November 14, 2025

Iterum Therapeutics Reports Third Quarter 2025 Financial Results

--Commercially Launched ORLYNVAH™ in the United States in August 2025--

--Extended Cash Runway into Q2 2026--

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

DUBLIN, Ireland and CHICAGO, Nov. 14, 2025 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM) (the Company or 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 quarter ended September 30, 2025.

“We are thrilled to have launched ORLYNVAH™ in the United States in August 2025 for the treatment of uncomplicated urinary tract infections (uUTIs),” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. “The significance of this milestone cannot be overstated—particularly given the importance of bringing a new treatment option to the uUTI space where antibiotic resistance continues to erode the efficacy of existing oral therapies and there have been no new branded launches for over 25 years. Given our limited commercial infrastructure and consistent with historical antibiotic launches, we anticipate modest sales in 2025. Looking ahead to 2026, as we continue to build momentum, we currently expect net product sales of ORLYNVAH™ to range between $5 million and $15 million, depending on uptake and payer coverage. We will continue to refine our guidance as market dynamics evolve over the next few quarters.”

Highlights and Recent Events

- **Launch of ORLYNVAH™ for uUTIs in August 2025**: Iterum commercially launched ORLYNVAH™ in the United States. with its commercialization partner, EVERSANA Life Science Services, LLC (EVERSANA), in August 2025.
- **Expansion of Patent Estate:** Iterum has been granted a patent in China as patent number ZL202180020106.6, entitled “Combinations of Beta-Lactam Compounds, Probenecid, and Valproic Acid and Uses Thereof”, that covers a combination of sulopenem etzadroxil, probenecid, and valproic acid for treating specified diseases. This Chinese patent is projected to expire in March 2041, absent any patent term extensions, and assuming timely payments of all maintenance fees during the lifetime of the patent. In addition, Iterum has been granted a patent in Mexico as patent number 426995, entitled “Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof”, that covers a bilayer tablet comprising sulopenem etzadroxil and probenecid, methods of preparing the bilayer tablet, and the bilayer tablet for use in treating specified diseases. This Mexican patent is projected to expire in December 2039, absent any patent term extensions, and assuming timely payments of all maintenance fees during the lifetime of the patent.

- **Presented at IDWeek:** Iterum presented two posters at the Infectious Disease Society of America's IDWeek 2025 conference in October 2025 and conducted a Learning Lounge at IDWeek titled '*An Overview of Urinary Tract Infection in Adult Women: Focus on Oral Sulopenem*.'

Third Quarter 2025 Financial Results

Cash and cash equivalents were $11.0 million as of September 30, 2025. Based on Iterum's current operating plan, Iterum expects that its cash and cash equivalents as of September 30, 2025, together with $2.6 million of net proceeds raised under its at-the-market offering program from October 1, 2025 through November 13, 2025, will be sufficient to fund its operations into the second quarter of 2026. As of November 13, 2025, Iterum had approximately 52.8 million ordinary shares outstanding.

Net product revenues for the third quarter 2025 were $0.4 million related to sales of ORLYNVAH™ which launched in August 2025 and included initial stocking at Iterum's specialty pharmacy locations for distribution in its targeted territories.

Cost of sales expense for the third quarter 2025 was $0.02 million and primarily consists of royalty payments pursuant to Iterum's license agreement with Pfizer Inc (Pfizer). Prior to approval in October 2024, costs incurred for the manufacture of ORLYNVAH™ were recorded as research and development expenses.

Amortization of intangible asset for the third quarter 2025 was $0.3 million and 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 third quarter 2025 were $1.3 million compared to $3.1 million for the same period in 2024. The decrease for the three-month period was primarily due to lower chemistry, manufacturing and control (CMC) related expenses. Following approval, costs incurred for the manufacture of ORLYNVAH™ have been capitalized to inventory.

Selling, general and administrative expenses for the third quarter 2025 were $6.5 million compared to $1.8 million for the same period in 2024. The increase for the three-month period was primarily due to the commercialization of ORLYNVAH™, which was launched in August 2025.

