

November 12, 2019



Iterum Therapeutics Reports Third Quarter 2019 Financial Results and Highlights

--Phase 3 topline data from the cIAI trial expected shortly--

--cUTI and uUTI Phase 3 trials remain on track to complete enrollment around year-end and report topline data in Q1 2020--

-- NDA Filings Expected in First Half of 2020--

DUBLIN, Ireland and CHICAGO, Nov. 12, 2019 (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, 2019 and provided an update on its clinical programs.

"We look forward to reporting topline data from the first of three Phase 3 studies of sulopenem in the very near future. The remaining studies will complete enrollment around the end of the year and produce topline data in the first quarter of 2020," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. "Assuming positive data, we anticipate submitting a New Drug Application (NDA) for our oral and IV formulations to the FDA in the first half of 2020."

Clinical Update

All three Phase 3 clinical trials of sulopenem have undergone pre-planned protocol specified analyses related to the potential opportunity for sample size adjustments. These analyses, performed by a Data Management Committee, were done to determine whether the initial protocol specified sample size was providing adequate statistical power. Based on the outcome of these analyses, the Company decided to add 225 patients to the complicated UTI study for a total of 1,381 patients and 400 patients to the uncomplicated UTI study for a total of 1,764 patients. No patients were added to the complicated intra-abdominal infections study.

Third Quarter 2019 Financial Results

As of September 30, 2019, Iterum had cash and cash equivalents of \$28.9 million and approximately 14.9 million shares outstanding. Iterum expects that its cash and cash equivalents will be sufficient to fund operations into 2020.

Research and development expenses for the third quarter of 2019 were \$28.1 million compared to \$22.6 million for the same period in 2018. The increase was primarily due to higher clinical trial expenses associated with our three Phase 3 clinical trials initiated in the third quarter of 2018, partially offset by the \$7.5 million milestone payment made to Pfizer in the third quarter of 2018 upon first patient dosing in the SURE 1 clinical trial.

General and administrative expenses for the third quarter of 2019 were \$2.9 million compared to \$2.7 million for the same period in 2018. The increase was primarily due to increased costs associated with operating as a public company, and additional headcount to support business activities.

For the third quarter of 2019, Iterum reported a net loss of \$31.3 million compared to a net loss of \$24.9 million for the same period in 2018.

Upcoming Corporate Event

Iterum's senior management will be presenting an overview of the Company at the Stifel 2019 Healthcare Conference on November 20, 2019 in New York City, NY.

About Sulopenem

Sulopenem, a novel penem anti-infective compound with oral and IV formulations, has demonstrated potent *in vitro* activity against a wide variety of gram-negative, gram-positive and anaerobic bacteria resistant to other antibiotics. If approved, sulopenem will help address the significant clinical and economic need for new oral antibiotics that enable the effective treatment of resistant pathogens in the community, make possible the avoidance

of hospitalization, and facilitate early hospital discharge by providing continuity-of-care step-down therapy. The safety profile of IV sulopenem has been documented in a Phase 2 program. Oral and IV sulopenem are being evaluated in three pivotal Phase 3 clinical trials for uUTI, cUTI, and cIAI.

Probenecid, which is being co-administered with sulopenem in a bilayer tablet, is approved as an adjuvant to therapy for elevation and prolongation of plasma levels of β -lactam compounds.

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 oral and IV formulations. 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 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>.

Forward Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding expectations about future revenue, expenses, cash flows and net income or loss, the sufficiency of cash resources, the development, therapeutic and market potential of sulopenem, and the timing, progress and results of clinical trials and regulatory submissions. 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,” “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 our 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 our control, including the uncertainties inherent in the conduct of clinical trials, clinical trial patient enrollment, availability and timing of data from clinical trials, changes in regulatory requirements or decisions of regulatory authorities, changes in public policy or legislation, commercialization plans and timelines, if approved, the actions of third-party clinical research organizations, suppliers and manufacturers, the accuracy of our expectations regarding how far into the future our cash on hand will fund our ongoing operations and other factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the “SEC”) on November 12, 2019, and other documents filed with the SEC from time to time. Forward-looking statements represent our beliefs and assumptions only as of the date of this press release. Except as required by law, we assume 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		Nine months ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Revenue	\$ -	\$ 254	\$ 37	\$ 630

Operating expenses:				
Research and development	(28,066)	(22,583)	(69,892)	(47,188)
General and administrative	(2,933)	(2,657)	(8,988)	(6,058)
Total operating expenses	(30,999)	(25,240)	(78,880)	(53,246)
Operating loss	(30,999)	(24,986)	(78,843)	(52,616)
Interest expense, net	(216)	(138)	(455)	(100)
Other income, net	48	328	204	183
Income tax expense	(104)	(109)	(395)	(266)
Net loss attributable to ordinary shareholders	\$ (31,271)	\$ (24,905)	\$ (79,489)	\$ (52,799)
Net loss per share attributable to ordinary shareholders – basic and diluted	\$ (2.15)	\$ (1.77)	\$ (5.52)	\$ (7.42)
Weighted average ordinary shares outstanding – basic and diluted	14,571,278	14,034,631	14,412,755	7,115,655

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

	As of September 30, 2019	As of December 31, 2018
Cash, cash equivalents and short-term investments	\$ 28,883	\$ 84,551
Other assets	22,059	13,320
Total assets	\$ 50,942	\$ 97,871
Long-term debt, less current portion	9,343	13,079
Other liabilities	44,695	13,170
Total liabilities	54,038	26,249
Total shareholders' equity (deficit)	(3,096)	71,622
Total liabilities and shareholders' equity (deficit)	\$ 50,942	\$ 97,871



Source: Iterum Therapeutics plc