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): December 18, 2020

Iterum Therapeutics plc		
(Exact name of registrant as specified in its charter)		
Ireland	**001-38503**	**98-1283**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Ide

Block 2 Floor 3, Harcourt Centre,	
Harcourt Street,	
Dublin 2, Ireland	**n/a**
(Address of principal executive offices)	(Zip Co

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(s)	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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On December 18, 2020, Michael Dunne, M.D., notified Iterum Therapeutics plc (the "Company") of his decision to resign as Chief Scientific Officer of the Company, effective December 21, 2020, to pursue other professional interests. Dr. Dunne has agreed to serve as a strategic advisor to the Company throughout the regulatory review of the Company's pending new drug application for oral sulopenem for the treatment of uncomplicated urinary tract infections in patients with a quinolone non-susceptible pathogen. In connection with his resignation and transition to service as a strategic advisor, the Company expects to enter into arrangements with Dr. Dunne, including a consulting agreement, that will, among other things, provide compensation to him, in an amount and on terms yet to be determined.

Steven Aronin, M.D., the Company's current Senior Vice President and Head of Clinical Development, will lead the Company's development and regulatory activities following the effective date of Dr. Dunne's resignation.
In addition, on December 22, 2020, the Board of Directors (the "Board") of the Company increased the size of the Board from seven members to eight members and the Board appointed Dr. Dunne as a member of the Board, effective immediately. Dr. Dunne was appointed to serve as a Class III director with a term expiring at the Company's 2021 annual meeting of shareholders until his successor is duly elected and qualified, or until his earlier death, resignation or removal.

Following the effective date of his resignation, Dr. Dunne will receive compensation for his service as a non-employee director in accordance with the Company's non-employee director compensation policy, as described in the proxy statement relating to the Company's 2020 annual meeting of shareholders as filed with the Securities and Exchange Commission (the "SEC") on May 7, 2020.

Dr. Dunne has no family relationship with any of the executive officers or directors of the Company. Other than as described above, there were no arrangements or understandings between Dr. Dunne and any other person pursuant to which he was appointed to this position.

Dr. Dunne had previously entered into the standard form of indemnification agreements with each of the Company and Iterum Therapeutics US Limited, the Company's indirect wholly owned subsidiary, copies of which were filed with the SEC as Exhibit 10.10 and Exhibit 10.11, respectively, to the Company's Registration Statement on Form S-1.

The Company issued the press release attached hereto as Exhibit 99.1 related to the events discussed above.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by Iterum Therapeutics plc, dated December 23, 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: December 23, 2020

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

EXHIBIT 99.1

Iterum Therapeutics Announces Transition of Michael Dunne, M.D. to Strategic Advisor and Member of the Board of Directors

--Dr. Dunne resigns as Chief Scientific Officer--

-- Steven Aronin, M.D., Senior Vice President and Head of Clinical Development, to lead Development and Regulatory Activities--

DUBLIN, Ireland and CHICAGO; December 23, 2020 (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 that Dr. Michael Dunne has resigned from his role as Chief Scientific Officer of the Company, effective December 21, 2020. Dr. Dunne has agreed to be a strategic advisor to the Company actively working as a consultant throughout the regulatory review and potential approval of the Company's pending NDA for oral sulopenem for the treatment of uncomplicated urinary tract infections (uUTIs) in patients with a quinolone non-susceptible pathogen upon terms and conditions to be agreed by the Company and Dr. Dunne. Dr. Dunne has also been elected to the Company's Board of Directors, effective as of December 22, 2020. The Company's Senior Vice President and Head of Clinical Development, Dr. Steve Aronin, will lead the Company's development and regulatory activities following the effective date of Dr. Dunne's resignation.

"Mike has been instrumental in the development of sulopenem, and we thank him for his many contributions to date. We are excited that he will continue on with the Company as a trusted advisor and Board member during this important phase of the regulatory review process," said Corey Fishman, Chief Executive Officer. "We are confident that with Steve's experience as an infectious disease physician and his deep understanding of sulopenem's clinical development program, he will provide exceptional leadership to our regulatory and development functions. As we move closer to an anticipated FDA decision regarding our pending NDA in the third quarter of 2021, we will continue to transition from a development to a commercial organization."

In November 2020, the Company submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for sulopenem etzadroxil/probenecid (oral sulopenem) for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen.

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.

Forward-Looking Statements

This press release contains forward-looking statements. These forward-looking statements include, without limitation, statements regarding the Company's plans, strategies and prospects for its business, Dr. Dunne's expected consultancy position with the Company and the regulatory review process of sulopenem.

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, risks regarding intellectual property rights in product candidates and the ability to defend and enforce any such intellectual property rights, 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 Stock 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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