March 25, 2019

Iterum Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results

--On Track to Complete its Three Phase 3 Clinical Trials in 2019-
--Received Qualified Infectious Disease Product Designation in Four Additional Indications--
--Fast Track Designation received from the FDA in seven potential indications--

DUBLIN, Ireland and CHICAGO, March 25, 2019 (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 fourth quarter and year ended December 31, 2018.

“We made tremendous progress in 2018. We raised over $80 million in an IPO to fund three Phase 3 trials in three indications of our lead asset, sulopenem, which were initiated in the third quarter,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics plc. “In 2019, we remain focused on completing all three trials, delivering top-line results, and preparing our New Drug Applications for submission to the U.S. Food and Drug Administration (FDA).”

2018 Highlights and Recent Events

- **Initiated three Phase 3 pivotal clinical trials:** In the third quarter of 2018, Iterum initiated three Phase 3 clinical trials in each of the following indications: uncomplicated urinary tract infections (uUTI), complicated urinary tract infections (cUTI), and complicated intra-abdominal infections (cIAI). Data from these trials are expected in the second half of 2019.
- **Strengthened the balance sheet:** In May 2018, Iterum raised approximately $80 million of gross proceeds in an initial public offering of ordinary shares. In April 2018, Iterum completed a debt financing with Silicon Valley Bank for up to $30 million, $15 million of which was funded upfront. In February 2018, Iterum closed its Series B-2 financing raising over $32 million.
- **Received QIDP and Fast Track designation from the FDA:** Oral sulopenem and sulopenem IV received QIDP designation in four new indications, community-acquired bacterial pneumonia, acute bacterial prostatitis, gonococcal urethritis, and pelvic inflammatory disease. These indications, as well as the three indications currently in Phase 3 development, have also received Fast Track designation from the FDA.
- **Presented data at scientific congresses:** Iterum presented important data at the American Society of Microbiology MICROBE meeting and during IDWeek that underscores the need for new antibiotics, particularly oral therapies like sulopenem, which can be used in both the community and hospital settings.

Fourth Quarter and Full-Year 2018 Financial Results

As of December 31, 2018, Iterum had cash, cash equivalents and short-term investments of $84.6 million and approximately 14.4 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 into the first quarter of 2020.

Research and development (R&D) expenses for the fourth quarter and full year 2018 were $21.5 million and $68.6 million, respectively, compared to $8.2 million and $25.5 million for the same periods in 2017. The increases for both the three-month and twelve-month periods were primarily due to higher clinical trial expenses associated with the three Phase 3 clinical trials initiated in the third quarter of 2018, as well as clinical milestone payments to Pfizer of $7.5 million and $15.0 million in the fourth quarter and full year, respectively.

General and administrative (G&A) expenses for the fourth quarter and full year 2018 were $2.7 million and $8.8 million, respectively, compared to $1.3 million and $4.5 million for the same periods in 2017. The increase was primarily due to increased costs associated with operating as a public company, additional headcount to support business activities, and increased marketing and market research expenses.

For the fourth quarter and full year 2018, Iterum reported a net loss of $24.3 million and $77.1 million, respectively, compared to a net loss of $9.1 million and $29.4 million for the same periods in 2017.

Upcoming Scientific and Investor Presentations

- Corporate presentation at the Needham & Company 18th Annual Healthcare Conference on Tuesday, April 9,

2019 at 1:30 p.m. in New York, New York
- Multiple scientific presentations at the 29th European Congress of Clinical Microbiology and Infectious Diseases from April 13-16, 2019 in Amsterdam, Netherlands
- Corporate presentation at the RBC Capital Markets Global Healthcare Conference from May 21-22, 2019 in New York, New York
- Multiple scientific presentations at American Society of Microbiology (ASM) Microbe 2019 from June 20-24, 2019 in San Francisco, California

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.

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 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.

Forward Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding expectations regarding future revenue, expenses, cash flows and net income or loss, the sufficiency of cash resources, 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 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, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 25, 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenue	$ 239	$ 349	$ 869	$ 508
Operating expenses:				
Research and development	(21,460)	(8,241)	(68,647)	(25,499)
General and administrative	(2,723)	(1,312)	(8,781)	(4,464)
Total operating expenses	(24,183)	(9,553)	(77,428)	(29,963)
Operating loss	(23,944)	(9,204)	(76,559)	(29,455)
Interest (expense) / income, net	(297)	108	(426)	277
Other income, net	189	29	401	216
Income tax expense	(206)	(51)	(472)	(444)
Net loss attributable to ordinary shareholders	$ (24,258)	$ (9,118)	$ (77,056)	$ (29,406)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.72)	$ (43.24)	$ (8.82)	$ (170.84)
Weighted average ordinary shares outstanding – basic and diluted	14,108,604	210,859	8,734,109	172,130
Net Loss - GAAP	(24,258)	(9,118)	(77,056)	(29,406)
Milestone Payments to Pfizer	7,500	-	15,000	-
Non-GAAP adjusted loss	(16,758)	(9,118)	(62,056)	(29,406)
Net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.72)	$ (43.24)	$ (8.82)	$ (170.84)
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	$ (1.19)	$ (43.24)	$ (7.11)	$ (170.84)

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

	Year Ended December 31,	
	2018	2017
Cash, cash equivalents, restricted cash and short-term investments	$ 84,671	$ 39,216
Other assets	13,200	7,541
Total assets	**$ 97,871**	**$ 46,757**
Long-term debt, less current portion	13,079	-
Other liabilities	13,170	7,206
Total liabilities	$ 26,249	$ 7,206
Total convertible preferred shares and shareholders' equity	71,622	39,551
Total liabilities, convertible preferred shares and shareholders' equity	**$ 97,871**	**$ 46,757**

Source: Iterum Therapeutics plc