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 13, 2025

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.)**
3 Dublin Landings North Wall Quay Dublin 1, , Ireland		**Not applicable**
(Address of Principal Executive Offices)		**(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 1.01 Entry into a Material Definitive Agreement.

As previously disclosed, pursuant to a license agreement, dated November 18, 2015, by and among Iterum Therapeutics plc (the "Company"), Iterum Therapeutics International Limited ("ITIL") and Pfizer Inc. ("Pfizer" and such agreement, the "Pfizer License Agreement"), ITIL agreed to make a regulatory milestone payment of $20.0 million to Pfizer (the "Milestone Payment") upon the approval of oral sulopenem for commercial sale in the United States by the U.S. Food and Drug Administration ("FDA"). The Company had the option to deliver notice of its election to defer such payment for up to two years from the date of such approval and have a promissory note issued by ITIL in the amount of the Milestone Payment to Pfizer (the "Note") within 30 calendar days of such approval. On October 25, 2024, the Company received FDA approval for ORLYNVAH™ (sulopenem etzadroxil and probenecid) for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli*, *Klebsiellapneumoniae*, or *Proteus mirabili*s in adult women who have limited or no alternative oral antibacterial treatment options. On October 28, 2024, the Company notified Pfizer that it was electing to defer payment of the Milestone Payment for two years, or until October 25, 2026 (such period, the "Deferral Period"), and delivered the Note to Pfizer.

On May 13, 2025, the Company and ITIL entered into an amended and restated promissory note (the "A&R Note") and a letter agreement relating to the A&R Note and amending the Pfizer License Agreement in connection therewith (the "Letter Agreement"). The A&R Note extends the Deferral Period by an additional three years, or until October 25, 2029 (the "Extended Deferral Period"). In connection with the extension to the Deferral Period, ITIL agreed in the A&R Note to increase the annual rate of interest from eight percent (8%) to ten percent (10%) on a daily compounded basis during the Extended Deferral Period, beginning on October 26, 2026. ITIL also agreed that it would not, directly or indirectly, (1) create, incur, assume, guaranty or otherwise become liable for any indebtedness that is senior in right of payment to the A&R Note, except for indebtedness incurred with the consent or waiver of Pfizer, or (2) create, grant or incur any lien on any of its property or assets, subject to specified exceptions (including liens securing permitted indebtedness and liens incurred with the consent or waiver of Pfizer). Pursuant to the Letter Agreement, in consideration of Pfizer entering into the A&R Note, ITIL agreed to pay to Pfizer a non-refundable, non-creditable transaction fee and to pay Pfizer's reasonable and documented out-of-pocket legal expenses in connection therewith (together, the "Pfizer Transaction Fees"), with no further payments obligated to be made upon execution. The Company has guaranteed all of the amounts payable by ITIL under the terms of the Pfizer License Agreement and the related Letter Agreement, which includes the Pfizer Transaction Fees, pursuant to the guarantee delivered by the Company to Pfizer on November 18, 2015.

The A&R Note incorporates other material terms of the Note. ITIL has the right to prepay the unpaid principal balance of the A&R together with accrued and unpaid interest at any time without premium or penalty. Pursuant to the terms of the A&R Note, ITIL may (i) assign the A&R Note to an affiliate of ITIL; (ii) designate one of its affiliates to perform its obligations thereunder; or (iii) assign the A&R Note in the event of a change of control, provided that in the case of clauses (i) and (ii) ITIL is not relieved of any liability thereunder. Pursuant to the terms of the Pfizer License Agreement, if a change of control of ITIL or the Company occurs during the Deferral Period, Pfizer may, in its sole discretion and at its sole option, declare the Milestone Payment to be immediately due and payable together with all interest accrued under the A&R Note.

The foregoing descriptions of the A&R Note and the Letter Agreement are qualified in their entirety by reference to the full text of the A&R Note and the Letter Agreement, copies of which the Company intends to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ended June 30, 2025.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant

The information set forth in Item 1.01 of this Current Report on Form 8-K is incorporated into this Item 2.03 by reference.

Item 7.01 Regulation FD Disclosure.

The information set forth in Item 1.01 of this Current Report on Form 8-K is incorporated into this Item 7.01 by reference.

On May 19, 2025, the Company issued a press release announcing that the Company, ITIL and Pfizer had entered into the A&R Note and the Letter Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and Exhibit 99.1 attached hereto is "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc, dated May 19, 2025
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: May 19, 2025

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Announces Extension of Term of Promissory Note

DUBLIN, Ireland and CHICAGO, May 19, 2025 -- Iterum Therapeutics plc (Nasdaq: ITRM) (the "Company" or "Iterum"), a company focused on delivering next generation oral and IV antibiotics to treat infections caused by multi-drug resistant pathogens in both community and hospital settings, today reported that Pfizer Inc. ("Pfizer") has agreed to extend the term for payment of the regulatory milestone payment of $20.0 million until October 25, 2029.

