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 05, 2025

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.)**
25 North Wall Quay Dublin 1, , Ireland		**Not applicable**
(Address of Principal Executive Offices)		**(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 5, 2025, Iterum Therapeutics plc issued a press release announcing its financial results for the second quarter ended June 30, 2025. 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 August 5, 2025
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 5, 2025

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

EXHIBIT 99.1

Iterum Therapeutics Reports Second Quarter 2025 Financial Results

-- Launch of ORLYNVAH™ Expected August 2025—

--Cash Runway into 2026--

--Company to host conference call today at 8:30amET--

DUBLIN, Ireland and CHICAGO, August 5, 2025 -- Iterum Therapeutics plc (Nasdaq: ITRM), 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 second quarter ended June 30, 2025.

"We are on track to launch ORLYNVAH™ this month for the treatment of uncomplicated urinary tract infections (uUTIs)," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. "We're proud to introduce the first branded antibiotic for uUTIs in over 25 years—a critical milestone as rising antimicrobial resistance has rendered many commonly used generic treatments ineffective across large parts of the U.S. ORLYNVAH™ is the only Food and Drug Administration (FDA) approved oral penem antibiotic in the U.S., offering a much-needed option for patients with limited alternatives due to resistant Gram-negative bacteria, including extended spectrum ß-lactamases (ESBL)-producing Enterobacterales."

Highlights and Recent Events

- **Expected Launch of ORLYNVAH™ for uUTIs in August 2025:** Iterum began pre-commercialization activities in the first quarter of 2025 and is now focusing the majority of its efforts and resources on preparing for the commercial launch of ORLYNVAH™ in the U.S. with its commercialization partner, EVERSANA Life Science Services, LLC (EVERSANA), which is expected to occur by the end of August 2025.

- **Entered into Partnership with EVERSANA:** In June 2025, Iterum entered into a Product Commercialization Agreement with EVERSANA for the commercialization of its approved product, ORLYNVAH™. Pursuant to the agreement, EVERSANA will provide sales and commercial operations services to Iterum in the U.S., as well as the provision of marketing, logistics, channel management, regulatory, medical affairs and other services related to the commercialization of ORLYNVAH™ in the U.S.

- **Entered into Manufacturing and Supply Agreement:** In July 2025, Iterum entered into a Commercial Manufacturing and Supply Agreement with ACS Dobfar S.p.A for the manufacture and supply of Iterum's approved product, being the ORLYNVAH™ bilayer tablets, for commercial supply purposes.

- **Hired Chief Commercial Officer:** Iterum appointed Christine Coyne to the newly created position of Chief Commercial Officer to lead all commercial efforts for Iterum, including the near-term launch of ORLYNVAH™ in the U.S.

- **Expansion of Patent Estate:** The Canadian Patent Office has issued Iterum Canadian patent 3,129,337 entitled "Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof" that covers the use of a combination of sulopenem etzadroxil and probenecid in treating multiple diseases, including uUTIs. The Canadian patent will expire in December 2039, absent any extensions, and assuming timely payments of all maintenance fees during the lifetime of the patent.

- **Publication in *NEJM Evidence*:** *NEJM Evidence* published results from Iterum's REASSURE (REnewed ASsessment of Sulopenem in uUTI caused by Resistant Enterobacterales) Phase 3 clinical trial comparing oral sulopenem (sulopenem etzadroxil combined with probenecid in a bilayer tablet) to oral Augmentin® (amoxicillin/clavulanate) in adult women with uUTIs. https://evidence.nejm.org/doi/full/10.1056/EVIDoa2400414

- **Extended Repayment of Pfizer Debt to 2029:** In May 2025, Pfizer Inc. (Pfizer) agreed to extend the deferral term for payment of the regulatory milestone payment of $20.0 million until October 25, 2029.

Second Quarter 2025 Financial Results

Cash and cash equivalents were $13.0 million as of June 30, 2025. Based on Iterum's current operating plan, Iterum expects that its cash and cash equivalents as of June 30, 2025, together with $2.2 million of net proceeds raised under its at-the-market offering program from July 1, 2025 through August 1, 2025, will be sufficient to fund its operations into 2026. The foregoing estimate gives effect to Iterum's currently planned commercial launch of ORLYNVAH™ in August 2025. As of August 1, 2025, Iterum had approximately 44.7 million ordinary shares outstanding.

Cost of sales expense for the second quarter 2025 was $0.3 million and represents the amortization related to the finite-lived intangible asset recognized in relation to the regulatory milestone payment payable to Pfizer upon approval of ORLYNVAH™ by the FDA.

Research and development expenses for the second quarter 2025 were $1.0 million compared to $2.1 million for the same period in 2024. The decrease for the three-month period was primarily due to a decrease in clinical trial costs associated with the REASSURE trial.

General and administrative expenses for the second quarter 2025 were $4.2 million compared to $1.9 million for the same period in 2024. The increase for the three-month period was primarily due to an increase in spend associated with pre-commercialization activities.

