August 14, 2019

Iterum Therapeutics Reports Second Quarter 2019 Financial Results

--Phase 3 Topline Data anticipated in the fourth quarter--

-- NDA filings expected in first quarter of 2020--

DUBLIN, Ireland and CHICAGO, Aug. 14, 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 second quarter ended June 30, 2019.

“The second quarter was marked by continued progress in our three pivotal Phase 3 clinical trials of sulopenem,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. “Based on current enrollment rates, we anticipate topline data from the complicated intra-abdominal (cIAI) and the complicated urinary tract infection (cUTI) trials in the fourth quarter. This would allow us the flexibility to file our new drug applications (NDAs) in the first quarter of 2020. Our trial for uncomplicated urinary tract infections (uUTI) just passed two-thirds enrollment, which triggers a pre-planned review of the blinded data for potential sample size adjustment. The outcome of this analysis will determine the enrollment timeline, which will guide our decision on the optimal filing strategy for the uUTI data.”

Recent Highlights

- **Presented research at ASM Microbe that supports the need for new antibiotics to treat uUTIs:** In June, Iterum presented data that showed patients with uUTIs in the community treated with the most commonly prescribed antibiotic for that infection, ciprofloxacin, have a significantly greater rate of treatment failure when the organism is quinolone resistant. Based on our uUTI trial, Iterum estimates that resistance to quinolones in the community is greater than 25% in many geographies in the U.S., and greater than 30% outside of the U.S.

Second Quarter 2019 Financial Results

As of June 30, 2019, Iterum had cash and cash equivalents of $51.2 million and approximately 14.4 million shares outstanding. Iterum expects that its cash and cash equivalents will be sufficient to fund operations into 2020.

Research and development (R&D) expenses for the second quarter of 2019 were $24.4 million compared to $13.7 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 a reduction in chemistry, manufacturing and control-related expenses as a result of the completion of manufacturing of clinical trial materials for our Phase 3 clinical trials by our primary suppliers.

General and administrative (G&A) expenses for the second quarter of 2019 were $2.9 million compared to $1.9 million for the same period in 2018. The increase was primarily due to increased costs associated with operating as a public company, additional headcount to support business activities, and increased marketing expenses.

For the second quarter of 2019, Iterum reported a net loss of $27.6 million compared to a net loss of $15.7 million for the same period in 2018.

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 uncomplicated urinary tract infections, complicated urinary tract infections, and complicated intra-abdominal infections.

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 including penicillin, ampicillin, methicillin, oxacillin, cloxacillin, and nafcillin.

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 Iterum Therapeutics’ 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 Therapeutics' control, including the uncertainties inherent in the initiation and 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 and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10- Q filed with the Securities and Exchange Commission (the "SEC") on August 14, 2019, and other documents filed with the SEC from time to time. Forward-looking statements represent Iterum Therapeutics' beliefs and assumptions only as of the date of this press release. Except as required by law, Iterum Therapeutics 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,	
	2019	**2018**	**2019**	**2018**
Revenue	$ -	$ 185	$ 37	$ 376
Operating expenses:				
Research and development	(24,439)	(13,725)	(41,826)	(24,604)
General and administrative	(2,939)	(1,886)	(6,055)	(3,401)
Total operating expenses	(27,378)	(15,611)	(47,881)	(28,005)
Operating loss	(27,378)	(15,426)	(47,844)	(27,629)
Interest (expense) / income, net	(135)	(76)	(239)	9
Other income / (expense), net	32	(177)	156	(116)
Income tax expense	(157)	(68)	(291)	(157)
Net loss attributable to ordinary shareholders	$ (27,638)	$ (15,747)	$ (48,218)	$ (27,893)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.93)	$ (2.22)	$ (3.37)	$ (6.72)
Weighted average ordinary shares outstanding – basic and diluted	14,340,231	7,085,655	14,316,497	4,148,535

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

	As of June 30, 2019	As of December 31, 2018
Cash, cash equivalents and short-term investments	$ 51,241	$ 84,551
Other assets	20,052	13,320
Total assets	**$ 71,293**	**$ 97,871**
Long-term debt, less current portion	10,771	13,079
Other liabilities	35,946	13,170
Total liabilities	46,717	26,249
Total shareholders' equity	24,576	71,622
Total liabilities and shareholders' equity	**$ 71,293**	**$ 97,871**

Source: Iterum Therapeutics plc