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): October 25, 2024

Iterum Therapeutics plc

(Exact name of Registrant as Specified in Its Charter)

Ireland	**001-38503**	**Not applicable**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
Fitzwilliam Court 1st Floor Leeson Close Dublin 2, , Ireland **(Address of Principal Executive Offices)**		**Not applicable** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: +353 1 6694820

(Former Name or Former Address, if Changed Since Last Report)

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:

☐ 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 7.01 Regulation FD Disclosure.

On October 25, 2024, Iterum Therapeutics plc (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") approved ORLYNVAH™ (sulopenem etzadroxil and probenecid) for the treatment of uncomplicated urinary tract infections ("uUTIs") caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis in adult women who have limited or no alternative oral antibacterial treatment options. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The Company will host a conference call to discuss the FDA approval of ORLYNVAH™ on Monday, October 28, 2024 at 8:30 a.m. Eastern Daylight Time. The conference call replay will be available in the Events & Presentations section of the Company's website following the call.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and Exhibit 99.1 attached hereto is "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended.

Item 8.01 Other Events.

On October 25, 2024, the Company announced that the FDA approved ORLYNVAH™ for the treatment of uUTIs caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumonia*e, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options. This is the first approved indication for ORLYNVAH™ and the first FDA-approved product for the Company.

The FDA approval of ORLYNVAH™ was based on a clinical development program supported by a robust data package, including two pivotal, Phase 3 clinical trials (known as SURE 1 and REASSURE) that evaluated the safety and efficacy of ORLYNVAH™ compared to ciprofloxacin (SURE 1) and Augmentin™ (REASSURE) in the treatment of adult women with uUTI. SURE 1 showed superiority to ciprofloxacin in fluoroquinolone res#istant infections, while REASSURE showed non-inferiority and statistical superiority to Augmentin™ in the Augmentin™ susceptible population. ORLYNVAH™ was generally well tolerated in both SURE 1 and REASSURE clinical trials.

UTIs are among the most common bacterial infections encountered in the community. uUTIs are infections of the bladder occurring mainly in women. Up to 60% of women will have an uUTI in their lifetime. Up to 40% of women with a history of uUTI will have a recurrence of their infection. There are approximately 40 million uUTIs prescriptions generated annually in the United States, and the Company's estimate approximately 1% of those infections are caused by pathogens that are resistant to all commonly available classes of oral antibiotics. Rising antibiotic resistance, an aging population with comorbidities and sub-optimal safety profiles of existing oral treatment options are making antibiotic selection more challenging for treating physicians.

The Company expects to renew its efforts to achieve a strategic transaction involving ORLYNVAH™ with the goal of maximizing value for its stakeholders. The Company has previously engaged an investment bank to advise it in this process. The Company cannot provide any commitment regarding when or if this strategic review process will result in any type of transaction and no assurance can be given that the Company will complete a potential sale, strategic partnership or licensing arrangement. In the event the Company's strategic process does not result in any type of transaction, and subject to the Company's ability to raise sufficient capital to fund operations, the Company may seek a commercial partner and/or look to commercialize oral sulopenem in the United States directly with a targeted sales force in the community setting.

Cautionary Note Regarding Forward-looking Statements.

This Form 8-K contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding the Company's plans, strategies and prospects for its business, including the development, therapeutic and market potential of ORLYNVAH™ and the Company's strategic process to sell, license, or otherwise dispose of its rights to ORLYNVAH™. 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 risks and uncertainties concerning the outcome, impact, effects and results of the Company's evaluation of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic alternatives, the Company's ability to complete a strategic alternative transaction,

the Company's ability to successfully prepare and implement commercialization plans for ORLYNVAH™ with a commercial partner or directly, including the Company's ability to build and maintain a sales force and prepare for commercial launch of ORLYNVAH™, if Iterum is unsuccessful at entering into or completing a strategic alternative transaction, the market opportunity for and the potential market acceptance of ORLYNVAH™ for uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, uncertainties inherent in the conduct of clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, changes in public policy or legislation, commercialization plans and timelines, 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 Company's ability to maintain its listing on the Nasdaq Capital Market and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q filed with the SEC on August 14, 2024, 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 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

Number	Exhibit Description
99.1	Press Release of Iterum Therapeutics plc, date October 25, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Iterum Therapeutics plc

