March 16, 2023

Iterum Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results

--Registration Trial for uUTI Ongoing and On Track–
--Cash Runway until Mid-2024--

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

DUBLIN, Ireland and CHICAGO, March 16, 2023 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM), 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 fourth quarter and year ended December 31, 2022.

“We made significant progress in 2022 to move the clinical development of oral sulopenem forward leading to a potential resubmission of our new drug application (“NDA”) next year,” said Corey Fishman, Iterum’s Chief Executive Officer. “Enrollment in our REASSURE trial, which is being conducted under a Special Protocol Assessment (“SPA”) agreement with the U.S. Food and Drug Administration (“FDA”), is expected to be completed in the first half of 2024.”

Highlights and Recent Events

- **Enrollment in REASSURE Clinical Trial 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 uncomplicated urinary tract infections (“uUTI”) in adult women in October 2022. Enrollment is ongoing and expected to be completed in the first half of 2024. An interim analysis at 50% patient enrollment is expected to occur in the second half of 2023. This trial is being conducted under a SPA agreement with the FDA. The SPA agreement provides that the design and planned analysis of the trial, as set out in the protocol submitted to the FDA, adequately addresses the objectives necessary to support the potential resubmission of Iterum’s NDA for oral sulopenem.

- **Two New U.S. Patents Issued:** The United States Patent and Trademark Office has issued Iterum two new patents: 1) US Patent No. 11,478,428, directed to the composition of the bilayer tablet of sulopenem etzadroxil and probenecid (“oral sulopenem”) and its related uses, and 2) US Patent No. 11,554,112 directed to the method of use of oral sulopenem in treating multiple diseases, including uncomplicated urinary tract infections. These U.S. patents are scheduled to expire no earlier than 2039, excluding any additional term for patent adjustments or patent term extensions. Existing patent protection for sulopenem etzadroxil is scheduled to expire in 2029, subject to potential extension. Iterum’s patent portfolio also contains pending patent

applications outside the U.S., including Europe and China, submitted following receipt of the Written Opinion of the International Search Authority indicating that several claims directed to the composition of the bilayer tablet of oral sulopenem are novel and inventive.

- **Shareholder Lawsuit Dismissed:** On January 25, 2023, the putative class action lawsuit filed against Iterum, its Chief Executive Officer and Chief Financial Officer in the United States District Court for the Northern District of Illinois on August 5, 2021, was dismissed and cannot be brought back to court (dismissed with prejudice).

Fourth Quarter and Full Year 2022 Financial Results

Cash, cash equivalents and short-term investments were $60.8 million at December 31, 2022. Based on the current operating plan, Iterum expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations until mid-2024. As of February 28, 2023, we had approximately 12.6 million ordinary shares outstanding.

Research and development (R&D) expenses for the fourth quarter and full year 2022 were $5.8 million and $17.6 million, respectively, compared to $3.7 million and $10.7 million for the same periods in 2021. The increase for the three-month period was primarily due to an increase in costs to support our REASSURE trial, which began enrollment in October 2022, partially offset by lower non-cash amortization of an intangible asset. The increase in R&D expenses for the full year was primarily due to the REASSURE trial, including an increase in headcount to support trial activities, partially offset by a decrease in consulting fees for R&D activities in 2022. Consulting fees for the year ending December 31, 2021 primarily related to consultants used during the FDA review of our NDA for oral sulopenem.

General and administrative (G&A) expenses for the fourth quarter and full year 2022 were $2.0 million and $12.8 million, respectively, compared to $3.1 million and $13.8 million for the same periods in 2021. The decrease for the three-month period was primarily due to a decrease in share-based compensation expense. The decrease for the full year period was primarily due to lower consulting fees used to support pre-commercialization activities versus the prior year, partially offset by an increase in compensation and headcount and an increase in legal fees associated with the lawsuit filed in August 2021 and dismissed with prejudice in January
2023.

Adjustments to the fair value of derivatives for the fourth quarter and full year 2022 were $3.0 million and $5.5 million, compared to $3.6 million and ($61.0) million for the same periods in 2021. The non-cash adjustment in the fourth quarter and full year 2022 primarily related to a decrease in the value of the derivative components associated with Iterum's 6.500% Exchangeable Senior Subordinated Notes due 2025 (the "Exchangeable Notes") as a result of a decrease in the price of its ordinary shares and market capitalization during the period. In addition, during the fourth quarter of 2022, a change in the discount rate impacted the fair value of the Limited Recourse Royalty-Linked Subordinated Notes (the "Royalty-Linked Notes"). The non-cash adjustment in the fourth quarter of 2021 primarily related to a decrease in the value of the derivative components associated with the Exchangeable Notes as a result of a decrease in the price of its ordinary shares and market capitalization during the period. The non-cash adjustment for the full year 2021 was largely due to the fair value

adjustments recorded at the time of conversion of $39.2 million of the Exchangeable Notes in 2021.