Adjustments to the fair value of derivatives for the second quarter 2025 was $0.6 million compared to $0.4 million for the same period in 2024. The non-cash adjustment for the second quarter 2025 and 2024 primarily related to an increase in the fair value of the Limited Recourse

Royalty-Linked Subordinated Notes (the Royalty-Linked Notes) due to the passage of time.

Net loss for the second quarter 2025 was $6.5 million compared to a net loss of $5.0 million for the same period in 2024. Non-GAAP[1] net loss for the second quarter 2025 of $5.1 million compared to a non-GAAP[1] net loss of $3.8 million for the same period in 2024.

Conference Call Details

- Iterum will host a conference call today, Tuesday, August 5, 2025 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: 740801

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 ($0.3 million and $0.7 million); share-based compensation expense ($0.1 million and $0.1 million); the interest expense associated with accrued interest on the Exchangeable Notes ($0.0 million and $0.1 million); the non-cash amortization of the Exchangeable Notes ($0.0 million and $0.2 million); the interest expense associated with accrued interest on the promissory note issued to Pfizer Inc. ($0.4 million and $0.9 million); and the non-cash adjustments to the fair value of the Royalty-Linked Notes ($0.6 million and $1.1 million) for the three and six months ended June 30, 2025, and share-based compensation expense ($0.1 million and $0.2 million); the interest expense associated with accrued interest on the Exchangeable Notes ($0.2 million and $0.4 million); the non-cash amortization of the Exchangeable Notes ($0.5 million and $1.1 million); and the non-cash adjustments to the fair value of the Royalty-Linked Notes ($0.4 million and $0.8 million) for the three and six months ended June 30, 2024.

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; the non-cash amortization of the Exchangeable Notes; the interest expense associated with accrued interest on the promissory note issued to Pfizer Inc.; and the non-cash adjustments to the fair value of the Royalty-Linked Notes for the three and six months ended June 30, 2025 and June 30, 2024. 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

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

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.

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 New Drug Application (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 FDA 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™

ORLYNVAH™ is a novel oral penem antibiotic for the treatment of uUTIs. ORLYNVAH™ possesses potent activity against species of Enterobacterales including those that encode ESBL or AmpC-type ß-lactamases that confer resistance to third generation cephalosporins.

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 2026, and Iterum's ability to complete pre-commercialization activities for ORLYNVAH™ and prepare for and implement the commercial launch of ORLYNVAH™ in the United States in August 2025. 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 Iterum's ability to raise sufficient capital and successfully prepare and implement commercialization plans for ORLYNVAH™ with its commercial partner, EVERSANA, including Iterum's ability to build and maintain a sales force and prepare for commercial launch of

ORLYNVAH™, 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 preparing and implementing its 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, Iterum's ability to continue as a going concern, 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 August 5, 2025, 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,	
	2025	**2024**	**2025**	**2024**
Costs and expenses:				
Cost of sales	(345)	—	(687)	—
Research and development	(1,000)	(2,075)	(1,591)	(6,052)
General and administrative	(4,184)	(1,901)	(6,961)	(4,087)
Total operating expenses	(5,529)	(3,976)	(9,239)	(10,139)
Operating loss	(5,529)	(3,976)	(9,239)	(10,139)
Interest expense, net	(316)	(571)	(850)	(1,058)
Adjustments to fair value of derivatives	(585)	(407)	(1,134)	(793)
Other expense, net	(20)	(12)	(58)	(29)
Income tax expense	(59)	(31)	(119)	(79)
Net loss	$ (6,509)	$ (4,997)	$ (11,400)	$ (12,098)
Net loss per share – basic and diluted	$ (0.16)	$ (0.30)	$ (0.31)	$ (0.76)
Weighted average ordinary shares outstanding – basic and diluted	39,935,213	16,552,214	37,013,653	15,992,454
Reconciliation of non-GAAP net loss to GAAP net loss				
Net loss - GAAP	$ (6,509)	$ (4,997)	$ (11,400)	$ (12,098)
Intangible asset amortization	345	—	687	—
Share based compensation	56	68	117	206
Interest expense - accrued interest and amortization on Exchangeable Notes	—	749	282	1,499
Interest on promissory note - non-cash	449	—	853	—
Adjustments to fair value of derivatives	585	407	1,134	793
Non-GAAP net loss	$ (5,074)	$ (3,773)	$ (8,327)	$ (9,600)
Net loss per share - basic and diluted	$ (0.16)	$ (0.30)	$ (0.31)	$ (0.76)
Non-GAAP net loss per share - basic and diluted	$ (0.13)	$ (0.23)	$ (0.22)	$ (0.60)

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

	As of June 30, 2025	**As of December 31, 2024**
Cash, cash equivalents and short-term investments	$ 13,026	$ 24,125
Inventory	948	-
Intangible asset, net	19,059	19,746
Other assets	981	724
Total assets	**$ 34,014**	**$ 44,595**
Pfizer Promissory Note	$ 20,653	$ 20,300
Exchangeable notes	—	14,463
Royalty-linked notes	11,905	10,771
Other liabilities	5,343	3,142
Total liabilities	37,901	48,676

Total shareholders' deficit		(3,887)		(4,081)
Total liabilities and shareholders' deficit	**$**	**34,014**	**$**	**44,595**