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): August 11, 2023

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 2.02 Results of Operations and Financial Condition.

On August 11, 2023, Iterum Therapeutics plc issued a press release announcing its financial results for the second quarter ended June 30, 2023. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in this current report on Form 8-K, including the press release attached as Exhibit 99.1 hereto, is being furnished, but shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Iterum Therapeutics, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of Iterum Therapeutics plc, dated August 11, 2023
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: August 11, 2023

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Second Quarter 2023 Financial Results

--Expect to Complete Enrollment in Q1 2024; Topline Data Expected in Q2 2024 --

--Cash Runway into Q3 2024--

DUBLIN, Ireland and CHICAGO, August 11, 2023 -- Iterum Therapeutics plc (Nasdaq: ITRM) (Iterum), 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 reported financial results for the second quarter ended June 30, 2023.

"We recently achieved 50% patient enrollment and expect to complete the planned enrollment of 1,966 patients in our REASSURE trial in the first quarter of next year. We have over 140 clinical trial sites currently open to enrollment in the U.S.," said Corey Fishman, Iterum's Chief Executive Officer. "Top-line data is expected in the second quarter of 2024, with a potential resubmission of our new drug application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2024."

Highlights and Recent Events

•**Enrollment in REASSURE Clinical Trial Ongoing:** Iterum began enrollment in its pivotal Phase 3 clinical trial, REASSURE (**RE**newed **AS**sessment of **S**ulopenem in u**U**TI caused by **R**esistant **E**nterobacterales), for the treatment of uncomplicated urinary tract infections (uUTI) in adult women in October 2022. Enrollment is ongoing and expected to be completed in the first quarter of 2024. Iterum will conduct an interim analysis for sample size re-estimation as specified in its special protocol assessment (SPA) agreement with the FDA following achievement of 50% patient enrollment. The SPA agreement provides that the design and planned analysis of the trial, as set out in the protocol submitted to the FDA, adequately addresses the objectives necessary to support the potential resubmission of Iterum's NDA for oral sulopenem for the treatment of uUTI.

•**New Japanese Patent Issued:** The Japanese Patent Office has issued a Certificate of Patent for Japanese Patent Registration No. 7295964 entitled "Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof" directed to the composition of the bilayer tablet of sulopenem etzadroxil and probenecid (oral sulopenem) and its preparation. This patent is scheduled to expire no earlier than 2039. In addition to in-licensed patents, Iterum also owns two U.S. patents for oral sulopenem, one directed to the composition of the bilayer tablet and its related uses, and the other directed to the method of use of oral sulopenem in treating multiple diseases, including uncomplicated urinary tract infections as well as a

number of pending patent applications in the U.S. and other jurisdictions including Europe and China.

Second Quarter 2023 Financial Results

Cash, cash equivalents and short-term investments were $44.7 million as of June 30, 2023. Based on its current operating plan, Iterum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into the third quarter of 2024. As of July 31, 2023, Iterum had approximately 13.0 million ordinary shares outstanding.

Research and development (R&D) expenses for the second quarter 2023 were $9.0 million, compared to $4.0 million for the same period in 2022. The increase for the three-month period was primarily due to an increase in costs incurred supporting Iterum's REASSURE trial, which began enrollment in October 2022, partially offset by a reduction in share-based compensation expense.

General and administrative (G&A) expenses for the second quarter 2023 were $1.9 million, compared to $4.1 million for the same period in 2022. The decrease for the three-month period was primarily due to a reduction in share-based compensation expense, as well as a decrease in legal fees associated with the lawsuit filed in August 2021 and dismissed with prejudice in January 2023.

Net loss for the second quarter 2023 was $12.2 million, compared to a net loss of $6.7 million for the same period in 2022. Non-GAAP[1] net loss for the second quarter 2023 was $10.0 million, compared to a non-GAAP[1] net loss of $5.7 million for the same period in 2022.

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 http://www.iterumtx.com.

[1] Reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release

Non-GAAP Financial Measures

To supplement Iterum's financial results presented in accordance with U.S. generally accepted accounting principles (GAAP), Iterum presents non-GAAP net loss and non-GAAP net loss per share to exclude from reported GAAP net loss and GAAP net loss per share, intangible asset amortization ($0.4 million and $0.9 million); share-based compensation expense ($0.1 million and $0.5 million); the interest expense associated with accrued interest on the 6.500% Exchangeable Senior Subordinated Notes due 2025 (Exchangeable Notes), payable in cash, shares or a combination of both upon exchange, redemption or at January 31, 2025 (the Maturity Date), whichever is earlier ($0.2 million and $0.4 million); the non-cash amortization of the Exchangeable Notes ($0.6 million and $1.2 million); and the non-cash adjustments to the fair value of derivatives and the Limited Recourse Royalty-Linked Subordinated Notes (Royalty-Linked Notes) ($1.0 million and $1.8 million) for the three and six months ended June 30, 2023, respectively, and intangible asset amortization ($0.4 million and $0.9 million); share-based compensation expense ($2.0 million and $3.9 million); the interest expense associated with accrued interest on the Exchangeable Notes payable in cash, shares or a combination of both upon exchange, redemption or at the Maturity Date, whichever is earlier ($0.2 million and $0.4 million); the non-cash amortization of the Exchangeable Notes ($0.6 million and $1.2 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($2.2 million and $7.3 million) for the three and six months ended June 30, 2022, respectively.

