August 14, 2024

Iterum Therapeutics Reports Second Quarter 2024 Financial Results

-- FDA PDUFA Action Date of October 25, 2024; Advisory Committee Meeting on September 9, 2024—

--Cash Runway into 2025, including through PDUFA Action Date--

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

DUBLIN and CHICAGO, Aug. 14, 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 second quarter ended June 30, 2024.

“We are pleased to have recently closed our rights offering, the proceeds of which allows us to continue to pursue our business plan and strategy, including funding our ongoing strategic process to maximize the value of sulopenem for our stakeholders,” said Corey Fishman, Iterum’s Chief Executive Officer. “We continue to work with the U.S. Food and Drug Administration (FDA) during their review of our resubmitted new drug application (NDA) for oral sulopenem for the treatment of uncomplicated urinary tract infections (uUTI) in adult women, including preparing for the Advisory Committee meeting in September where we will address the FDA’s discussion topics regarding stewardship and patient population, among other things. If approved, oral sulopenem would be the first oral penem approved in the U.S.”

Highlights and Recent Events

- **NDA Review by FDA Ongoing:** 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. In May 2024, Iterum received a notice from the FDA acknowledging receipt of the resubmitted NDA and indicating that the FDA deemed the resubmitted NDA to be a Class II complete response under the Prescription Drug User Fee Act (PDUFA), which has a six-month review period from the date of resubmission. As a result, the FDA has assigned a PDUFA action date to Iterum’s resubmitted NDA of October 25, 2024. In June 2024, the FDA notified Iterum that it had determined that its NDA for oral sulopenem for the treatment of uUTIs in adult women will be taken to Advisory Committee. In its communication, the FDA highlighted that the purpose of the Advisory Committee meeting was to discuss (a) antimicrobial stewardship issues raised by potential approval and subsequent use of what would be the first oral penem in the U.S. and (b) the most appropriate target patient population(s) for treatment of uUTI with oral sulopenem. The Advisory Committee meeting is scheduled for September 9, 2024.

- **Completed Rights Offering:** On August 9, 2024, Iterum closed its rights offering (2024 Rights Offering) and issued 6.1 million ordinary shares at a share price of $1.21 per ordinary share to subscribing rights holders along with warrants to purchase 3.1 million ordinary shares at an exercise price of $1.21 per ordinary share for one year from the date of issuance, and warrants to purchase 6.1 million ordinary shares at an exercise price of $1.21 per ordinary share for five years from the date of issuance. Iterum received aggregate gross proceeds of $7.4 million in connection with the rights offering ($5.8 million, net of fees and expenses).

- **Notices of Allowance:**
    - The United States Patent and Trademark Office (USPTO) has issued Iterum a Notice of Allowance for U.S. patent application number 18/065,400 entitled “Combinations of Beta-Lactam Compounds and Probenecid and Uses Thereof” that covers the use of Iterum's candidate combination of sulopenem etzadroxil and probenecid in treating uncomplicated urinary tract infection. This Notice of Allowance concludes the substantive examination of the patent application and will result in the issuance of a U.S. patent after administrative processes are completed. The U.S. patent scheduled to issue from this application will expire April 1, 2039, absent any extensions.
    - The USPTO has also issued Iterum a Notice of Allowance for U.S. patent application number 17/198,335 entitled “Combinations of Beta-Lactam Compounds, Probenecid, and Valproic Acid and Uses Thereof” that covers the use of sulopenem etzadroxil, probenecid, and valproic acid in treating specified infections. This Notice of Allowance concludes the substantive examination of the patent application and will result in the issuance of a U.S. patent after administrative processes are completed. The U.S. patent scheduled to issue from this application will expire March 11, 2041, absent any extensions.
    - The Canadian Intellectual Property Office issued Iterum a Notice of Allowance for Canadian patent application number 3129337 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 use of the bilayer tablet in treating specified diseases. This Notice of Allowance concludes the substantive examination of the patent application and will result in the issuance of a Canadian patent after administrative processes are completed. The Canadian patent scheduled to issue from this application will expire December 23, 2039, absent any extensions.

Second Quarter 2024 Financial Results

Cash, cash equivalents and short-term investments were $11.7 million at June 30, 2024. Based on Iterum’s current operating plan, Iterum expects that its current cash, cash equivalents and short-term investments, including amounts raised in the 2024 Rights Offering, will be sufficient to fund its operations into 2025, including through the PDUFA date of October 25, 2024.

