UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 01, 2021

Iterum Therapeutics plc		
(Exact name of registrant as specified in its charter)		
Ireland	**001-38503**	**98-1283148**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Block 2 Floor 3, Harcourt Centre,	
Harcourt Street,	**Not Applicable**
Dublin 2, Ireland	
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **+353 1 903 8920**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Ordinary Shares, par value $0.01 per share	ITRM	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 8.01 Other Events

Ordinary Shares Issued and Outstanding; Ordinary Shares Reserved

As of January 31, 2021, Iterum Therapeutics plc (the "Company") had 81,149,910 ordinary shares issued and outstanding. The number of ordinary shares issued and outstanding as of January 31, 2021 reflects, among other things, the exercise of certain warrants issued in the previously disclosed registered public offering the Company completed on October 27, 2020 (the "October 2020 Offering") and receipt of an aggregate of $12,160,002.89 in consideration for exercise thereof and ordinary shares issued upon exchange of certain of the outstanding 6.500% exchangeable senior subordinated notes due 2025 issued by Iterum Therapeutics Bermuda Limited in connection with the previously disclosed private placement completed in January 2020 and the previously disclosed rights offering completed in September 2020 (the "Exchangeable Notes").

In addition, as of January 31, 2021, the board of directors had reserved 1,432,556 shares for issuance upon exercise of outstanding options, performance share unit awards and restricted share unit awards granted under the Company's equity compensation plans, 2,652,326 ordinary shares that may be issued pursuant to future grants or rights under the Company's equity compensation plans, and up to 7,323,483 ordinary shares that may be issued upon exercise of warrants outstanding as of such date. The number of ordinary shares that may be issued upon exercise of warrants that are outstanding as of January 31, 2021, includes, among other things, warrants issued in the previously disclosed registered direct offerings completed by the Company on June 5, 2020, and July 2, 2020, and the October 2020 Offering, in each case a substantial portion of which remain unexercised as of such date. Additionally, as of January 31, 2021, the board of directors had reserved 53,449,179 ordinary shares that may be issued upon full exchange of the principal amount (assuming physical settlement) of the Company's outstanding Exchangeable Notes. The number of ordinary shares issuable upon full exchange of the principal amount of the Exchangeable Notes (assuming physical settlement) and the number of ordinary shares reserved for such potential issuance may increase depending on the exchange rate of the Exchangeable Notes from time to time, which may be adjusted pursuant to the terms of the indenture governing the Exchangeable Notes, in addition to the amount of accrued and unpaid interest due upon exchange from time to time. As of January 31, 2021, the Company has approximately 153,992,546 ordinary shares which are unissued, unreserved, or unallocated and therefore available for future use (i.e., not already outstanding or reserved for future issuance under the Company's Exchangeable Notes, warrants, options, performance share unit awards, restricted share unit awards, equity plans, or otherwise allocated for other purposes).

Cash Runway

The Company estimates that its existing cash and cash equivalents should be sufficient to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2021, including through the PDUFA (Prescription Drug User Fee Act) goal date of July 25, 2021 for completion of the U.S. Food and Drug Administration's review of the Company's new drug application for oral sulopenem for the treatment of uncomplicated urinary tract infections ("uUTI") in patients with quinolone-resistant pathogens. The Company could deplete its capital resources sooner than it currently expects. The Company may need to secure additional resources to support its continued operations, including its potential commercial launch of oral sulopenem in the fourth quarter of 2021 subject to approval by the FDA. This estimate assumes, among other things, the continuation of regular monthly amortization payments of the principal amount outstanding under the Company's credit facility with Silicon Valley Bank and that the balance of the principal amount does not become due and payable until the maturity date of March 1, 2022. The Company has based this estimate on assumptions that may prove to be wrong, and its operating plans may change as a result of many factors and various risks and uncertainties.

