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 14, 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 2.02 Results of Operations and Financial Condition.

On November 14, 2024, Iterum Therapeutics plc (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2024. 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 the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc, dated November 14, 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: November 14, 2024

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

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Iterum Therapeutics Reports Third Quarter 2024 Financial Results

-- ORLYNVAH™ Approved by FDA on October 25, 2024—

--Company to Host Conference Call Today at 8:30 a.m. EDT--

DUBLIN, Ireland and CHICAGO, November 14, 2024 -- Iterum Therapeutics plc (Nasdaq: ITRM), (Iterum), a company focused on delivering 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, 2024.

"With last month's approval of ORLYNVAH™, we have renewed our outreach to potential strategic partners," said Corey Fishman, Iterum's Chief Executive Officer. "As the only oral penem antibiotic approved for commercial sale in the U.S. and the potentially first branded uncomplicated urinary tract infection (uUTI) product to enter this underserved market in over 25 years, the value proposition of ORLYNVAH™ is significant. There is substantial unmet need in the uUTI market due to antibiotic resistance to existing oral antibiotics which is affecting their efficacy, and reinforces the need for new treatment options like ORLYNVAH™."

Highlights and Recent Events

- **Approval by U.S. Food and Drug Administration (FDA) of ORLYNVAH™ for uUTI:** On October 25, 2024, Iterum received approval from the FDA of its new drug application (NDA) for ORLYNVAH™ for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options.
- **FDA's Orange Book:** Iterum has submitted patent information for four U.S. patents for ORLYNVAH™ that will be listed in FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.
- **Generating Antibiotic Incentives Now (GAIN) Act Exclusivity:** Iterum received confirmation from FDA that an additional five years of marketing exclusivity under the GAIN Act will be added to the exclusivity granted on approval of ORLYNVAH™, giving a total of 10 years of marketing exclusivity.

Third Quarter 2024 Financial Results

Cash, cash equivalents and short-term investments were $14.5 million at September 30, 2024. Based on Iterum's current operating plan, Iterum expects that its current cash, cash equivalents and short-term investments, including proceeds received from the exercise of certain warrants

and amounts raised under an ATM offering subsequent to quarter-end through November 4, 2024, will be sufficient to fund its operations into 2025, including through the repayment date of the 6.500% Exchangeable Notes due January 31, 2025 ("Exchangeable Notes").

Research and development (R&D) expenses for the third quarter 2024 were $3.1 million compared to $14.9 million for the same period in 2023. The decrease for the three-month period was primarily due to higher costs incurred in 2023 to support its REASSURE trial, which began enrollment in October 2022 and completed enrollment in October 2023.

General and administrative (G&A) expenses for the third quarter 2024 were $1.8 million compared to $1.8 million for the same period in 2023.

Adjustments to the fair value of derivatives for the third quarter of 2023 were $13.2 million and primarily related to a decrease in the Limited Recourse Royalty-Linked Subordinated Notes (the "Royalty-Linked Notes") as a result of the decrease in management's estimate of the expected cash flows to be received by holders of the Royalty-Linked Notes.

Net loss for the third quarter 2024 was $6.1 million compared to a net loss of $3.9 million for the same period in 2023. Non-GAAP[1] net loss for the third quarter 2024 was $4.8 million compared to a non-GAAP[1] net loss of $15.7 million in 2023.

Conference Call Details

- Iterum will host a conference call today, Thursday, November 14, 2024 at 8:30 a.m. Eastern Time. The dial-in information for the call is as follows: United States: 1 833 470 1428; International: 1 404 975 4839; Access code: 969798

About Iterum Therapeutics plc

Iterum Therapeutics plc is focused on delivering 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 advancing the development of its first compound, sulopenem, a novel penem anti-infective compound, with an oral formulation and 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 approval of its NDA for ORLYNVAH™ (oral sulopenem) for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options by the U.S. Food and Drug Administration and 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.

About ORLYNVAH™

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

ORLYNVAH™ is a novel oral penem antibiotic for the treatment of uUTI. ORLYNVAH™ possesses potent activity against species of Enterobacterales including those that encode extended spectrum beta-lactamase (ESBL) or AmpC-type beta-lactamases that confer resistance to third generation cephalosporins.

