

Iterum Reports Third Quarter 2018 Financial Results and Recent Highlights

DUBLIN, Ireland and CHICAGO, Nov. 14, 2018 (GLOBE NEWSWIRE) -- Iterum Therapeutics plc (Nasdaq: ITRM), a clinical-stage pharmaceutical company developing anti-infectives against multi-drug resistant pathogens, today reported financial results for the quarter ended September 30, 2018.

"The third quarter was highlighted by the initiation of our entire Phase 3 program for sulopenem. With all three clinical trials underway, we reiterate our goal of delivering top-line data in the second half of 2019," said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. "Iterum is now that much closer to bringing this important oral therapy to market, allowing effective treatment in the community when a multi-drug resistant infection in one of our three indications is suspected or confirmed."

Third Quarter and Recent Highlights

- **Initiated all three planned Phase 3 pivotal clinical trials for sulopenem, which includes**
 - 1) a Phase 3 uncomplicated urinary tract infections (uUTI) clinical trial, known as SUopenem for Resistant Enterobacteriaceae (SURE) 1, comparing oral sulopenem to oral ciprofloxacin in women with uUTI; 2) a Phase 3 complicated urinary tract infections (cUTI) clinical trial, known as SURE 2, comparing IV sulopenem followed by oral sulopenem to IV ertapenem followed by oral ciprofloxacin in adults with cUTI; and 3) a Phase 3 complicated intra-abdominal infections (cIAI) clinical trial known as SURE 3, comparing IV sulopenem followed by oral sulopenem to IV ertapenem followed by a combination of oral ciprofloxacin and oral metronidazole in adults with cIAI.
- **Presented data at IDWeek:** In October 2018, Iterum presented three posters including data on the pharmacokinetics of sulopenem, the *in vitro* antibacterial activity of sulopenem and the prevalence of enterobacteriaceae resistant to all major classes of oral antibiotics from outpatient urine cultures in the United States and the effect on clinical outcomes at the Infectious Diseases Society of America (IDSA) meeting in San Francisco.

Third Quarter 2018 Financial Results

As of September 30, 2018, Iterum had cash, cash equivalents and short-term investments of \$108.1 million and approximately 14.2 million shares outstanding. Iterum expects that its cash, cash equivalents and short-term investments, along with its available borrowings, will be sufficient to fund operations through the fourth quarter of 2019.

For the full year 2018, operating expenses are expected to be approximately \$85-90 million, which includes the milestone payments owed to Pfizer on first patient dosed in a Phase 3 trial with oral and IV sulopenem of \$7.5 million for each product (or \$15 million total).

Research and development (R&D) expenses for the third quarter of 2018 were \$22.6 million compared to \$7.4 million for the same period in 2017. One of the two \$7.5 million milestone payments owed to Pfizer as described above was recorded and paid in the third quarter. The remaining \$7.5 million milestone is expected to be recorded and paid in the fourth quarter of 2018. Excluding the Pfizer milestone payment, the \$7.7 million increase in R&D expenses was primarily due to the increase in clinical trial expenses associated with the three Phase 3 clinical trials initiated in the third quarter of 2018.

General and administrative expenses for the third quarter of 2018 were \$2.7 million compared to \$1.0 million for the same period in 2017. This increase was primarily due to increased headcount to support research and development efforts, increased costs associated with operating as a public company and pre-commercialization activities.

Iterum reported a net loss for the third quarter of 2018 of \$24.9 million compared to a net loss of \$8.2 million for the same period in 2017.

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 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 has received QIDP designations for its oral and IV formulations for the treatment of uncomplicated urinary tract infection, complicated urinary tract infection and complicated intra-abdominal infection. 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 financial guidance for 2018, expectations regarding future revenue, expenses, cash flows and net income or loss, the development, therapeutic and market potential of sulopenem, the timing, progress and results of clinical trials, and the expected timing of NDA filings. 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’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 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, 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 November 14, 2018, 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		Nine months ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenue	\$ 254	\$ 159	\$ 630	\$ 159
Operating expenses:				
Research and development	(22,583)	(7,434)	(47,188)	(17,258)
General and administrative	(2,657)	(1,021)	(6,058)	(3,152)
Total operating expenses	(25,240)	(8,455)	(53,246)	(20,410)
Operating loss	(24,986)	(8,296)	(52,616)	(20,251)
Interest income / (expense), net	(138)	123	(100)	169
Other income / (expense), net	328	90	183	187
Income tax expense	(109)	(88)	(266)	(393)

Net loss attributable to ordinary shareholders	<u>\$ (24,905)</u>	<u>\$ (8,171)</u>	<u>\$ (52,799)</u>	<u>\$ (20,288)</u>
Net loss per share attributable to ordinary shareholders – basic				
and diluted	<u>\$ (1.77)</u>	<u>\$ (44.16)</u>	<u>\$ (7.42)</u>	<u>\$ (127.42)</u>
Weighted average ordinary shares outstanding – basic				
and diluted	<u>14,034,631</u>	<u>185,040</u>	<u>7,115,655</u>	<u>159,221</u>
Net Loss - GAAP	(24,905)	(8,171)	(52,799)	(20,288)
Milestone Payment to Pfizer	<u>7,500</u>	<u>—</u>	<u>7,500</u>	<u>—</u>
Non-GAAP adjusted loss	<u>(17,405)</u>	<u>(8,171)</u>	<u>(45,299)</u>	<u>(20,288)</u>
Net loss per share attributable to ordinary shareholders – basic				
and diluted	<u>\$ (1.77)</u>	<u>\$ (44.16)</u>	<u>\$ (7.42)</u>	<u>\$ (127.42)</u>
Non-GAAP net loss per share attributable to ordinary shareholders – basic				
and diluted	<u>\$ (1.24)</u>	<u>\$ (44.16)</u>	<u>\$ (6.37)</u>	<u>\$ (127.42)</u>

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

	September 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	\$ 108,107	\$ 39,216
Other assets	8,758	7,541
Total assets	\$ 116,865	\$ 46,757
Long-term debt	14,541	-
Other liabilities	8,226	7,206
Total liabilities	\$ 22,767	\$ 7,206
Total convertible preferred shares and shareholders' equity	94,098	39,551
Total liabilities, convertible preferred shares and shareholders' equity	\$ 116,865	\$ 46,757



Source: Iterum Therapeutics plc