

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 12, 2021

Iterum Therapeutics plc		
(Exact name of registrant as specified in its charter)		
Ireland	001-38503	98-1283148
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
Fitzwilliam Court, 1st Floor Leeson Close Dublin 2, D02 YW24 Ireland		Not Applicable
(Address of principal executive offices)		(Zip Code)
Registrant's telephone number, including area code: +353 1 669 4820		

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 November 12, 2021, Iterum Therapeutics plc issued a press release announcing its financial results for the third quarter ended September 30, 2021. 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
<u>99.1</u>	<u>Press Release of Iterum Therapeutics plc, dated November 12, 2021</u>
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: November 12, 2021

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

FOR IMMEDIATE RELEASE**Iterum Therapeutics Reports Third Quarter 2021 Financial Results and Provides Business Update**

--Type B meeting with FDA requested to affirm design for additional Phase 3 trial needed for resubmission of NDA for Oral Sulopenem --

--Cash Runway into 2024--

--Iterum to host conference call today at 8:30am ET--

DUBLIN, Ireland and CHICAGO, November 12, 2021 -- Iterum Therapeutics plc (Nasdaq: ITRM), 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, 2021.

“We had a productive Type A meeting with the U.S. Food and Drug Administration (FDA) in the third quarter in which various potential paths forward to support potential resubmission of our New Drug Application (NDA) for oral sulopenem for the treatment of uncomplicated urinary tract infections (uUTI) were discussed. We have since requested a Type B meeting with the FDA with the goal of reaching agreement on the design of a Phase 3 trial for oral sulopenem for the treatment of uUTI that, if successful, could lead to a resubmission of our NDA,” said Corey Fishman, Chief Executive Officer.

Highlights and Recent Events

- **Held Type A Meeting with FDA in Q3; Type B Meeting with FDA Requested:** In September 2021, we had a Type A meeting with the FDA to discuss the steps required for potential resubmission of the NDA for oral sulopenem following receipt of the Complete Response Letter (CRL) in July 2021. We have requested a Type B meeting with the FDA to discuss the design of a potential new clinical trial to support such potential resubmission.
- **Cash runway into 2024:** Based on the current operating plan and subject to final determination of the design and planned conduct of potential additional clinical and non-clinical development of oral sulopenem, we believe that we are well positioned financially to fund operations into 2024 with our existing cash resources, which includes completing the proposed additional development of oral sulopenem to support, if successful, the resubmission of our NDA to the FDA. As of September 30, 2021, we had approximately 182.8 million ordinary shares outstanding.

Third Quarter 2021 Financial Results

As of September 30, 2021, Iterum had cash, cash equivalents and short-term investments of \$85.7 million. Based on the current operating plan and subject to final determination of the design and planned conduct of potential additional clinical and non-clinical development of sulopenem, Iterum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2024.

Research and development expenses for the third quarter of 2021 were \$1.8 million compared to \$3.9 million for the same period in 2020. The decrease for the period was primarily due to the completion of Iterum's Phase 3 clinical trials in 2020.

General and administrative (G&A) expenses for the third quarter of 2021 were \$3.0 million compared to \$2.4 million for the same period in 2020. The increase for the period was primarily due to an increase in share-based compensation for employees and directors.

Adjustments to the fair value of derivatives for the third quarter of 2021 were \$9.8 million compared to (\$0.6) million for the same period in 2020. The non-cash adjustment in the third quarter of 2021 primarily 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, partially offset by an increase in the fair value of Iterum's Limited Recourse Royalty-Linked Subordinated Notes (the Royalty-Linked Notes).

For the third quarter of 2021, Iterum reported net income of \$3.7 million compared to a net loss of \$12.2 million for the same period in 2020 due largely to the non-cash adjustment of the derivative liabilities in the third quarter of 2021. Iterum reported a non-GAAP¹ net loss of \$5.2 million for the third quarter of 2021 compared to a non-GAAP net loss of \$7.0 million for the same period in 2020.

Upcoming Investor Presentation

- Corporate presentation at H.C. Wainwright BIOCONNECT Virtual Conference to be held January 10-13, 2022.

Conference Call Details

- Iterum will host a conference call today, Friday, November 12, 2021 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: 442364

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

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

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>.