Date: October 25, 2024

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

EXHIBIT 99.1

Iterum Therapeutics Receives U.S. FDA Approval of ORLYNVAH™ (Oral Sulopenem) for the Treatment of Uncomplicated Urinary Tract Infections

ORLYNVAH™ is the first oral penem approved for use in the U.S. and the second FDA-approved treatment for uUTIs in the past two decades

--Company to Host Conference Call on Monday, October 28th at 8:30 a.m. EDT--

DUBLIN, Ireland and CHICAGO, October 25, 2024 -- Iterum Therapeutics plc (Nasdaq: ITRM) (Iterum), today announced that the U.S. Food and Drug Administration (FDA) has approved Iterum's new drug application for ORLYNVAH™ (sulopenem etzadroxil and probenecid) for the treatment of uncomplicated urinary tract infections (uUTIs) caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options. This is the first approved indication for ORLYNVAH™ and the first FDA-approved product for Iterum.

"We are so pleased to have achieved this historic milestone and would like to thank all the patients, investigators, Iterum colleagues and Iterum consultants and vendors who participated in the development of ORLYNVAH™. ORLYNVAH™ offers new hope for patients suffering from difficult-to-treat uUTIs. The introduction of novel products, like ORLYNVAH™, is an important way to combat antimicrobial resistance to other approved oral agents and offers a potential solution to patients and physicians," said Corey Fishman, Iterum's Chief Executive Officer. "As the first oral penem approved in the U.S., ORLYNVAH™ offers an excellent alternative treatment option for appropriate patients in the underserved uUTI market. With FDA approval and a clear label, we will renew our efforts to achieve a strategic transaction involving ORLYNVAH™ with the goal of maximizing value for our stakeholders."

The FDA approval of ORLYNVAH™ was based on a clinical development program supported by a robust data package, including two pivotal, Phase 3 clinical trials (known as SURE 1 and REASSURE) that evaluated the safety and efficacy of ORLYNVAH™ compared to ciprofloxacin (SURE 1) and Augmentin™ (REASSURE) in the treatment of adult women with uUTI. SURE 1 showed superiority to ciprofloxacin in fluoroquinolone resistant infections, while REASSURE showed non-inferiority and statistical superiority to Augmentin™ in the Augmentin™ susceptible population. ORLYNVAH™ was generally well tolerated in both SURE 1 and REASSURE clinical trials.

"The FDA approval of ORLYNVAH™ is tremendous news for those of us who have been hoping for a new option to treat appropriate at-risk patients suffering from UTIs", said Marjorie Golden, MD, FIDSA, Site Chief, Infectious Disease, St. Raphael Campus Yale New Haven Hospital. "Based on the totality of clinical data generated, ORLYNVAH™ has the potential to be an important treatment alternative for use in the community."

Conference Call

Iterum will host a conference call on Monday, October 28, 2024, at 8:30 a.m. Eastern Time. The dial-in information for the call is as follows:
United States: 1 833 470 1428 / International: 1 404 975 4839
Access code: 936149
The conference call replay will be available in the Events & Presentations section of Iterum's website following the call.

About uUTIs

UTIs are among the most common bacterial infections encountered in the community. uUTIs are infections of the bladder occurring mainly in women. Up to 60% of women will have a uUTI in their lifetime. Up to 40% of women with a history of uUTI will have a recurrence of their infection. There are approximately 40 million uUTI prescriptions generated annually in the United States, and we estimate approximately 1% of those infections are caused by pathogens that are resistant to all commonly available classes of oral antibiotics. Rising antibiotic resistance, an aging population with comorbidities and sub-optimal safety profiles of existing oral treatment options are making antibiotic selection more challenging for treating physicians.

About ORLYNVAH™

ORLYNVAH™ is a novel oral penem antibiotic for the treatment of uUTI. ORLYNVAH™ possesses potent activity against species of Enterobacterales including those that encode extended spectrum beta-lactamase (ESBL) or AmpC-type beta-lactamases that confer resistance to third generation cephalosporins.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS & USAGE

ORLYNVAH™ a combination of sulopenem etzadroxil, a penem antibacterial, and probenecid, a renal tubular transport inhibitor, is indicated for the treatment of uUTI caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial treatment options.

Limitations of Use

ORLYNVAH™ is not indicated for the treatment of:

• Complicated urinary tract infections (cUTI) or as step-down treatment after intravenous antibacterial treatment of cUTI.