Iterum believes that the presentation of non-GAAP net loss and non-GAAP net loss per share, when viewed with its results under GAAP and the accompanying reconciliation, provides useful supplementary information to, and facilitates additional analysis by, investors, analysts, and Iterum's management in assessing Iterum's performance and results from period to period. These non-GAAP financial measures closely align with the way management measures and evaluates Iterum's performance. These non-GAAP financial measures should be considered in addition to, and not a substitute for, or superior to, net loss or other financial measures calculated in accordance with GAAP. Non-GAAP net loss and non-GAAP net loss per share are not based on any standardized methodology prescribed by GAAP and represents GAAP net loss, which is the most directly comparable GAAP measure, adjusted to exclude intangible asset amortization; share-based compensation expense; the interest expense associated with accrued interest on the Exchangeable Notes payable in cash, shares or a combination of both upon exchange, redemption or at the Maturity Date, whichever is earlier; the non-cash amortization of the Exchangeable Notes; and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes for the three and six months ended June 30, 2023 and June 30, 2022. Because of the non-standardized definitions of non-GAAP financial measures, non-GAAP net loss and non-GAAP net loss per share used by Iterum in this press release and accompanying tables has limits in its usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies. A reconciliation of non-GAAP net loss to GAAP net loss and non-GAAP net loss per share to GAAP net loss per share have been provided in the tables included in this press release.

Special 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 sulopenem, the timing, conduct, progress and results of Iterum's ongoing REASSURE clinical trial, including the ability to complete planned enrollment within the projected timeframe and the timing of top-line results, the expected timing of resubmission of the NDA, the term and coverage provided by Iterum's patents, and the sufficiency of Iterum's cash resources. 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 design, initiation and conduct of clinical and non-clinical development, including the REASSURE clinical trial, availability and timing of data from the REASSURE clinical trial, 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 evaluation of corporate, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, strategic, financial or financing alternative 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 August 11, 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.

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ITERUM THERAPEUTICS PLC
Condensed Consolidated Statement of Operations
(In thousands except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	(8,964)	(3,984)	(15,396)	(7,424)
General and administrative	(1,858)	(4,066)	(3,956)	(7,999)
Total operating expenses	(10,822)	(8,050)	(19,352)	(15,423)
Operating loss	(10,822)	(8,050)	(19,352)	(15,423)
Interest expense, net	(324)	(766)	(723)	(1,805)
Adjustments to fair value of derivatives	(960)	2,155	(1,838)	7,332
Other income, net	50	269	91	431
Income tax expense	(187)	(343)	(310)	(770)
Net loss	$ (12,243)	$ (6,735)	$ (22,132)	$ (10,235)
Net loss per share – basic and diluted	$ (0.95)	$ (0.55)	$ (1.73)	$ (0.84)
Weighted average ordinary shares outstanding – basic and diluted	12,942,969	12,224,324	12,812,398	12,208,961
Reconciliation of non-GAAP net loss to GAAP net loss				
Net loss - GAAP	$ (12,243)	$ (6,735)	$ (22,132)	$ (10,235)
Intangible asset amortization	429	429	858	858
Share based compensation	110	1,984	503	3,879
Interest expense - accrued interest and amortization on Exchangeable Notes	789	789	1,572	1,572
Adjustments to fair value of derivatives	960	(2,155)	1,838	(7,332)
Non-GAAP net loss	$ (9,955)	$ (5,688)	$ (17,361)	$ (11,258)
Net loss per share - basic and diluted	$ (0.95)	$ (0.55)	$ (1.73)	$ (0.84)
Non-GAAP net loss per share - basic and diluted	$ (0.77)	$ (0.47)	$ (1.36)	$ (0.92)

ITERUM THERAPEUTICS PLC
Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	As of June 30, 2023	**As of December 31, 2022**
Cash, cash equivalents and short-term investments	$ 44,732	$ 60,804
Other assets	6,289	6,029
Total assets	**$ 51,021**	**$ 66,833**
Long-term debt, less current portion	$ 11,666	$ 10,094
Royalty-linked notes	20,251	18,372
Derivative liabilities	154	196
Other liabilities	11,821	10,172
Total liabilities	43,892	38,834
Total shareholders' equity	7,129	27,999
Total liabilities and shareholders' equity	**$ 51,021**	**$ 66,833**