"We are very pleased to announce that Pfizer has agreed to extend the due date for payment of the regulatory milestone associated with ORLYNVAH™'s approval by the FDA," said Corey Fishman, Iterum's Chief Executive Officer. "The $20.0 million promissory note was due October 2026 and is now due October 2029. As a result, any capital raised or earned in the near term from the sales of ORLYNVAH™ can be strategically invested to enable a successful launch of ORLYNVAH™, including through the expansion into new territories or concentration of resources in high prescribing geographies."

Pursuant to the license agreement entered into on November 18, 2015, by and among the Company, Iterum Therapeutics International Limited ("ITIL") and Pfizer (the "Pfizer License Agreement"), ITIL agreed to make a regulatory milestone payment of $20.0 million to Pfizer (the "Milestone Payment") upon the approval of oral sulopenem for commercial sale in the United States by the U.S. Food and Drug Administration ("FDA"). The Company had the option to deliver notice of its election to defer such payment for up to two years from the date of approval and have a promissory note issued by ITIL in the amount of the Milestone Payment to Pfizer. After receiving FDA approval for ORLYNVAH™ on October, 25, 2024, the Company notified Pfizer on October 28, 2024, that it was electing to defer payment of the Milestone Payment for two years, or until October 25, 2026 (the "Deferral Period"), and a promissory note was issued to Pfizer by ITIL.

On May 13, 2025, the Company and ITIL entered into an amended and restated promissory note (the "A&R Note") and a letter agreement relating to the A&R Note and amending the Pfizer License Agreement. The A&R Note extends the Deferral Period by an additional three years, or until October 25, 2029. In connection with the extension, ITIL agreed in the A&R Note to increase the annual rate of interest from eight percent (8%) to ten percent (10%) on a daily compounded basis, beginning on October 26, 2026. ITIL also agreed that it would not, directly or indirectly, (1) create, incur, assume, guaranty or otherwise become liable for any indebtedness that is senior in right of payment to the A&R Note, except for indebtedness incurred with the consent or waiver of Pfizer, or (2) create, grant or incur any lien on any of its property or assets, subject to specified exceptions (including liens securing permitted indebtedness and liens incurred with the consent or waiver of Pfizer). ITIL also agreed to pay Pfizer a transaction fee and to pay Pfizer's legal expenses.

About Iterum Therapeutics plc

Iterum is focused on delivering 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. Iterum is advancing the development of its first compound, sulopenem, a novel penem anti-infective compound, 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. Iterum has received approval of its NDA for ORLYNVAH™ (oral sulopenem) for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options by the FDA and has received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications. For more information, please visit www.iterumtx.com.

About ORLYNVAH™

ORLYNVAH™ is a novel oral penem antibiotic for the treatment of uUTIs. ORLYNVAH™ possesses potent activity against species of Enterobacterales including those that encode extended spectrum beta-lactamase (ESBL) or AmpC-type beta-lactamases that confer resistance to third generation cephalosporins.

Cautionary Note Regarding 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 Iterum's plans, strategies and prospects for its business, including the development, therapeutic and market potential of ORLYNVAH™, Iterum's ability to complete pre-commercialization activities for ORLYNVAH™ and Iterum's ability to prepare and implement commercialization plans for ORLYNVAH™, including Iterum's ability to expand into new territories and put additional resources in high prescribing geographies. 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 Iterum'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 Iterum's control, including risks and uncertainties concerning the outcome, impact, effects and results of Iterum's evaluation of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic alternatives, Iterum's ability to complete a strategic alternative transaction, Iterum's ability to raise sufficient capital and successfully prepare and implement commercialization plans for ORLYNVAH™ with a commercial partner or directly, including Iterum's ability to build and maintain a sales force and prepare for a potential commercial launch of ORLYNVAH™, the ability of shareholders and other stakeholders to realize any value or recovery as part of a wind down process if Iterum is unsuccessful at entering into or completing a strategic transaction or preparing and implementing commercialization plans for ORLYNVAH™, the market opportunity for and the potential market acceptance of ORLYNVAH™ for uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, Iterum's ability to continue as a going concern, uncertainties inherent in the conduct of clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, changes in public policy or legislation, commercialization plans and timelines, the actions

of third-party clinical research organizations, suppliers and manufacturers, the accuracy of Iterum's expectations regarding how far into the future Iterum's cash on hand will fund Iterum's ongoing operations, Iterum's ability to maintain its listing on the Nasdaq Capital Market and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q filed with the SEC on May 13, 2025, and other documents filed with the Securities and Exchange Commission from time to time. Forward-looking statements represent Iterum's beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum 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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