• Complicated intra-abdominal infections (cIAI) or as step-down treatment after intravenous antibacterial treatment of cIAI.

Usage to Reduce Development of Drug-Resistant Bacteria

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ORLYNVAH™ and other antibacterial drugs, ORLYNVAH™ should be used only to treat uUTI that are proven or strongly suspected to be caused by susceptible bacteria. Culture and susceptibility information should be utilized in selecting or modifying antibacterial therapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

• Patients with a history of hypersensitivity to the components of ORLYNVAH™ (sulopenem etzadroxil and probenecid) or other beta-lactam antibacterial drugs.

• Patients with known blood dyscrasias.

• Patients with known uric acid kidney stones.

• Concomitant use of ORLYNVAH™ and ketorolac tromethamine is contraindicated.

WARNINGS AND PRECAUTIONS

• Hypersensitivity Reactions: Hypersensitivity reactions have been reported in patients treated with ORLYNVAH™. Serious and occasionally fatal hypersensitivity reactions, including anaphylaxis, have been reported with beta-lactam antibacterial drugs. Severe allergic reactions and anaphylaxis have been reported with the use of probenecid (a component of ORLYNVAH™). If an allergic reaction to ORLYNVAH™ occurs, discontinue the drug and institute appropriate therapy.

• *Clostridioides difficile*-Associated Diarrhea (CDAD): This has been reported with nearly all systemic antibacterial agents. Evaluate if diarrhea occurs.

• Exacerbation of Gout: When prescribing ORLYNVAH™ to patients with a known history of gout, ensure appropriate therapy of gout is instituted.

ADVERSE REACTIONS

The most common adverse reactions (≥2%) in patients treated with ORLYNVAH™ were diarrhea, nausea, vulvovaginal mycotic infection, headache, and vomiting.

DRUG INTERATIONS

• Ketoprofen: Concomitant use is not recommended.

• See full prescribing information for additional clinically significant drug interactions with ORLYNVAH™.

USE IN SPECIFIC POPULATIONS

•There are no available data on ORLYNVAH™ use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

•There are no data on the presence of ORLYNVAH™ or its metabolite in human milk, the effects on the breastfed infant, or the effects on milk production.
•The safety and effectiveness of ORLYNVAH™ in pediatric patients have not been established.
•No dosage adjustment based on age is required. ORLYNVAH™ is known to be substantially excreted by the kidney, and geriatric patients are anticipated to have reduced renal function. Recommendations for use in elderly patients should be based on renal function.
•Increases in sulopenem plasma concentrations were observed with mild, moderate and severe renal impairment; however, the available safety information does not suggest a need for dosage adjustments in these patients. Administration of ORLYNVAH™ is not recommended in patients with creatinine clearance (CrCL) less than 15 mL/min and patients on hemodialysis because the pharmacokinetics of sulopenem have not been studied in this population.

To report SUSPECTED ADVERSE REACTIONS, contact Iterum Therapeutics plc at 1-866-414-SULO or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Iterum Therapeutics plc

Iterum Therapeutics plc is focused on delivering 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 the development of its first compound, sulopenem, a novel penem anti-infective compound, 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 has received approval of its NDA for ORLYNVAH™ (oral sulopenem) for the treatment of uncomplicated urinary tract infections caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women with limited or no alternative oral antibacterial treatment options by the U.S. Food and Drug Administration and 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 www.iterumtx.com.

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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 risks and uncertainties concerning the outcome, impact, effects and results of Iterum's evaluation of strategic alternatives, including the terms, timing, structure, value, benefits and costs of any strategic alternatives, Iterum's ability to complete a strategic alternative transaction, the market opportunity for and the potential market acceptance of ORLYNVAH™ for uUTIs caused by certain designated microorganisms in adult women who have limited or no alternative oral antibacterial treatment options, uncertainties inherent in the conduct of clinical and non-clinical development, changes in regulatory requirements or decisions of regulatory authorities, the timing or likelihood of regulatory filings and approvals, changes in public policy or legislation, commercialization plans and timelines, the actions of third-party clinical research organizations, suppliers and manufacturers, the accuracy of Iterum's expectations regarding how far into the future Iterum's cash on hand will fund Iterum's ongoing operations, Iterum's ability to maintain its listing on the Nasdaq Capital Market and other factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q filed with the SEC on August 14, 2024, 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.

Investor Contact:
Judy Matthews
Chief Financial Officer
312-778-6073
IR@iterumtx.com