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 10, 2022

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 November 10, 2022, Iterum Therapeutics plc issued a press release announcing its financial results for the third quarter ended September 30, 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 plc, 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 November 10, 2022
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: November 10, 2022

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Third Quarter 2022 Financial Results

--Patient Enrollment in Registration Trial for uUTI Underway--

--Cash Runway into 2024-

DUBLIN, Ireland and CHICAGO, November 10, 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 third quarter ended September 30, 2022.

"We are thrilled to have the REASSURE clinical trial underway," said Corey Fishman, Chief Executive Officer. "We are one step closer to potentially bringing oral sulopenem to market as a viable treatment option for health care providers and patients impacted by the lack of available antibiotics to fight against growing bacterial resistance in infections found in the community. We also continue to look forward and see utility in developing sulopenem for the treatment of diseases beyond urinary tract infections, particularly respiratory infections."

Highlights and Recent Events

•**Initiation of REASSURE Clinical Trial:** 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 expected to be completed in the first half of 2024. This trial is being conducted under a Special Protocol Assessment ("SPA") agreement with the U.S. Food and Drug Administration ("FDA"). 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 new drug application ("NDA") for oral sulopenem.

•**U.S. Patent Issued Extending Protection:** The United States Patent and Trademark Office ("USPTO") has issued Iterum a new patent, No. US 11,478,428, directed to the composition of the bilayer tablet of sulopenem etzadroxil and probenecid ("oral sulopenem") and its related uses. The U.S. patent is scheduled to expire no earlier than 2039, absent any extensions. Existing patent protection for sulopenem etzadroxil is scheduled to expire in 2029, subject to potential extension. Iterum's patent portfolio also contains pending patent applications outside the U.S., including Europe and China, submitted following receipt of the Written Opinion of the International Search Authority indicating that several claims directed to the composition of the bilayer tablet of oral sulopenem are novel and inventive.

•**Regained Compliance with NASDAQ Bid Price Rule:** On August 31, 2022, Iterum regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) ("Bid Price Rule") for continued listing on The Nasdaq Capital Market. In order to regain compliance with the Bid Price Rule, on August 17, 2022, Iterum effected a 1-for-15 reverse share split ("Reverse Share Split") of its outstanding ordinary shares. Accordingly, all authorized and issued and authorized and unissued ordinary shares, 6.500% Exchangeable Senior Subordinated Notes due 2025 ("Exchangeable Notes"), share options, restricted share units, warrants and shares reserved for future issuance under Iterum's share plans have been adjusted in the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 10, 2022 to reflect the Reverse Share Split for all prior periods presented.

Third Quarter 2022 Financial Results

Cash, cash equivalents and short-term investments were $64.3 million at September 30, 2022. Based on the current operating plan, Iterum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2024, including through topline data from the REASSURE clinical trial. As of October 31, 2022, Iterum had approximately 12.2 million ordinary shares outstanding.

Research and development ("R&D") expenses for the third quarter of 2022 were $4.4 million compared to $1.8 million for the same period in 2021. The increase was primarily due to an increase in costs incurred to support the activities for the REASSURE clinical trial.

General and administrative ("G&A") expenses for the third quarter of 2022 were $2.7 million compared to $3.0 million for the same period in 2021. The decrease was primarily due to lower share-based compensation expense, partially offset by an increase in legal fees associated with the class action lawsuit filed in August 2021.

Adjustments to the fair value of derivatives for the third quarter of 2022 were $4.8 million compared to $9.8 million for the same period in 2021. The non-cash adjustment in the third quarter of 2022 related to an increase in the fair value of the Limited Recourse Royalty-Linked Subordinated Notes (the "Royalty-Linked Notes") due to the newly issued patent directed to oral sulopenem to the composition of the bilayer tablet which provides patent protection at least until 2039, partially offset by a decrease in the value of the derivative components associated with Iterum's Exchangeable Notes, primarily as a result of a decrease in the price of our ordinary shares and our market capitalization during the period. The non-cash adjustment in the third quarter of 2021 primarily related to a decrease in the value of the derivative components associated with the Exchangeable Notes as a result of a decrease in the price of its ordinary shares and market capitalization during the period, partially offset by an increase in the fair value of the Royalty-Linked Notes.

Cancellation of share options for the third quarter of 2022 was $17.4 million and related to the non-cash charge in connection with employee share options that were surrendered and cancelled in July 2022.

Net loss for the third quarter of 2022 was $29.1 million compared to net income of $3.7 million for the same period in 2021. Non-GAAP[1] net loss was $5.3 million in the third quarter of 2022 compared to the non-GAAP net loss of $3.7 million for the same period in 2021.

