resubmitted new drug application for oral sulopenem for the treatment of uncomplicated urinary tract infections in adult women (the “Services”). In consideration for the provision of the Services, Dr. Puttagunta is entitled to a consulting fee of \$400 per hour. Either party may terminate the Consulting Agreement with two weeks’ prior written notice to the other party.

The foregoing description of the terms of the Consulting Agreement is a summary and is qualified in all respects by reference to the text of the Consulting Agreement, a copy of which will be filed as an exhibit to the Company’s quarterly report on Form 10-Q for the quarter ending June 30, 2024.

Item 8.01 Other Events.*Acceptance of plan for regaining compliance with Nasdaq Listing Rule 5550(b)(1)*

As previously disclosed, on April 3, 2024, the Company received a letter from Nasdaq Stock Market LLC (“Nasdaq”) indicating that it was not in compliance with Nasdaq Listing Rule 5550(b)(1), because (i) the stockholders’ equity (deficit) of the Company of (\$6,403,000) as of December 31, 2023, as reported in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, was below the minimum stockholders’ equity requirement of \$2,500,000 and (ii) the Company did not, as of April 3, 2024, meet the alternatives standards of market value of listed securities or net income from continuing operations for compliance with Nasdaq Listing Rule 5550(b)(1). The letter indicated that the Company had a period of 45 calendar days from the date of the letter to submit a plan to regain compliance. The Company submitted its plan to regain compliance to Nasdaq on May 20, 2024.

On May 29, 2024, the Company received a letter from Nasdaq notifying the Company that Nasdaq had reviewed the Company’s plan for regaining compliance with Nasdaq Listing Rule 5550(b)(1) and granted the Company a 180-calendar day extension from April 3, 2024 (or until September 30, 2024) to evidence compliance with Nasdaq Listing Rule 5550(b)(1).

If the Company fails to evidence compliance with Nasdaq Listing Rule 5550(b)(1) on or before September 30, 2024, the Company may be subject to delisting. Were this to occur, Nasdaq will provide the Company notice that the Company’s ordinary shares are to be subject to delisting. At that time, the Company may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. However, there can be no assurance that, if the Company does appeal any delisting determination by Nasdaq to the panel, that such appeal would be successful.

The Company intends to take all reasonable measures available to regain compliance under the Nasdaq Listing Rule 5550(b)(1) and remain listed on Nasdaq. However, there can be no assurance that the Company will be able to regain compliance with Nasdaq Listing Rule 5550(b)(1), maintain compliance with the other Nasdaq listing requirements or be successful in appealing any delisting determination.

FDA acknowledgment of Oral Sulopenem NDA resubmission and PDUFA action date

On May 31, 2024, the Company issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) had acknowledged receipt of the resubmission of the new drug application (“NDA”) for sulopenem etzadroxil/probenecid, or oral sulopenem, for the treatment of uncomplicated urinary tract infections in adult women. Under the Prescription Drug User Fee Act (“PDUFA”), the FDA has deemed the Company’s NDA resubmission to be a Class II complete response which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date of October 25, 2024.

The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Iterum Therapeutics plc dated May 31, 2024

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.

Iterum Therapeutics plc

Date: May 31, 2024

By: /s/ Corey N. Fishman
Chief Executive Officer

Iterum Therapeutics Receives FDA Acceptance of Resubmission of NDA for Oral Sulopenem for the treatment of Uncomplicated Urinary Tract Infections

--Oral Sulopenem NDA has been assigned a PDUFA action date of October 25, 2024--

DUBLIN, Ireland and CHICAGO, May 31, 2024 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (the Company), a clinical-stage pharmaceutical company focused on developing next generation oral and IV antibiotics to treat infections caused by multi-drug resistant pathogens in both community and hospital settings, today announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of the resubmission of the New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTIs) in adult women. Under the Prescription Drug User Fee Act ("PDUFA"), the FDA has deemed the Company's NDA resubmission to be a Class II complete response which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date of October 25, 2024.

"We are very pleased that the FDA has accepted the resubmission of the NDA for oral sulopenem," said Corey Fishman, Chief Executive Officer. "This significant milestone brings us one step closer to the potential approval of oral sulopenem for uUTIs providing patients and physicians with a much-needed treatment option for this underserved market. We look forward to continuing to work with the FDA during its review."

The resubmission includes additional evidence from the REASSURE (**RE**newed **AS**essment of **S**ulopenem in **u**UTI caused by **R**esistant **E**nterobacteriales) clinical trial, conducted under Special Protocol Assessment agreement from the FDA, comparing oral sulopenem to oral Augmentin® in adult women with a uUTI, demonstrated that oral sulopenem was non-inferior to Augmentin® for the primary efficacy endpoint of clinical and microbiologic response at the test-of-cure visit for patients with an Augmentin® susceptible pathogen, with the difference in the overall success rate demonstrating statistically significant superiority of oral sulopenem versus Augmentin®.

About Iterum Therapeutics plc

Iterum Therapeutics plc is a clinical-stage pharmaceutical company dedicated to developing differentiated anti-infectives aimed at combatting the global crisis of multi-drug resistant pathogens to significantly improve the lives of people affected by serious and life-threatening diseases around the world. The Company is advancing its first compound, sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development with an oral formulation and IV formulation. Sulopenem has demonstrated potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. The Company has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding the Company's plans, strategies and prospects for its business, including the development, therapeutic and market potential of sulopenem. In some cases, forward-looking statements can be identified by words such as "may," "believes," "intends," "seeks," "anticipates," "plans," "estimates," "expects," "should," "assumes," "continues," "could," "would," "will," "future," "potential" or the negative of these or similar terms and phrases. Forward-looking statements involve known and unknown risks, uncertainties

and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include all matters that are not historical facts. Actual future results may be materially different from what is expected due to factors largely outside the Company's control, including the uncertainties inherent in the initiation and conduct of clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing of approval of any submission, changes in public policy or legislation, commercialization plans and timelines, if oral sulopenem is approved, the actions of third-party clinical research organizations, suppliers and manufacturers, the accuracy of the Company's expectations regarding how far into the future the Company's cash on hand will fund the Company's ongoing operations, the sufficiency of the Company's cash resources and the Company's ability to continue as a going concern, the Company's ability to maintain listing on the Nasdaq Capital Market, risks and uncertainties concerning the outcome, impact, effects and results of the Company's pursuit of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic process and the Company's ability to complete one, whether on attractive terms or at all, and other factors discussed under the caption "Risk Factors" in its most recently filed Annual Report on Form 10-K filed with the US Securities and Exchange Commission (SEC) on March 28, 2024, and other documents filed with the SEC from time to time. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this press release. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

Investor Contact:

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