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): June 19, 2024

Iterum Therapeutics plc

(Exact name of Registrant as Specified in Its Charter)

Ireland	**001-38503**	**Not applicable**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 5.07 Submission of Matters to a Vote of Security Holders.

On June 19, 2024, Iterum Therapeutics plc (the "**Company**") held its 2024 annual general meeting (the "**AGM**"), at which the Company's shareholders voted on the following proposals, each of which is described in the Company's definitive proxy statement (the "**Proxy Statement**"), filed with the Securities and Exchange Commission on April 26, 2024.

Proposal No. 1: Election of Directors. The shareholders elected, by separate resolutions, Corey Fishman and Ronald Hunt to the Company's board of directors as Class III directors, each to serve for a three-year term expiring at the Company's 2027 annual general meeting of shareholders. The results of the shareholders' vote for the election of such Class III directors were as follows:

Nominee	For	Against	Abstain	Broker Non-Votes
Corey Fishman	1,807,302	751,976	44,598	4,069,360
Ronald Hunt	1,450,446	1,108,449	44,981	4,069,360

Proposal No. 2: Ratification of Appointment of the Company's Independent Registered Public Accounting Firm for 2024 and Authorization of the Board of Directors to Approve the Remuneration of the Independent Registered Public Accounting Firm. The shareholders ratified, in a non-binding vote, the appointment of KPMG as the Company's independent registered public accounting firm for its fiscal year ended December 31, 2024 and authorized the Company's board of directors, acting through its audit committee, to set the independent registered public accounting firm's remuneration. The results of the shareholders' vote were as follows:

For	Against	Abstain
5,481,253	1,126,772	65,211

Proposal No. 3: Advisory vote on the compensation of the Company's Named Executive Officers. The shareholders approved, on a non-binding, advisory basis, the compensation of the Company's named executive officers as disclosed in the Proxy Statement. The results of the shareholders' vote were as follows:

For	Against	Abstain	Broker Non-Votes
1,693,628	856,073	54,175	4,069,360

Proposal No. 4: Advisory vote on the frequency of future advisory votes on the compensation of the Company's Named Executive Officers. A majority of the shareholders that voted on the matter indicated, on a non-binding, advisory basis, a preference for holding future advisory votes to approve the compensation of the Company's named executive officers every year. The results of the shareholders' vote were as follows:

1 Year	2 Years	3 Years	Abstain
2,343,747	13,408	147,733	98,988

In light of the voting results with respect to the frequency of future advisory votes on the compensation of the Company's named executive officers set forth above and the Company's board of directors' recommendation that shareholders vote to hold future advisory votes on executive compensation every year, the Company will hold advisory votes on executive compensation every year until the next required advisory vote on the frequency of such votes.

Item 8.01 Other Events.

On June 20, 2024, Iterum Therapeutics plc issued a press release announcing that the U.S. Food and Drug Administration (FDA) has determined that the New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTIs) in adult women will be taken to Advisory Committee, with September 9, 2024 being the proposed date for the Advisory Committee meeting. In its communication, the FDA highlighted that the purpose of the Advisory Committee was to discuss a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem.

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.

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc dated June 21, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: June 21, 2024

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

EXHIBIT 99.1

Iterum Therapeutics Announces FDA Advisory Committee Meeting to discuss NDA for Oral Sulopenem for the treatment of Uncomplicated Urinary Tract Infections

--Proposed Date for Advisory Committee meeting is September 9, 2024--

DUBLIN, Ireland and CHICAGO, June 21, 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 determined that the New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTIs) in adult women will be taken to Advisory Committee, and in its communication, highlighted that the purpose of the Advisory Committee was to discuss a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S.; and b) the most appropriate target patient population(s) for treatment of uUTI with sulopenem etzadroxil/probenecid. The proposed date for the Advisory Committee meeting is September 9, 2024.

“We look forward to having this important discussion around stewardship and patients that would benefit from oral sulopenem with the FDA and its advisors at the Advisory Committee in September,” said Corey Fishman, Chief Executive Officer.

In April 2024, the Company announced that it had resubmitted its NDA to the FDA for oral sulopenem for the treatment of uUTIs in adult women. In May 2024, the FDA acknowledged receipt of the resubmission of the NDA. Under the Prescription Drug User Fee Act (PDUFA), the FDA 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.

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 topics that will be covered at the upcoming Advisory Committee meeting regarding the Company’s NDA, the date by which the FDA will take action regarding the Company’s NDA and 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 Quarterly Report on Form 10-Q filed with the US Securities and Exchange Commission (SEC) on May 13, 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.

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