Conference Call Details

Iterum will host a conference call today, Thursday, November 10, 2022 at 8:30 a.m. Eastern Time. The dial-in information for the call is as follows: United States: 1 844 200 6205; International: 1 929 526 1599; Access code: 819977

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) / income and GAAP net (loss) / income per share, intangible asset amortization ($0.4 million and $1.3 million); share-based compensation expense ($0.4 million and $4.3 million); the cancellation of share options ($17.4 million and $17.4 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 and $0.6 million); the non-cash amortization of the Exchangeable Notes and Royalty-Linked Notes ($0.6 million and $1.8 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($4.8 million and $2.5 million) for the three and nine months ended September 30, 2022, respectively, and share-based compensation expense ($1.5 million and $2.4 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 $0.9 million); the non-cash amortization of the Exchangeable Notes and Royalty-Linked Notes ($0.6 million and $3.5 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($9.8 million and $64.5 million) for the three and nine months ended September 30, 2021, 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) / income 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) / income, which is the most directly comparable GAAP measure, adjusted to exclude intangible asset amortization; share-based compensation expense; the non-cash expense for the cancellation of share options; 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 and Royalty-Linked Notes for the three and nine months ended September 30, 2022 and September 30, 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) / income and non-GAAP net loss per share to GAAP net (loss) / income 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 the development, therapeutic and market potential of sulopenem, the timing, conduct, progress and results of Iterum's ongoing REASSURE clinical trial, 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 expected timing of resubmission of the NDA, the term and coverage provided by Iterum's patent and other intellectual property rights, 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 and the non-clinical development being conducted in response to the CRL, availability and timing of

data from the REASSURE clinical trial and the on-going 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, the impact of COVID-19 and related responsive measures thereto, 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 November 10, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	(4,353)	(1,845)	(11,777)	(7,010)
General and administrative	(2,681)	(3,029)	(10,680)	(10,698)
Total operating expenses	(7,034)	(4,874)	(22,457)	(17,708)
Operating loss	(7,034)	(4,874)	(22,457)	(17,708)
Interest expense, net	(636)	(849)	(2,441)	(4,781)
Adjustments to fair value of derivatives	(4,834)	9,783	2,498	(64,526)
Cancellation of share options	(17,350)	-	(17,350)	-
Other income, net	175	33	606	167
Income tax expense	570	(352)	(200)	(534)
Net (loss) / income attributable to ordinary shareholders	$ (29,109)	$ 3,741	$ (39,344)	$ (87,382)
Net (loss) / income per share attributable to ordinary shareholders – basic	$ (2.38)	$ 0.31	$ (3.22)	$ (8.40)
Net (loss) / income per share attributable to ordinary shareholders – diluted	$ (2.38)	$ 0.28	$ (3.22)	$ (8.40)
Weighted average ordinary shares outstanding – basic	12,233,374	12,182,002	12,217,188	10,403,889
Weighted average ordinary shares outstanding – diluted	12,233,374	13,483,807	12,217,188	10,403,889
Reconciliation of GAAP net (loss) / income to non-GAAP net loss				
Net (loss) / income - GAAP	$ (29,109)	$ 3,741	$ (39,344)	$ (87,382)
Intangible asset amortization	429	—	1,287	—
Share based compensation	422	1,512	4,301	2,352
Cancellation of share options	17,350	-	17,350	-
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	796	796	2,368	4,379
Adjustments to fair value of derivatives	4,834	(9,783)	(2,498)	64,526
Non-GAAP net loss	$ (5,278)	$ (3,734)	$ (16,536)	$ (16,125)
Net (loss) / income per share attributable to ordinary shareholders – basic	$ (2.38)	$ 0.31	$ (3.22)	$ (8.40)
Net (loss) / income per share attributable to ordinary shareholders – diluted	$ (2.38)	$ 0.28	$ (3.22)	$ (8.40)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.43)	$ (0.31)	$ (1.35)	$ (1.55)

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

	As of September 30, 2022	As of December 31, 2021
Cash, cash equivalents, restricted cash and short-term investments	$ 64,387	$ 81,408
Other assets	7,168	10,101
Total assets	**$ 71,555**	**$ 91,509**
Long-term debt, less current portion	$ 9,298	$ 6,930
Royalty-linked notes	20,917	17,968
Derivative liabilities	610	6,058
Other liabilities	8,181	10,319
Total liabilities	39,006	41,275
Total shareholders' equity	32,549	50,234
Total liabilities and shareholders' equity	**$ 71,555**	**$ 91,509**