Research and development (R&D) expenses for the second quarter 2024 were $2.1 million compared to $9.0 million for the same period in 2024. 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 second quarter 2024 were $1.9 million compared to $1.9 million for the same period in 2023.

Net loss for the second quarter 2024 was $5.0 million compared to a net loss of $12.2 million for the same period in 2023. Non-GAAP1 net loss for the second quarter 2024 was $3.8 million compared to a non-GAAP[1] net loss of $10.0 million in 2024.

[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, Wednesday, August 14, 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: 775539

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 Therapeutics 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 Therapeutics has submitted an NDA for oral sulopenem for the treatment of uncomplicated urinary tract infections in adult women, which has been accepted for review by the U.S. Food and Drug Administration 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 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 and $0.2 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 and $0.4 million); the non-cash amortization of the 6.500% Exchangeable Notes due January 2025 ("Exchangeable Notes") ($0.5 million and $1.1 million); and the non-cash adjustments to the fair value of the Limited Recourse Royalty-Linked Notes (the "Royalty-Linked Notes") ($0.4 million and $0.8 million) for the three and six months ended June 30, 2024, and intangible asset amortization ($0.4 million and $0.9 million); share-based compensation expense ($0.1 million and $0.5 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 $0.4 million); the non-cash amortization of the Exchangeable Notes ($0.6 million and $1.2 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($1.0 million and $1.8 million) for the three

and six months ended June 30, 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 and six months ended June 30, 2024 and June 30, 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 statements regarding the topics that will be covered at the upcoming Advisory Committee meeting in relation to Iterum's NDA for oral sulopenem for the treatment of uUTIs in adult women, the date by which the FDA will take action regarding such NDA, Iterum's plans, strategies and prospects for its business, including the development, therapeutic and market potential of sulopenem, the term and coverage provided by Iterum's patent and other intellectual property rights, the sufficiency of Iterum's cash resources to fund its operating expenses into 2025, the expected use of proceeds from the recently completed rights offering, 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 regain and 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 or 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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	(2,075)	(8,964)	(6,052)	(15,396)
General and administrative	(1,901)	(1,858)	(4,087)	(3,956)
Total operating expenses	(3,976)	(10,822)	(10,139)	(19,352)
Operating loss	(3,976)	(10,822)	(10,139)	(19,352)
Interest expense, net	(571)	(324)	(1,058)	(723)
Adjustments to fair value of derivatives	(407)	(960)	(793)	(1,838)
Other (expense) / income, net	(12)	50	(29)	91
Income tax expense	(31)	(187)	(79)	(310)
Net loss	$ (4,997)	$ (12,243)	$ (12,098)	$ (22,132)
Net loss per share – basic and diluted	$ (0.30)	$ (0.95)	$ (0.76)	$ (1.73)

Weighted average ordinary shares outstanding – basic and diluted	16,552,214	12,942,969	15,992,454	12,812,398
Reconciliation of non-GAAP net loss to GAAP net loss				
Net loss - GAAP	$ (4,997)	$ (12,243)	$ (12,098)	$ (22,132)
Intangible asset amortization	—	429	—	858
Share based compensation	68	110	206	503
Interest expense - accrued interest and amortization on Exchangeable Notes	749	789	1,499	1,572
Adjustments to fair value of derivatives	407	960	793	1,838
Non-GAAP net loss	$ (3,773)	$ (9,955)	$ (9,600)	$ (17,361)
Net loss per share - basic and diluted	$ (0.30)	$ (0.95)	$ (0.76)	$ (1.73)
Non-GAAP net loss per share - basic and diluted	$ (0.23)	$ (0.77)	$ (0.60)	$ (1.36)

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

	As of June 30, 2024	As of December 31, 2023
Cash, cash equivalents and short-term investments	$ 11,717	$ 23,930
Other assets	2,457	2,329
Total assets	**$ 14,174**	**$ 26,259**
Exchangeable notes	$ 12,952	$ 11,453
Royalty-linked notes	8,296	7,503
Other liabilities	3,839	13,706
Total liabilities	25,087	32,662
Total shareholders' deficit	(10,913)	(6,403)
Total liabilities and shareholders' deficit	**$ 14,174**	**$ 26,259**

Source: Iterum Therapeutics PLC