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, share-based compensation expense ($0.1 million and $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 January 31, 2025 ("the Maturity Date"), whichever is earlier ($0.2 million and $0.6 million); the non-cash amortization of the Exchangeable Notes ($0.6 million and $1.7 million); and the non-cash adjustments to the fair value of the Royalty-Linked Notes ($0.4 million and $1.2 million) for the three and nine months ended September 30, 2024, and intangible asset amortization ($0.4 million and $1.3 million); share-based compensation expense ($0.1 million and $0.6 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 $0.6 million); the non-cash amortization of the Exchangeable Notes ($0.6 million and $1.8 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($13.2 million and $11.4 million) for the three and nine months ended September 30, 2023, 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, 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 nine months ended September 30, 2024 and September 30, 2023. 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.

Cautionary 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 ORLYNVAH™, the sufficiency of Iterum's cash resources to fund its operating expenses into 2025, the listing of patents for ORLYNVAH™ in the FDA's Orange Book and Iterum's strategic process to sell, license, or otherwise dispose of its rights to ORLYNVAH™. 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 risks and uncertainties concerning the outcome, impact, effects and results of Iterum's evaluation of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic alternatives, Iterum's ability to complete a strategic alternative transaction, Iterum's ability to successfully prepare and implement commercialization plans for ORLYNVAH™ with a commercial partner or directly, including the Iterum's ability to build and maintain a sales force and prepare for commercial launch of ORLYNVAH™, if Iterum is unsuccessful at entering into or completing a strategic transaction, the ability of shareholders and other stakeholders to realize any value or recovery as part of a wind down process if Iterum is unsuccessful at entering into or completing a strategic transaction or preparing and implementing commercialization plans for ORLYNVAH™, the market opportunity for and the potential market acceptance of ORLYNVAH™ for uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, 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, changes in public policy or legislation, commercialization plans and timelines, 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 and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q filed with the SEC on November 14, 2024, 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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	(3,107)	(14,852)	(9,159)	(30,248)
General and administrative	(1,780)	(1,833)	(5,867)	(5,789)
Total operating expenses	(4,887)	(16,685)	(15,026)	(36,037)
Operating loss	(4,887)	(16,685)	(15,026)	(36,037)
Interest expense, net	(590)	(300)	(1,648)	(1,023)
Adjustments to fair value of derivatives	(433)	13,199	(1,226)	11,361
Other (expense) / income, net	(48)	70	(77)	161
Income tax expense	(136)	(161)	(215)	(471)
Net loss	$ (6,094)	$ (3,877)	$ (18,192)	$ (26,009)
Net loss per share – basic and diluted	$ (0.30)	$ (0.30)	$ (1.05)	$ (2.02)
Weighted average ordinary shares outstanding – basic and diluted	20,044,270	13,039,437	17,352,918	12,888,869
Reconciliation of non-GAAP net loss to GAAP net loss				
Net loss - GAAP	$ (6,094)	$ (3,877)	$ (18,192)	$ (26,009)
Intangible asset amortization	—	429	—	1,287
Share based compensation	68	142	274	645
Interest expense - accrued interest and amortization on Exchangeable Notes	756	796	2,255	2,368
Adjustments to fair value of derivatives	433	(13,199)	1,226	(11,361)
Non-GAAP net loss	$ (4,837)	$ (15,709)	$ (14,437)	$ (33,070)
Net loss per share - basic and diluted	$ (0.30)	$ (0.30)	$ (1.05)	$ (2.02)
Non-GAAP net loss per share - basic and diluted	$ (0.24)	$ (1.20)	$ (0.83)	$ (2.57)

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

	As of September 30, 2024	**As of December 31, 2023**
Cash, cash equivalents and short-term investments	$ 14,502	$ 23,930
Other assets	1,422	2,329
Total assets	**$ 15,924**	**$ 26,259**
Exchangeable notes	$ 13,708	$ 11,453
Royalty-linked notes	8,728	7,503
Other liabilities	4,995	13,706
Total liabilities	27,431	32,662
Total shareholders' deficit	(11,507)	(6,403)
Total liabilities and shareholders' deficit	**$ 15,924**	**$ 26,259**