May 13, 2025

Iterum Therapeutics Reports First Quarter 2025 Financial Results

--Preparing for Potential Launch of ORLYNVAH™ by Q4 2025--

--Extended Cash Runway into 2026--

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

DUBLIN, Ireland and CHICAGO, May 13, 2025 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2025.

“Based on pre-commercialization work completed to date, we expect to be able to launch ORLYNVAH™ for the treatment of uncomplicated urinary tract infections (uUTIs) by the fourth quarter of this year,” said Corey Fishman, Iterum’s Chief Executive Officer. “While we continue to pursue our strategy of seeking a strategic transaction acceptable to our Board, there is an urgency to bring ORLYNVAH™ to the U.S. market to serve patients suffering with uUTIs who have limited or no treatment options given the lack of innovation over the past 25 years and the increasing rate of antimicrobial resistance to the generic drugs used to treat uUTIs today.”

Highlights and Recent Events

- **Potential Launch of ORLYNVAH™ for uUTIs:** Since receipt of FDA approval for ORLYNVAH™ in October 2024 for the treatment of adult women with uUTIs, Iterum has primarily focused its efforts on a strategic process to sell, license, or otherwise dispose of its rights to sulopenem, and more recently, on pre-commercialization activities in the event that a strategic transaction is not consummated. Iterum is preparing for the potential launch of ORLYNVAH™ in the United States with a commercial partner and/or on its own with a targeted sales force in the community setting to ensure ORLYNVAH™ is brought to the U.S. market as soon as possible to serve patients with limited or no treatment options.

- **Extended Cash Runway into 2026:** On April 30, 2025, Iterum issued and sold an aggregate of 5,555,556 ordinary shares (or pre-funded warrants in lieu thereof) at a purchase price of $0.90 per ordinary share (or pre-funded warrant in lieu thereof) in a registered direct offering (the Registered Direct Offering) with a single institutional investor for gross proceeds to Iterum of approximately $5 million, before deducting the placement agent’s fees and other expenses payable by Iterum. Additionally, from April 1, 2025 through April 22, 2025, Iterum raised approximately $1 million under its at-the-market offering program. Iterum expects that its cash and cash equivalents as of March

31, 2025, together with the amounts raised pursuant to the Registered Direct Offering and amounts raised under its at-the-market offering program, will be sufficient to fund its operations into 2026.

- **Repaid 6.500% Exchangeable Senior Subordinated Notes due 2025 (Exchangeable Notes):** In January 2025, Iterum repaid the outstanding principal and interest due under its Exchangeable Notes, in accordance with their terms.

First Quarter 2025 Financial Results

Cash and cash equivalents were $12.7 million as of March 31, 2025. Based on Iterum's current operating plan, Iterum expects that its cash and cash equivalents as of March 31, 2025, together with $1.0 million of net proceeds raised under its at-the-market offering program from April 1, 2025 through April 22, 2025 and net proceeds of $4.2 million from the Registered Direct Offering that closed April 30, 2025, will be sufficient to fund its operations into 2026. The foregoing estimate gives effect to Iterum's currently planned pre-commercialization activities and potential commercial launch of ORLYNVAH™ by the fourth quarter of 2025. As of May 12, 2025, Iterum had approximately 40.0 million ordinary shares outstanding.

Cost of sales expenses for the first quarter 2025 were $0.3 million and represent 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 first quarter 2025 were $0.6 million compared to $4.0 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 first quarter 2025 were $2.8 million compared to $2.2 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 first quarter 2025 was $0.6 million compared to $0.4 million for the same period in 2024. The non-cash adjustment for the first quarter 2025 and 2024 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 first quarter 2025 was $4.9 million compared to a net loss of $7.1 million for the same period in 2024. Non-GAAP[1] net loss for the first quarter 2025 of $3.3 million compared to a non-GAAP[1] net loss of $5.8 million for the same period in 2024.

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

Conference Call Details

- Iterum will host a conference call today, Tuesday, March 13, 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: 371859

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); share-based compensation expense ($0.1 million); the interest expense associated with accrued interest on the Exchangeable Notes ($0.0 million); the non-cash amortization of the Exchangeable Notes ($0.3 million); the interest expense associated with accrued interest on the promissory note issued to Pfizer Inc. ($0.4 million); and the non-cash adjustments to the fair value of the Royalty-Linked Notes ($0.5 million) for the three months ended March 31, 2025, and share-based compensation expense ($0.1 million); the interest expense associated with accrued interest on the Exchangeable Notes ($0.2 million); the non-cash amortization of the Exchangeable Notes ($0.6 million); and the non-cash adjustments to the fair value of the Royalty-Linked Notes ($0.4 million) for the three months ended March 31, 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 months ended March 31, 2025 and March 31, 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 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 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 extended spectrum beta-lactamase (ESBL) or AmpC-type beta-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, Iterum's strategic process to sell, license, or otherwise dispose of its rights to sulopenem, and Iterum's ability to complete pre-commercialization activities for ORLYNVAH™ and prepare for a potential launch of ORLYNVAH™ by the fourth quarter of 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 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 raise sufficient capital and successfully prepare and implement commercialization plans for ORLYNVAH™ with a commercial partner or directly, 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 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, 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 May 13, 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 March 31,	
	2025	**2024**
Costs and expenses:		
Cost of sales	(342)	—
Research and development	(591)	(3,977)
General and administrative	(2,777)	(2,186)
Total operating expenses	(3,710)	(6,163)
Operating loss	(3,710)	(6,163)
Interest expense, net	(534)	(487)
Adjustments to fair value of derivatives	(549)	(386)
Other expense, net	(38)	(17)
Income tax expense	(60)	(48)
Net loss	$ (4,891)	$ (7,101)
Net loss per share – basic and diluted	$ (0.14)	$ (0.46)
Weighted average ordinary shares outstanding – basic and diluted	34,059,630	15,432,693
Reconciliation of non-GAAP net loss to GAAP net loss		
Net loss - GAAP	$ (4,891)	$ (7,101)
Intangible asset amortization	342	—
Share based compensation	61	138

Interest expense - accrued interest and amortization on Exchangeable Notes	282	750
Interest on promissory note - non-cash	404	—
Adjustments to fair value of derivatives	549	386
Non-GAAP net loss	$ (3,253)	$ (5,827)
Net loss per share - basic and diluted	$ (0.14)	$ (0.46)
Non-GAAP net loss per share - basic and diluted	$ (0.10)	$ (0.38)

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

	As of March 31, 2025	As of December 31, 2024
Cash, cash equivalents and short-term investments	$ 12,652	$ 24,125
Inventory	533	-
Intangible asset, net	19,404	19,746
Other assets	386	724
Total assets	**$ 32,975**	**$ 44,595**
Pfizer Promissory Note	$ 20,705	$ 20,300
Exchangeable notes	—	14,463
Royalty-linked notes	11,320	10,771
Other liabilities	3,504	3,142
Total liabilities	35,529	48,676
Total shareholders' deficit	(2,554)	(4,081)
Total liabilities and shareholders' deficit	**$ 32,975**	**$ 44,595**

Source: Iterum Therapeutics PLC