Cancellation of share options for the full year 2022 was $17.4 million and related to the non-cash charge in connection with employee share options that were surrendered and cancelled in July 2022.

Net loss for the fourth quarter and full year 2022 was $5.1 million and $44.4 million, respectively, compared to a net loss of $4.2 million and $91.6 million for the same periods in 2021. Non-GAAP[1] net loss for the fourth quarter and full year 2022 of $6.4 million and $22.9 million, respectively, compared to a non-GAAP[1] net loss of $3.3 million and $19.4 million for the same periods in 2021.

Conference Call Details

- Iterum will host a conference call today, Thursday, March 16, 2023 at 8:30 a.m. Eastern Time. The dial-in information for the call is as follows: United States: 1 844 200 6205; International: 1 929 526 1599; Access code: 846586

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 $1.7 million); share-based compensation expense ($0.5 million and $4.8 million); the non-cash cancellation expense of share options ($0.0 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 January 31, 2025 ("the Maturity Date"), whichever is earlier ($0.2 million and $0.8 million); the non-cash amortization of the Exchangeable Notes ($0.6 million and $2.4 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($3.0 million and $5.5 million) for the three and twelve months ended December 31, 2022, respectively, and intangible asset amortization ($1.7 million and $1.7 million); share-based compensation expense ($2.0 million and $4.3 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 $1.1 million); the non-cash amortization of the

Exchangeable Notes and Royalty-Linked Notes ($0.6 million and $4.1 million); and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes ($3.6 million and $61.0 million) for the three and twelve months ended December 31, 2021, 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) / income, 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 Royalty-Linked Notes; and the non-cash adjustments to the fair value of derivatives and Royalty-Linked Notes for the three and twelve months ended December 31, 2022 and December 31, 2021. 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 Therapeutics 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) / income and non-GAAP net loss per share to GAAP net (loss) / income per share have been provided in the tables included in this press release.

[1] Definition and reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of 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, the timing, conduct, progress and results of Iterum's ongoing REASSURE clinical trial, the expected timing of resubmission of the NDA, the term and coverage provided by Iterum's patent and other intellectual property rights, 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 Annual Report on Form 10-K filed with the SEC on March 16, 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)

	For the three months ended December 31,		Year ended December 31,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	(5,840)	(3,702)	(17,617)	(10,712)
General and administrative	(2,086)	(3,127)	(12,766)	(13,825)
Total operating expenses	(7,926)	(6,829)	(30,383)	(24,537)
Operating loss	(7,926)	(6,829)	(30,383)	(24,537)
Interest income / (expense), net	80	(772)	(2,361)	(5,553)
Adjustments to fair value of derivatives	2,960	3,562	5,458	(60,964)
Cancellation of share options	-	-	(17,350)	-
Other (expense) income, net	(103)	28	503	195

Income tax expense	(101)	(171)	(301)	(705)
Net loss attributable to ordinary shareholders	$ (5,090)	$ (4,182)	$ (44,434)	$ (91,564)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (041)	$ (0.34)	$ (3.63)	$ (8.41)
Weighted average ordinary shares outstanding – basic and diluted	12,294,865	12,185,019	12,236,607	10,891,178
Reconciliation of non-GAAP net loss to GAAP net loss				
Net loss - GAAP	$ (5,090)	$ (4,182)	$ (44,434)	$ (91,564)
Intangible asset amortization	429	1,713	1,716	1,713
Share based compensation	457	1,967	4,758	4,319
Cancellation of share options	-	-	17,350	-
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	786	796	3,154	5,175
Adjustments to fair value of derivatives	(2,960)	(3,562)	(5,458)	60,964
Non-GAAP net loss	$ (6,378)	$ (3268)	$ (22,914)	$ (19,393)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.41)	$ (0.34)	$ (3.63)	$ (8.41)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.52)	$ (0.27)	$ (1.87)	$ (1.78)

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

	As of December 31, 2022	As of December 31, 2021
Cash, cash equivalents and short-term investments	$ 60,838	$ 81,344
Other assets	5,995	10,165
Total assets	**$ 66,833**	**$ 91,509**
Long-term debt, less current portion	$ 10,094	$ 6,930
Royalty-linked notes	18,372	17,968
Derivative liabilities	196	6,058
Other liabilities	10,172	10,319
Total liabilities	38,834	41,275
Total shareholders' equity	27,999	50,234

Total liabilities and shareholders' equity	**$ 66,833**	**$ 91,509**

Source: Iterum Therapeutics PLC