November 14, 2023

Iterum Therapeutics Reports Third Quarter 2023 Financial Results

-- Top-line Data for Pivotal REASSURE Trial Expected in Early Q1 2024 –

--Resubmission of NDA for uUTI Expected in Q2 2024-

DUBLIN, Ireland and CHICAGO, Nov. 14, 2023 (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 third quarter ended September 30, 2023.

“Last month, we completed the enrollment of 2,229 patients in our REASSURE trial in a 12-month period and expect to report top-line data early in the first quarter of 2024,” said Corey Fishman, Iterum’s Chief Executive Officer. “Subject to our analysis of the data, we plan to resubmit our NDA for the treatment of uncomplicated urinary tract infections (uUTI) in the second quarter of 2024 and expect the FDA to have completed its review of the NDA in the fourth quarter of 2024. If approved, oral sulopenem will be the first oral penem available in the United States and the first treatment approved in the U.S. for uUTI since the turn of the century.”

Highlights and Recent Events

- **Enrollment in REASSURE Clinical Trial Complete:** 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 uncomplicated urinary tract infections (uUTI) in adult women in October 2022 and completed enrollment in October 2023 enrolling 2,229 patients. Iterum expects to report top-line data early in the first quarter of 2024 and, subject to its analysis of the data, to resubmit its New Drug Application (NDA) in the second quarter of 2024. Provided that the resubmitted NDA addresses all of the deficiencies identified in the Complete Response Letter (CRL), Iterum expects that the U.S. Food and Drug Administration (FDA) will complete its review and take action six months from the date the FDA receives the resubmitted NDA (or during the second half of 2024).

- **New Patents Issued:** The Korean Patent Office has granted a Korean Patent No. 10-2577614 entitled “Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof” directed to the composition of the bilayer tablet of sulopenem etzadroxil and probenecid (oral sulopenem). This patent is scheduled to expire no earlier than 2039. The Australian Patent Office has also granted an Australian Patent No. 2019429755 entitled “Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof” also directed to the composition of the bilayer table and its related uses. This patent is also scheduled to expire no earlier than 2039. In addition to in-licensed

patents and the new Korean and Australian patents, Iterum also owns two U.S. patents and one Japanese patent, with one US patent and the Japanese patent directed to the composition of the bilayer tablet of oral sulopenem and its related preparations and/or uses, and the other US patent directed to the method of use of oral sulopenem in treating multiple diseases, including uncomplicated urinary tract infections, as well as a number of pending patent applications in the U.S. and other jurisdictions including Europe and China.

Third Quarter 2023 Financial Results

Cash, cash equivalents and short-term investments were $35.9 million as of September 30, 2023. Based on its current operating plan, Iterum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into the third quarter of 2024. As of October 31, 2023, Iterum had approximately 13.1 million ordinary shares outstanding.

Research and development (R&D) expenses for the third quarter 2023 were $14.9 million, compared to $4.4 million for the same period in 2022. The increase for the three-month period was primarily due to an increase in costs incurred supporting Iterum's REASSURE trial, which began enrollment in October 2022 and completed enrollment in October 2023.

General and administrative (G&A) expenses for the third quarter 2023 were $1.8 million, compared to $2.7 million for the same period in 2022. The decrease for the three-month period was primarily due to a reduction in legal fees largely associated with the lawsuit filed in August 2021 and dismissed with prejudice in January 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 2023 was $3.9 million, compared to a net loss of $29.1 million for the same period in 2022. Non-GAAP[1] net loss for the third quarter 2023 was $15.7 million, compared to a non-GAAP1 net loss of $5.3 million for the same period in 2022.

Conference Call Details

Iterum will host a conference call today, Tuesday, November 14, 2023 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: 388052

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, 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 6.500% Exchangeable Senior Subordinated Notes due 2025 (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 $1.8 million); and the non-cash adjustments to the fair value of derivatives and the Limited Recourse Royalty-Linked Subordinated Notes (Royalty-Linked Notes) ($13.2 million and $11.4 million) for the three and nine months ended September 30, 2023, respectively, and intangible asset amortization ($0.4 million and $1.3 million); share-based compensation expense ($0.4 million and $4.3 million); the cancellation of share options ($17.4 million and $17.4 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 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 ($4.8 million and $2.5 million) for the three and nine months ended September 30, 2022, 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 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 non-cash expense for the cancellation of share options; 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, 2023 and September 30, 2022. 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 the development, therapeutic and market potential of sulopenem, the timing and results of top-line data from the REASSURE clinical trial, our ability to address the deficiencies set out in the complete response letter received from the FDA in July 2021, the expected timing of resubmission of the NDA and timing of review of such NDA by the FDA, the term and coverage provided by Iterum's patents, and the sufficiency of Iterum's cash resources. 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, including the REASSURE clinical trial, availability and timing of data from the REASSURE clinical trial, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, including the potential resubmission of the NDA for oral sulopenem, 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, 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 evaluation of corporate, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, strategic, financial or financing alternative and Iterum's ability to complete one at all and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q filed with the SEC on November 14, 2023, 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,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	(14,852)	(4,353)	(30,248)	(11,777)
General and administrative	(1,833)	(2,681)	(5,789)	(10,680)
Total operating expenses	(16,685)	(7,034)	(36,037)	(22,457)
Operating loss	(16,685)	(7,034)	(36,037)	(22,457)
Interest expense, net	(300)	(636)	(1,023)	(2,441)
Adjustments to fair value of derivatives	13,199	(4,834)	11,361	2,498
Cancellation of share options	—	(17,350)	—	(17,350)
Other income, net	70	175	161	606
Income tax (expense) / benefit	(161)	570	(471)	(200)
Net loss	$ (3,877)	$ (29,109)	$ (26,009)	$ (39,344)
Net loss per share – basic and diluted	$ (0.30)	$ (2.38)	$ (2.02)	$ (3.22)
Weighted average ordinary shares outstanding – basic and diluted	13,039,437	12,233,374	12,888,869	12,217,188
Reconciliation of non-GAAP net loss to GAAP net loss				
Net loss - GAAP	$ (3,877)	$ (29,109)	$ (26,009)	$ (39,344)
Intangible asset amortization	429	429	1,287	1,287
Share based compensation	142	422	645	4,301
Cancellation of share options	—	17,350	—	17,350
Interest expense - accrued interest and amortization on Exchangeable Notes	796	796	2,368	2,368
Adjustments to fair value of derivatives	(13,199)	4,834	(11,361)	(2,498)
Non-GAAP net loss	$ (15,709)	$ (5,278)	$ (33,070)	$ (16,536)
Net loss per share - basic and diluted	$ (0.30)	$ (2.38)	$ (2.02)	$ (3.22)
Non-GAAP net loss per share - basic and diluted	$ (1.20)	$ (0.43)	$ (2.57)	$ (1.35)

ITERUM THERAPEUTICS PLC
Condensed Consolidated Balance Sheet Data

(In thousands)
(Unaudited)

	As of September 30, 2023	As of December 31, 2022
Cash, cash equivalents and short-term investments	$ 35,892	$ 60,804
Other assets	3,836	6,029
Total assets	**$ 39,728**	**$ 66,833**
Long-term debt, less current portion	$ 12,462	$ 10,094
Royalty-linked notes	7,131	18,372
Derivative liabilities	75	196
Other liabilities	16,628	10,172
Total liabilities	36,296	38,834
Total shareholders' equity	3,432	27,999
Total liabilities and shareholders' equity	**$ 39,728**	**$ 66,833**

[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