November 16, 2020

Iterum Therapeutics Reports Third Quarter 2020 Financial Results

NDA Filing Expected Q4 2020

DUBLIN, Ireland and CHICAGO, Nov. 16, 2020 (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 third quarter ended September 30, 2020.

“Following the positive feedback we received from the FDA at our pre-NDA meeting in September, we have been diligently preparing our new drug application (NDA) for oral sulopenem for the treatment of uncomplicated urinary tract infections (uUTIs) due to quinolone-resistant pathogens for submission in the coming weeks, and are making preparations for a potential commercial launch of oral sulopenem in the U.S.,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. “With potential approval anticipated within the next three quarters, we are pleased to be the first oral penem to market in the U.S., and the first approved product in uUTI in over 20 years, where quinolone-resistant pathogens now cause as many as one third of the 22 million uUTIs annually.”

Q3 2020 Highlights and Recent Events

- **Positive meeting with the FDA resulting in continued preparation for submission of the NDA filing in the near-term:** Based on discussions with the FDA at a pre-NDA meeting in September 2020 and previous correspondence with the FDA, the Company plans to proceed with an NDA submission for oral sulopenem (sulopenem etzadroxil/probenecid) for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020. In June 2020, as previously disclosed, the Company announced topline data from the SURE-1 clinical trial demonstrating that oral sulopenem was statistically superior to ciprofloxacin in the treatment of patients with uUTI caused by a quinolone non-susceptible pathogen.
- **Extended cash runway:** In October 2020, the Company raised approximately $17.4 million gross proceeds (approximately $15.3 million net proceeds) in a registered public offering of ordinary shares, pre-funded warrants exercisable for ordinary shares and warrants exercisable for ordinary shares, which extended the Company’s expected cash runway into the third quarter of 2021.
- **Presented results from two Phase 3 studies at the Infectious Disease Society of America (IDSA) IDWeek™ 2020 (IDWeek):** In October 2020, the Company presented results from two of its Phase 3 clinical trials at IDWeek. The two data presentations included a poster presentation of the results of the SURE-2 clinical trial in complicated urinary tract infections, and an oral abstract presentation of the results from the SURE-1 clinical trial in uUTIs.

Third Quarter 2020 Financial Results

As of September 30, 2020, the Company had cash and cash equivalents of $8.6 million and approximately 21.2 million shares outstanding. In October 2020, the Company issued and sold, in a public offering, ordinary shares, pre-funded warrants exercisable for ordinary shares and warrants exercisable for ordinary shares for aggregate gross proceeds of approximately $17.4 million and net proceeds of approximately $15.3 million after deducting fees payable to the placement agent and other estimated offering expenses. The Company expects that its current cash and cash equivalents, including the proceeds from the October 2020 financing, will be sufficient to fund its operations into the third quarter of 2021. The Company is continuing to evaluate its corporate, organizational, strategic, financial and financing alternatives with the goal of maximizing value for its stakeholders, while prudently managing its resources.

Research and development (R&D) expenses for the third quarter of 2020 were $3.9 million compared to $28.1 million for the same period in 2019. The decrease was primarily due to reduced clinical trial expenses and headcount associated with the completion of the Company's Phase 3 clinical trials, which had been initiated in the third quarter of 2018.

General and administrative (G&A) expenses for the third quarter of 2020 were $2.4 million compared to $2.9 million in the same period in 2019. The decrease was primarily due to a decrease in headcount and related costs, lower spending on pre-commercialization activities and reduced share-based compensation to directors, partially offset by an increase in share-based compensation for employees in our general and administrative functions.

Interest expense, net in the third quarter of 2020 was $4.2 million compared to $0.2 million in the same period in 2019, primarily due to non-cash interest expense and amortization of debt discounts and deferred financing costs relating to the Company's Exchangeable Notes and Royalty-Linked Notes issued in 2020.

For the third quarter of 2020, the Company reported a net loss of $12.2 million compared to a net loss of $31.3 million for the same period in 2019.

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 its first compound, sulopenem, a novel penem anti-infective compound, in Phase 3 clinical development 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 received Qualified Infectious Disease Product (QIDP) and Fast Track designations for its oral and IV formulations of sulopenem in seven indications.

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding the Company's plans, strategies and

prospects for its business, including with respect to the Company's planned filing and FDA review of an NDA for oral sulopenem and the sufficiency of the Company'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 the Company'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 the Company's control, including the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, 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 the Company's expectations regarding how far into the future the Company's cash on hand will fund the Company's ongoing operations, the Company's ability to continue as a going concern, the impact of COVID-19 and related responsive measures thereto, the Company's ability to maintain its listing on the Nasdaq Stock Market, risks and uncertainties concerning the outcome, impact, effects and results of the Company's evaluation of corporate, organizational, strategic, financial and financing alternatives, including the terms, timing, structure, value, benefits and costs of any corporate, organizational, strategic, financial or financing alternative and the Company's ability to complete one at all, the price of the Company's securities and other factors discussed under the caption "Risk Factors" in its most recently filed Quarterly Report on Form 10-Q, and other documents filed with the Securities and Exchange Commission from time to time. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this press release. Except as required by law, the Company 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,	
	2020	**2019**	**2020**	**2019**

Revenue	$ —	$ —	$ —	$ 37
Operating expenses:				
Research and development	(3,937)	(28,066)	(18,723)	(69,892)
General and administrative	(2,398)	(2,933)	(8,759)	(8,988)
Total operating expenses	(6,335)	(30,999)	(27,482)	(78,880)
Operating loss	(6,335)	(30,999)	(27,482)	(78,843)
Interest expense, net	(4,183)	(216)	(10,854)	(455)
Financing transaction costs	(685)	—	(2,815)	—
Adjustments to fair value of derivatives	(644)	—	1,023	—
Other income, net	68	48	27	204
Income tax expense	(420)	(104)	(719)	(395)
Net loss attributable to ordinary shareholders	$ (12,199)	$ (31,271)	$ (40,820)	$ (79,489)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.60)	$ (2.15)	$ (2.39)	$ (5.52)
Weighted average ordinary shares outstanding – basic and diluted	20,392,357	14,571,278	17,078,326	14,412,755
Net loss - GAAP	$ (12,199)	$ (31,271)	$ (40,820)	$ (79,489)
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	3,859	—	9,829	—
Financing transaction costs - not capitalized	685	—	2,815	—
Adjustments to fair value of derivatives	644	—	(1,023)	—
Non-GAAP adjusted loss	$ (7,011)	$ (31,271)	$ (29,199)	$ (79,489)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.60)	$ (2.15)	$ (2.39)	$ (5.52)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (0.34)	$ (2.15)	$ (1.71)	$ (5.52)

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

	As of	As of

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 8,570	$ 4,801
Other assets	17,700	20,950
Total assets	**$ 26,270**	**$ 25,751**
Long-term debt, less current portion	$ 21,653	$ 7,625
Royalty-linked notes, less current portion	12,492	—
Derivative liabilities	26,097	—
Other liabilities	21,931	44,364
Total liabilities	82,173	51,989
Total shareholders' deficit	(55,903)	(26,238)
Total liabilities and shareholders' deficit	**$ 26,270**	**$ 25,751**

Source: Iterum Therapeutics plc