May 13, 2024

Iterum Therapeutics Reports First Quarter 2024 Financial Results

--NDA Resubmitted; FDA Action Expected in Early Q4 24--

--Cash Runway into 2025, including through Potential FDA Approval--

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

DUBLIN, Ireland and CHICAGO, May 13, 2024 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM), (Iterum) 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 first quarter ended March 31, 2024.

“We are pleased to have recently resubmitted our new drug application (NDA) for oral sulopenem just three months after reporting positive topline data from our REASSURE trial in January 2024,” said Corey Fishman, Iterum’s Chief Executive Officer. “We continue to believe that the strong results from this trial, which was conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA), addresses the FDA’s recommendations for additional data to support approval of oral sulopenem for the treatment of adult women with uncomplicated urinary tract infections (uUTIs). The potential approval of oral sulopenem would mark the first oral penem approved in the U.S., and the second antibiotic approved for the treatment of uUTIs over the past 25 years.”

Highlights and Recent Events

- **NDA Review Underway:** Iterum began enrollment in its pivotal Phase 3 clinical trial, REASSURE (**RE**newed **AS**sessment of **S**ulopenem in u**U**TI caused by **R**esistant **E**nterobacterales), for the treatment of uUTIs in adult women in October 2022 and completed enrollment in October 2023 enrolling 2,222 patients. Iterum reported positive topline data in January 2024 and resubmitted its NDA in April 2024. Provided the FDA is satisfied that the resubmitted NDA addresses all of the deficiencies identified in the Complete Response Letter (CRL) Iterum received from the FDA in July 2021, Iterum expects that the FDA will complete its review and take action six months from the date the FDA received the resubmitted NDA (or early in the fourth quarter of 2024).

- **Extended Cash Runway:** During the first quarter of 2024, Iterum sold 3.0 million ordinary shares under an at-the-market offering (ATM) agreement, at an average price of $2.51 per share for net proceeds of $7.2 million, which has extended its cash runway into 2025 based on its current operating plan. As of April 30, 2024, Iterum had approximately 16.6 million ordinary shares outstanding.

First Quarter 2024 Financial Results

Cash, cash equivalents and short-term investments were $18.2 million at March 31, 2024. Based on Iterum's current operating plan, Iterum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2025, including through the expected Prescription Drug User Fee Act (PDUFA) date early in the fourth quarter of 2024.

Research and development (R&D) expenses for the first quarter 2024 were $4.0 million compared to $6.4 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 our REASSURE trial, which began enrollment in October 2022 and completed enrollment in October 2023.

General and administrative (G&A) expenses for the first quarter 2024 were $2.2 million compared to $2.1 million for the same period in 2023. The increase for the three-month period was primarily due to an increase in legal fees and an increase in consultants used to support pre-commercial activities.

Net loss for the first quarter 2024 was $7.1 million compared to a net loss of $9.9 million for the same period in 2023. Non-GAAP1 net loss for the first quarter 2024 was $5.8 million compared to a non-GAAP[1] net loss of $7.4 million in 2024.

Conference Call Details

- Iterum will host a conference call today, Monday, May 13, 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: 818440

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 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 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); 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); 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, and intangible asset amortization ($0.4 million); share-based compensation expense ($0.4 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); the non-cash amortization of the Exchangeable Notes ($0.6 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($0.9 million) for the three months ended March 31, 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 months ended March 31, 2024 and March 31, 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.

Special 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 sulopenem, Iterum's ability to address the deficiencies set out in the CRL received in July 2021, the expected timing of review of the resubmitted NDA by the FDA, potential action by the FDA with respect to the resubmitted NDA, the sufficiency of Iterum's cash resources to fund its operating expenses into 2025, and Iterum's strategic process to sell, license, or otherwise dispose of its rights to sulopenem. 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 design, initiation and 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, 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, the sufficiency of Iterum's cash resources and the Company's ability to continue as a going concern, Iterum's ability to maintain its listing on the Nasdaq Capital Market, risks and uncertainties concerning the outcome, impact, effects and results of Iterum's pursuit of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic process and Iterum's ability to complete one whether on attractive terms at all and other factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-Q filed with the SEC on May 13, 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 March 31,	
	2024	**2023**
Operating expenses:		
Research and development	(3,977)	(6,432)
General and administrative	(2,186)	(2,098)
Total operating expenses	(6,163)	(8,530)
Operating loss	(6,163)	(8,530)
Interest expense, net	(487)	(399)
Adjustments to fair value of derivatives	(386)	(878)
Other (expense) / income, net	(17)	41

Income tax expense	(48)	(123)
Net loss	$ (7,101)	$ (9,889)
Net loss per share – basic and diluted	$ (0.46)	$ (0.78)
Weighted average ordinary shares outstanding – basic and diluted	15,432,693	12,681,900
Reconciliation of non-GAAP net loss to GAAP net loss		
Net loss - GAAP	$ (7,101)	$ (9,889)
Intangible asset amortization	—	429
Share based compensation	138	393
Interest expense - accrued interest and amortization on exchangeable notes	750	783
Adjustments to fair value of derivatives	386	878
Non-GAAP net loss	$ (5,827)	$ (7,406)
Net loss per share - basic and diluted	$ (0.46)	$ (0.78)
Non-GAAP net loss per share - basic and diluted	$ (0.38)	$ (0.58)

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

	As of March 31, 2024	As of December 31, 2023
Cash, cash equivalents and short-term investments	$ 18,214	$ 23,930
Other assets	1,411	2,329
Total assets	**$ 19,625**	**$ 26,259**
Exchangeable notes	$ 12,203	$ 11,453
Royalty-linked notes	7,889	7,503
Other liabilities	5,683	13,706
Total liabilities	25,775	32,662
Total shareholders' deficit	(6,150)	(6,403)
Total liabilities and shareholders' deficit	**$ 19,625**	**$ 26,259**

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

Source: Iterum Therapeutics PLC