

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, 2022

Iterum Therapeutics plc

(Exact name of registrant as specified in its charter)

Ireland

(State or other jurisdiction
of incorporation)

001-38503

(Commission File Number)

98-1283148

(IRS Employer Identification No.)

**Fitzwilliam Court, 1st Floor
Leeson Close
Dublin 2, D02 YW24
Ireland**

(Address of principal executive offices)

Not Applicable

(Zip Code)

Registrant's telephone number, including area code: +353 1 6694820

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 (see General Instruction A.2. below):

- ☐ 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:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
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 May 13, 2022, Iterum Therapeutics plc issued a press release announcing its financial results for the first quarter ended March 31, 2022. 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 May 13, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Iterum Therapeutics plc

Dated: May 13, 2022

By: /s/ Corey N. Fishman

Corey N. Fishman
Chief Executive Officer

FOR IMMEDIATE RELEASE**Iterum Therapeutics Reports First Quarter 2022 Financial Results**

*-General Alignment with FDA on Key Aspects of Design of Proposed Additional Clinical Trial-
-Cash Runway into 2024-*

DUBLIN, Ireland and CHICAGO, May 13, 2022 -- 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 first quarter ended March 31, 2022.

“As reported earlier this week, we have reached general alignment with the U.S. Food and Drug Administration (“FDA”) on key aspects of the proposed design of an additional clinical trial comparing oral sulopenem to Augmentin® (amoxicillin/clavulanate) for the treatment of uncomplicated urinary tract infection (“uUTI”) in adult women to support a potential resubmission of our new drug application (“NDA”) for oral sulopenem,” said Corey Fishman, Iterum’s Chief Executive Officer. “We plan to request an agreement with the FDA regarding the proposed protocol under the special protocol assessment (“SPA”) process. Subject to finalizing the SPA agreement with the FDA, we expect to initiate enrollment in the second half of 2022.”

Highlights and Recent Events

- Met with FDA:** We reached general alignment with the FDA at a meeting in early May 2022 on key aspects of the design of an additional clinical trial required to support the potential resubmission of the NDA for oral sulopenem for uUTI.
- Reduced outstanding debt:** We completed the repayment of our term loan with Silicon Valley Bank in March 2022.

First Quarter 2022 Financial Results

Cash, cash equivalents and short-term investments was \$75.3 million at March 31, 2022. Based on the current operating plan, which includes the planned conduct of the additional Phase 3 clinical trial, Iterum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2024. As of April 30, 2022, Iterum had approximately 183.4 million ordinary shares outstanding.

Research and development (R&D) expenses for the first quarter of 2022 were \$3.4 million compared to \$2.5 million for the same period in 2021. The increase was primarily due to the

non-cash amortization of an intangible asset in 2022, trial start-up costs associated with the registrational trial expected to begin in the second half of 2022, higher personnel costs due to an increase in headcount to support additional clinical trial efforts and higher share-based compensation, partially offset by lower consulting spend.

General and administrative (G&A) expenses for the first quarter of 2022 were \$3.9 million compared to \$3.4 million for the same period in 2021. The increase was primarily due to an increase in share-based compensation expense, partially offset by lower consulting spend.

Adjustments to the fair value of derivatives for the first quarter of 2022 were \$5.2 million compared to (\$90.1) million for the same period in 2021. The non-cash adjustment in the first quarter of 2022 related to a decrease in the value of the derivative components associated with Iterum's 6.500% Exchangeable Senior Subordinated Notes due 2025 (the Exchangeable Notes) as a result of a decrease in the price of its ordinary shares and market capitalization during the period, as well as a reduction in the liability associated with the Limited Recourse Royalty-Linked Subordinated Notes (the "Royalty-Linked Notes") due to a change to the expected timing of payments. The non-cash adjustment in the first quarter of 2021 related to an increase in the value of the derivative components associated with the Exchangeable Notes and the Royalty-Linked Notes primarily as a result of an increase in the price of Iterum's ordinary shares and an increase in Iterum's market capitalization during the period.

