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): March 06, 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 8.01 Other Events.

On March 6, 2024, Iterum Therapeutics plc (the “Company”) issued a press release providing a business update.

The Company announced that it now expects to resubmit its new drug application ("NDA") for oral sulopenem to the U.S. Food and Drug Administration ("FDA") in the first half of the second quarter of 2024, earlier than originally planned. Provided that the resubmitted NDA addresses all of the deficiencies identified in the complete response letter ("CRL") the Company received from the FDA in July 2021, the Company expects that the FDA will complete its review and take action six months from the date the FDA receives the resubmitted NDA (or during the first half of the fourth quarter of 2024).

Based on its current operating plan, the Company believes that its existing cash and cash equivalents and short-term investments as of December 31, 2023, together with the net proceeds from the sale of ordinary shares under its “at-the-market” offering agreement through February 29, 2024, are expected to fund its operating expenses into 2025, including through the expected Prescription Drug User Fee Act date in the first half of the fourth quarter of 2024.

The Company plans to engage a financial advisor in the near-term to assist management and the Board in evaluating the Company's strategic alternatives.

The full text of the press release issued in connection with the business update is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Cautionary Note Regarding Forward-looking Statements

This Current Report contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation the Company's ability to address the deficiencies set out in the complete response letter received in July 2021, the expected timing of resubmission of the NDA, the expected timing of review by the FDA, the sufficiency of the Company's cash resources to enable it to fund its operating expenses into 2025**,** and the Company’s strategic process to sell, license, or otherwise dispose of its rights to sulopenem, including its expectation to engage a financial advisor in the near-term. 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 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, including the potential resubmission of the NDA for oral sulopenem, 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 Company’s ability to maintain its 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 at all and other factors discussed under the caption “Risk Factors” in its Quarterly Report on Form 10-Q filed with the SEC on November 14, 2023, and other documents filed with the U.S. Securities and Exchange Commission (“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.

Item 9.01 Financial Statements and Exhibits.

The following exhibit relates to Item 8.01, and shall be deemed to be furnished, and not filed:

(d) Exhibits.

Number	Exhibit Description
99.1	Press Release of Iterum Therapeutics plc, dated March 6, 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: March 6, 2024

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

EXHIBIT 99.1

Iterum Therapeutics Provides Business Update

Resubmission of NDA is On Track for First Half of Q2 24

Extended Cash Runway into 2025

DUBLIN, Ireland and CHICAGO, March 6, 2024 -- Iterum Therapeutics plc (Nasdaq: ITRM) (Iterum), a clinical-stage pharmaceutical company focused on developing next-generation oral antibiotics to treat infections caused by multi-drug resistant pathogens in community settings, today provided a general business update.

Iterum announced that it now expects to resubmit its new drug application (NDA) for oral sulopenem to the U.S. Food and Drug Administration (FDA) in the first half of the second quarter of 2024, earlier than originally planned. Provided that the resubmitted NDA addresses all of the deficiencies identified in the complete response letter (CRL) Iterum received from the FDA in July 2021, Iterum expects that the FDA will complete its review and take action six months from the date the FDA receives the resubmitted NDA (or during the first half of the fourth quarter of 2024).

Based on Iterum's current operating plan, Iterum believes that its existing cash and cash equivalents and short-term investments as of December 31, 2023, together with the net proceeds from the sale of ordinary shares under its "at-the-market" offering agreement through February 29, 2024, are expected to enable it to fund its operating expenses into 2025, including through the expected Prescription Drug User Fee Act date in the first half of the fourth quarter of 2024.

In January 2024, Iterum announced positive top-line results from the REASSURE trial and that it would be focusing on a strategic process to sell, license, or otherwise dispose of its rights to sulopenem with the goal of maximizing value for its stakeholders. Iterum plans to engage a financial advisor in the near-term to assist management and the Board in evaluating Iterum's strategic alternatives.

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. Iterum is currently advancing its first compound – sulopenem – a novel penem anti-infective compound, in Phase 3 clinical development with an oral formulation.
Sulopenem also has an 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 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.

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 development, therapeutic and market potential of sulopenem, our ability to address the deficiencies set out in the CRL received in July 2021, the expected timing of resubmission of the NDA, the expected timing of review by the FDA, the sufficiency of Iterum's cash resources to enable it to fund its operating expenses into 2025, and Iterum's strategic process to sell, license, or otherwise dispose of its rights to sulopenem, including its expectation to engage a financial advisor in the near-term. 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 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, including the potential resubmission of the NDA for oral sulopenem, 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 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, risks and uncertainties concerning the outcome, impact, effects and results of Iterum's pursuit of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic process and Iterum's ability to complete one at all and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q filed with the SEC on November 14, 2023, 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:
Judy Matthews
Chief Financial Officer
312-778-6073
IR@iterumtx.com