

August 6, 2020



# Iterum Therapeutics Reports Second Quarter 2020 Financial Results

## --Meeting with FDA Scheduled for end of Q3--

DUBLIN, Ireland and CHICAGO, Aug. 06, 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 second quarter ended June 30, 2020.

“Based on data generated in our Phase 3 clinical program, we continue to believe that sulopenem can play a vital role in the treatment of infections caused by multi-drug resistant pathogens that have become prevalent in our community,” said Corey Fishman, Chief Executive Officer of Iterum Therapeutics. “We have been granted a meeting with the FDA at the end of the third quarter and plan to share the results of that meeting shortly thereafter.”

## Q2 2020 Highlights and Recent Events

- **Announced topline results in cUTI and uUTI Phase 3 trials and planning for a meeting with the FDA:** In June 2020, the Company announced that it achieved one of its two independent primary endpoints in the uncomplicated urinary tract infection (uUTI) trial by demonstrating superiority to ciprofloxacin in the treatment of patients with quinolone resistant pathogens. The Company also announced that sulopenem failed to achieve the primary endpoint in its complicated urinary tract infection (cUTI) trial. Based on these trial results and previous discussions with the U.S. Food and Drug Administration (FDA), the Company plans to discuss its potential regulatory filing options with the FDA in a meeting scheduled for the end of the third quarter.
- **Strengthened the balance sheet:** Raised \$10.0 million gross proceeds (\$8.7 million net of estimated fees and expenses) in two registered direct offerings to certain institutional investors of ordinary shares and concurrent private placements of warrants to purchase ordinary shares in June 2020 and July 2020.
- **Set record date for rights offering:** As previously disclosed, the Company established 5:00 p.m. on August 5, 2020, as the record date for its planned rights offering. The Company had agreed to undertake a rights offering of subscription rights to purchase additional units in connection with the Company’s January 2020 private placement of units consisting of 6.500% Exchangeable Senior Subordinated Notes due 2025 and Limited Recourse Royalty-Linked Subordinated Notes.

## Second Quarter 2020 Financial Results

As of June 30, 2020, the Company had cash and cash equivalents of \$12.3 million and

approximately 17.9 million shares outstanding. In July 2020, the Company received net proceeds of approximately \$4.4 million from a registered direct offering of ordinary shares and concurrent private placement of warrants to purchase ordinary shares. The Company expects that its current cash and cash equivalents, including the proceeds from the July 2020 financing, will be sufficient to fund its operations into the fourth quarter of 2020. 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 second quarter of 2020 were \$5.0 million compared to \$24.4 million for the same period in 2019. The decrease was primarily due to reduced clinical trial expenses associated with the completion of the Company's Phase 3 clinical trials initiated in the third quarter of 2018.

General and administrative (G&A) expenses for the second quarter of 2020 were \$3.2 million compared to \$2.9 million in the same period in 2019. The increase was primarily due to an increase in share-based compensation for employees in our general and administrative and commercial functions partially offset by a decrease in headcount and related costs.

Interest expense, net in the second quarter of 2020 was \$4.1 million compared to \$0.1 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 January 2020 private placement.

For the second quarter of 2020, the Company reported a net loss of \$12.5 million compared to a net loss of \$27.6 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 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 expected timing, terms and completion of the planned rights offering and the Company's plans, strategies and prospects for its business, including with respect to the Company's scheduled meeting with the FDA. 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 Company's ability to apply for regulatory approval, changes in public policy or legislation, commercialization plans and timelines, if 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 sufficiency of the Company's cash resources and the Company's ability to continue as a going concern, the impact of COVID-19 and related responsive measures thereto, 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, the expected use of proceeds from the planned rights offering 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 SEC 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.

**Investor Contact:**

Judy Matthews  
 Chief Financial Officer  
 312-778-6073  
[IR@iterumtx.com](mailto:IR@iterumtx.com)

**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,	
	2020	2019	2020	2019
Revenue	\$ —	\$ —	\$ —	\$ 37
Operating expenses:				
Research and development	(5,043 )	(24,439 )	(14,786 )	(41,826 )
General and administrative	(3,210 )	(2,939 )	(6,361 )	(6,055 )
Total operating expenses	<u>(8,253 )</u>	<u>(27,378 )</u>	<u>(21,147 )</u>	<u>(47,881 )</u>
Operating loss	(8,253 )	(27,378 )	(21,147 )	(47,844 )

Interest expense, net	(4,075 )	(135 )	(6,671 )	(239 )
Private placement transaction costs	—	—	(2,130 )	—
Adjustments to fair value of derivatives	(12 )	—	1,667	—
Other (expense) / income, net	(3 )	32	(41 )	156
Income tax expense	(178 )	(157 )	(299 )	(291 )
Net loss attributable to ordinary shareholders	<u>\$ (12,521 )</u>	<u>\$ (27,638 )</u>	<u>\$ (28,621 )</u>	<u>\$ (48,218 )</u>
Net loss per share attributable to ordinary shareholders – basic and diluted	<u>\$ (0.80 )</u>	<u>\$ (1.93 )</u>	<u>\$ (1.87 )</u>	<u>\$ (3.37 )</u>
Weighted average ordinary shares outstanding – basic and diluted	<u>15,614,767</u>	<u>14,340,231</u>	<u>15,295,141</u>	<u>14,316,497</u>
Net loss - GAAP	\$ (12,521 )	\$ (27,638 )	\$ (28,621 )	\$ (48,218 )
Interest expense - accrued interest and amortization on Exchangeable Notes and Royalty-Linked Notes	3,704	—	5,970	—
Private placement transaction costs - not capitalized	-	—	2,130	—
Adjustments to fair value of derivatives	12	—	(1,667 )	—
Non-GAAP adjusted loss	<u>\$ (8,805 )</u>	<u>\$ (27,638 )</u>	<u>\$ (22,188 )</u>	<u>\$ (48,218 )</u>
Net loss per share attributable to ordinary shareholders – basic and diluted	<u>\$ (0.80 )</u>	<u>\$ (1.93 )</u>	<u>\$ (1.87 )</u>	<u>\$ (3.37 )</u>
Non-GAAP net loss per share attributable to ordinary shareholders – basic and diluted	<u>\$ (0.56 )</u>	<u>\$ (1.93 )</u>	<u>\$ (1.45 )</u>	<u>\$ (3.37 )</u>

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

	<b>As of June 30, 2020</b>	<b>As of December 31, 2019</b>
Cash and cash equivalents	\$ 12,250	\$ 4,801
Other assets	19,437	20,950
<b>Total assets</b>	<b>\$ 31,687</b>	<b>\$ 25,751</b>
Long-term debt, less current portion	\$ 20,931	\$ 7,625
Royalty-linked notes, less current portion	11,826	—
Derivative liability	25,371	—
Other liabilities	22,348	44,364
Total liabilities	80,476	51,989
Total shareholders' deficit	(48,789 )	(26,238 )

<b>Total liabilities and shareholders' deficit</b>	<b>\$</b>	<b>31,687</b>	<b>\$</b>	<b>25,751</b>
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Source: Iterum Therapeutics plc