Adjustments to the fair value of derivatives for the third quarter 2025 was $0.7 million compared to $0.4 million for the same period in 2024. The non-cash adjustment for the third 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 third quarter 2025 was $9.0 million compared to a net loss of $6.1 million for the same period in 2024. Non-GAAP1 net loss for the third quarter 2025 of $7.3 million compared to a non-GAAP[1] net loss of $4.8 million for the same period in 2024.

Conference Call Details

- Iterum will host a conference call today, Friday, November 14, 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: 459214

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 $1.0 million); share-based compensation expense ($0.1 million and $0.2 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 ($0.6 million and $1.4 million); and the non-cash adjustments to the fair value of the Royalty-Linked Notes ($0.7 million and $1.8 million) for the three and nine months ended September 30, 2025, and share-based compensation expense ($0.1 million and $0.3 million); the interest expense associated with accrued interest on the Exchangeable Notes ($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.

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; and the non-cash adjustments to the fair value of the Royalty-Linked Notes for the three and nine months ended September 30, 2025 and September 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 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 our expectation that ORLYNVAH™ 2026 net product sales will be between $5 million and $15 million, the development, therapeutic and market potential of ORLYNVAH™ and the sufficiency of Iterum's cash resources to fund its operating expenses into the second quarter of 2026. 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 implement its commercialization plans for ORLYNVAH™ with its commercial partner, EVERSANA, including Iterum's ability to expand and maintain a sales force, the protection provided by Iterum's patents, 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 implementing its commercialization of 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, uptake of ORLYNVAH™ by physicians and payer coverage, existing or new competition for ORLYNVAH™, 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 November 14, 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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[1] Definition and reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release

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,	
	2025	**2024**	**2025**	**2024**
Product Revenue, net	$ 390	$ —	$ 390	$ —
Costs and expenses:				
Cost of sales	$ (20)	$ —	$ (20)	$ —
Amortization of intangible asset	(349)	—	(1,036)	—
Research and development	(1,261)	(3,107)	(2,852)	(9,159)
Selling, general and administrative	(6,491)	(1,780)	(13,452)	(5,867)
Total operating expenses	(8,121)	(4,887)	(17,360)	(15,026)
Operating loss	(7,731)	(4,887)	(16,970)	(15,026)
Interest expense, net	(441)	(590)	(1,291)	(1,648)
Adjustments to fair value of derivatives	(673)	(433)	(1,807)	(1,226)
Other expense, net	(2)	(48)	(60)	(77)
Income tax expense	(132)	(136)	(251)	(215)
Net loss	$ (8,979)	$ (6,094)	$ (20,379)	$ (18,192)
Net loss per share – basic and diluted	$ (0.20)	$ (0.30)	$ (0.51)	$ (1.05)
Weighted average ordinary shares outstanding – basic and diluted	45,801,927	20,044,270	39,975,269	17,352,918

Reconciliation of non-GAAP net loss to GAAP net loss				
Net loss - GAAP	$ (8,979)	$ (6,094)	$ (20,379)	$ (18,192)
Intangible asset amortization	349	—	1,036	—
Share based compensation	53	68	170	274
Interest expense - accrued interest and amortization on Exchangeable Notes	—	756	282	2,255
Interest on promissory note - non-cash	562	—	1,415	—
Adjustments to fair value of derivatives	673	433	1,807	1,226
Non-GAAP net loss	$ (7,342)	$ (4,837)	$ (15,669)	$ (14,437)
Net loss per share - basic and diluted	$ (0.20)	$ (0.30)	$ (0.51)	$ (1.05)
Non-GAAP net loss per share - basic and diluted	$ (0.16)	$ (0.24)	$ (0.39)	$ (0.83)

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

	As of September 30, 2025	As of December 31, 2024
Cash, cash equivalents and short-term investments	$ 11,002	$ 24,125
Accounts receivable	448	—
Inventory	1,149	—
Intangible asset, net	18,710	19,746
Other assets	1,194	724
Total assets	**$ 32,503**	**$ 44,595**
Pfizer Promissory Note	$ 21,215	$ 20,300
Exchangeable notes	—	14,463
Royalty-linked notes	12,520	10,771
Other liabilities	6,149	3,142
Total liabilities	39,884	48,676
Total shareholders' deficit	(7,381)	(4,081)
Total liabilities and shareholders' deficit	**$ 32,503**	**$ 44,595**

Source: Iterum Therapeutics PLC