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 adjusted net loss and non-GAAP net loss per share to exclude from reported GAAP net income/(loss) and GAAP net income/(loss) per share, 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 \$0.9 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 (\$9.8 million and \$64.5 million) for the three and nine months ended September 30, 2021, respectively, and 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 (\$0.9 million and \$2.3 million); the non-cash amortization of the Exchangeable Notes and Royalty-Linked Notes (\$3.0 million and \$7.5 million); one-time, non-capitalized financing transaction costs (\$0.7 million and \$2.8 million); and the non-cash adjustments to the fair value of derivatives (\$0.6 million and \$1.0 million) for the three and nine months ended September 30, 2020, respectively.

Iterum believes that the presentation of non-GAAP adjusted 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 income/(loss) or other financial measures calculated in accordance with GAAP. Non-GAAP adjusted net loss and non-GAAP net loss per share are not based on any standardized methodology prescribed by GAAP and represents GAAP net income/(loss), which is the most directly comparable GAAP measure, adjusted to exclude 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; one-time, non-capitalized financing transaction costs and the non-cash adjustments to the fair value of derivatives for the three and nine months ended September 30, 2021 and September 30, 2020. Because of the non-standardized definitions of non-GAAP financial measures, non-GAAP adjusted net loss and non-GAAP net loss per share used by Iterum Therapeutics in the accompanying press release and tables therein 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 adjusted net loss to GAAP net income/(loss) and non-GAAP net loss per share to GAAP net income/(loss) per share have been provided in the tables included in the accompanying 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 and communications with the FDA and Iterum's ability to reach agreement with the FDA on the design of any potential future clinical trials, Iterum's expectations with regard to its ability to resolve the matters set forth in the CRL received by Iterum in July 2021 and obtain approval for oral sulopenem, the conduct of potential future clinical and non-clinical development of 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 initiation and conduct of clinical and non-clinical development, including any potential 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, 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 including completing potential additional clinical and non-clinical development of oral sulopenem, 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 November 12, 2021, 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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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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	(1,845)	(3,937)	(7,010)	(18,723)
General and administrative	(3,029)	(2,398)	(10,698)	(8,759)
Total operating expenses	(4,874)	(6,335)	(17,708)	(27,482)
Operating loss	(4,874)	(6,335)	(17,708)	(27,482)
Interest expense, net	(849)	(4,183)	(4,781)	(10,854)
Financing transaction costs	—	(685)	—	(2,815)
Adjustments to fair value of derivatives	9,783	(644)	(64,526)	1,023
Other income, net	33	68	167	27
Income tax expense	(352)	(420)	(534)	(719)
Net income/ (loss) attributable to ordinary shareholders	\$ 3,741	\$ (12,199)	\$ (87,382)	\$ (40,820)
Net income / (loss) per share attributable to ordinary shareholders – basic	\$ 0.02	\$ (0.60)	\$ (0.56)	\$ (2.39)
Net income / (loss) per share attributable to ordinary shareholders – diluted	\$ 0.02	\$ (0.60)	\$ (0.56)	\$ (2.39)
Weighted average ordinary shares outstanding – basic	182,730,032	20,392,357	156,058,343	17,078,326
Weighted average ordinary shares outstanding – diluted	202,257,112	20,392,357	156,058,343	17,078,326
Reconciliation of non-GAAP net income / (loss) to GAAP net loss				
Net income / (loss) - GAAP	\$ 3,741	\$ (12,199)	\$ (87,382)	\$ (40,820)
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	796	3,859	4,379	9,829
Financing transaction costs - not capitalized	—	685	—	2,815
Adjustments to fair value of derivatives	(9,783)	644	64,526	(1,023)
Non-GAAP net loss	\$ (5,246)	\$ (7,011)	\$ (18,477)	\$ (29,199)
Net income / (loss) per share attributable to ordinary shareholders – basic	\$ 0.02	\$ (0.60)	\$ (0.56)	\$ (2.39)
Net income / (loss) per share attributable to ordinary shareholders – diluted	\$ 0.02	\$ (0.60)	\$ (0.56)	\$ (2.39)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	\$ (0.03)	\$ (0.34)	\$ (0.12)	\$ (1.71)

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

	As of September 30, 2021	As of December 31, 2020
Cash, cash equivalents and short-term investments	\$ 85,711	\$ 14,508
Other assets	12,711	18,284
Total assets	\$ 98,422	\$ 32,792
Long-term debt, less current portion	\$ 6,134	22,462
Royalty-linked notes, less current portion	18,403	13,389
Derivative liabilities	9,183	28,865
Other liabilities	12,254	18,635
Total liabilities	45,974	83,351
Total shareholders' equity / (deficit)	52,448	(50,559)
Total liabilities and shareholders' equity / (deficit)	\$ 98,422	\$ 32,792