Net loss for the first quarter of 2022 was \$3.5 million compared to a net loss of \$98.9 million for the same period in 2021. Non-GAAP¹ net loss of \$5.6 million in the first quarter of 2022 was relatively flat compared to the non-GAAP¹ net loss of \$5.8 million for the same period in 2021.

Upcoming Presentations

- Corporate presentation at the 2022 H.C. Wainwright Global Investment Conference to be held on Wednesday, May 25, 2022 at 11:30am ET
- Presentation at the FDA's Public Workshop for uUTI to be held on June 3, 2022. The purpose of this virtual public workshop, entitled "Development Considerations of Antimicrobial Drugs for the Treatment of Uncomplicated Urinary Tract Infections (uUTI)," is to discuss nonclinical and clinical considerations regarding developing antimicrobial drugs for the treatment of uUTI.

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); share-based compensation expense (\$1.9 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 January 31, 2025 ("the Maturity Date"), whichever is earlier (\$0.2 million); the non-cash amortization of the Exchangeable Notes and Royalty-Linked Notes (\$0.6 million); and the non-cash adjustments to the fair value of derivatives (\$5.2 million) for the three months ended March 31, 2022, and share-based compensation expense (\$0.3 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 (\$0.4 million); the non-cash amortization of the Exchangeable Notes and Royalty-Linked Notes (\$2.3 million); and the non-cash adjustments to the fair value of derivatives (\$90.1 million) for the three months ended March 31, 2021.

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 Royalty-Linked Notes; and the non-cash adjustments to the fair value of derivatives for the three months ended March 31, 2022 and March 31, 2021. 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 Therapeutics 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.

Forward Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding Iterum's plans, strategies and prospects for its business, including with respect to planned interactions with the FDA and Iterum's ability to finalize a SPA agreement with the FDA, Iterum's expectations with regard to its ability to resolve the matters set forth in the complete response letter (CRL) received by Iterum in July 2021 and obtain approval for oral sulopenem, the design, timing and conduct of future clinical and non-clinical development of sulopenem to support a potential resubmission of the NDA for oral sulopenem, 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

any additional clinical trials and non-clinical development that may be conducted in response to the CRL, availability and timing of data from such potential clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, including any 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, the impact of COVID-19 and related responsive measures thereto, Iterum's ability to maintain its listing on the Nasdaq Stock 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 Securities and Exchange Commission (the "SEC") on May 13, 2022, 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 March 31,	
	2022	2021
Operating expenses:		
Research and development	(3,440)	(2,451)
General and administrative	(3,933)	(3,396)
Total operating expenses	(7,373)	(5,847)
Operating loss	(7,373)	(5,847)
Interest expense, net	(1,039)	(2,952)
Adjustments to fair value of derivatives	5,177	(90,103)
Other income, net	162	41
Income tax expense	(427)	(60)
Net loss attributable to ordinary shareholders	\$ (3,500)	\$ (98,921)
Net loss per share attributable to ordinary shareholders – basic and diluted	\$ (0.02)	\$ (0.81)
Weighted average ordinary shares outstanding – basic and diluted	182,901,530	121,549,083

Reconciliation of non-GAAP net income / (loss) to GAAP net loss

Net loss - GAAP	\$ (3,500)	\$ (98,921)
Intangible asset amortization	429	—
Share based compensation	1,895	281
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	783	2,748
Adjustments to fair value of derivatives	(5,177)	90,103
Non-GAAP net loss	\$ (5,570)	\$ (5,789)
Net loss per share attributable to ordinary shareholders – basic and diluted	\$ (0.02)	\$ (0.81)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	\$ (0.03)	\$ (0.05)

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

	As of March 31, 2022	As of December 31, 2021
Cash, cash equivalents, restricted cash and short-term investments	\$ 75,334	\$ 81,408
Other assets	8,729	10,101
Total assets	\$ 84,063	\$ 91,509
Long-term debt, less current portion	\$ 7,713	\$ 6,930
Royalty-linked notes	14,397	17,968
Derivative liabilities	4,451	6,058
Other liabilities	8,867	10,319
Total liabilities	35,428	41,275
Total shareholders' equity	48,635	50,234
Total liabilities and shareholders' equity	\$ 84,063	\$ 91,509