Business Update

On February 1, 2021, the Company issued a press release announcing it has engaged EVERSANA™, a leading provider of commercial services to the life science industry, to immediately initiate pre-launch activities for oral sulopenem, followed by planned commercialization services upon final agreement. Ahead of an anticipated decision by the FDA in July 2021 with respect to the NDA for oral sulopenem, the Company will utilize EVERSANA's pre-launch activities, including U.S. market access, strategic marketing, medical education and patient services. Fully integrated commercialization services would then be expected to include clinical and commercial field teams, market access, channel management and distribution, health economics and outcomes research, compliance and medical science liaison teams, with each service optimized by data and predictive analytics.

The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Forward-looking Statements

This Current Report on Form 8-K contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding, among other things, the sufficiency of existing cash resources to fund ongoing operations, entering into a final binding agreement with EVERSANA with respect to pre-launch and future commercial services, including obtaining all necessary approvals that may be required, the timing and outcome of the review of regulatory filings and the market opportunity for, and potential market acceptance of, oral sulopenem for uUTIs, and the Company's plans, strategies and prospects for its business. 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 timing of approval of any submission, changes in public policy or legislation, commercialization plans and timelines, if oral 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, the Company's ability to maintain listing on the Nasdaq Capital Market, 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 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 Current Report on Form 8-K. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Iterum Therapeutics plc dated February 1, 2020

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Iterum Therapeutics plc

Dated: February 1, 2021

By: /s/ Corey N. Fishman
Corey N. Fishman
Chief Executive Officer

EXHIBIT 99.1

Iterum Therapeutics Announces Collaboration with EVERSANA to Support Oral Sulopenem Launch

DUBLIN, Ireland and CHICAGO, February 1, 2021 (GLOBE NEWSWIRE)- Iterum Therapeutics plc (Nasdaq: ITRM) (the Company), 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 announced it has engaged EVERSANA™, a leading provider of commercial services to the life science industry, to immediately initiate pre-launch activities, followed by planned commercialization services upon final agreement.

As previously announced, the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uncomplicated urinary tract infections (uUTIs) in patients with a quinolone non-susceptible pathogen.

Ahead of an anticipated decision by the FDA in July 2021, Iterum will utilize EVERSANA's pre-launch activities including U.S. market access, strategic marketing, medical education, and patient services. Fully integrated commercialization services would then be expected to include clinical and commercial field teams, market access, channel management and distribution, health economics and outcomes research, compliance and medical science liaison teams, with each service optimized by data and predictive analytics. The agreement with EVERSANA builds on the strong commercial strategies the Company has developed over the last few years.

"We are very pleased to partner with EVERSANA and are confident in their ability to provide end-to-end services to ensure oral sulopenem will reach patients and their families efficiently and effectively once oral sulopenem is available for prescribing," said Corey Fishman, Chief Executive Officer at Iterum Therapeutics. "We will be working diligently to ensure we are ready for the potential launch of oral sulopenem in the U.S. in the fourth quarter of 2021."

"We believe in sulopenem's value to meet a long-standing, unmet clinical need and look forward to providing Iterum's patients with access to comprehensive support at launch using our ready-to-deploy complete commercialization infrastructure and experts," said Jim Lang, Chief Executive Officer of EVERSANA.

The FDA has designated the NDA for priority review and consequently assigned a PDUFA (Prescription Drug User Fee Act) goal date for completion of the review of oral sulopenem of July 25, 2021.

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 formulation 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.

About EVERSANA

EVERSANA™ is the leading provider of global services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies, to advance life science solutions for a healthier world.

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding, among other things, entering into a final binding agreement with EVERSANA with respect to launch and future commercial services, including obtaining all necessary approvals that may be required, timing and outcome of the review of regulatory filings and the market opportunity for, and potential market acceptance of, oral sulopenem for uUTIs, and the Company's plans, strategies and prospects for its business. 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 timing of approval of any submission, changes in public policy or legislation, commercialization plans and timelines, if oral 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, the Company's ability to maintain listing on the Nasdaq Capital Market, 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 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.

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