

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): November 20, 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 8.01 Other Events.

On November 20, 2024, Iterum Therapeutics plc (the “Company”) received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC informing the Company that its deficiency under Listing Rule 5550(b) has been cured and that the Company is in compliance with applicable continued listing requirements. Based on the foregoing, the previously scheduled hearing before the Hearings Panel on November 21, 2024 has been cancelled. The Company will continue to be traded on The Nasdaq Capital Market.

On November 21, 2024, the Company issued a press release announcing it had regained compliance with with applicable continued listing requirements. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc dated November 21, 2024
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: November 21, 2024

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



FOR IMMEDIATE RELEASE

Iterum Therapeutics Regains Full Nasdaq Compliance

--Iterum will Continue to be Listed and Traded on the Nasdaq Stock Market--

DUBLIN, Ireland and CHICAGO, November 21, 2024 -- Iterum Therapeutics plc (Nasdaq: ITRM), (the Company), 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 announced receipt of written notice from the Listing Qualifications Staff of The Nasdaq Stock Market LLC informing the Company that its deficiency under Listing Rule 5550(b) has been cured and that the Company is in compliance with applicable continued listing requirements.

Based on the foregoing, the previously scheduled Nasdaq hearing before the Hearings Panel on November 21, has been cancelled. The Company will continue to be traded on The Nasdaq Capital Market.

“We are pleased to have addressed this very important matter to us and our shareholders,” said Corey Fishman, Iterum’s Chief Executive Officer. “We will continue to do everything we can to adhere to the Nasdaq listing requirements as we move forward with executing our business strategy.”

About Iterum Therapeutics plc

Iterum Therapeutics plc 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 U.S. Food and Drug Administration 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 uUTI. 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. 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 successfully prepare and implement commercialization plans for ORLYNVAH™ with a commercial partner or directly, including the Iterum's ability to build and maintain a sales force and prepare for commercial launch of ORLYNVAH™, if Iterum is unsuccessful at entering into or completing a strategic transaction, 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, 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 November 14, 2024, and other documents filed with the SEC 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.

Investor Contact:

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