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 20, 2019**

NABRIVA THERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

Ireland	**001-37558**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

25-28 North Wall Quay, IFSC, Dublin 1, Ireland	**Not Applicable**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(610) 816-6640**

Not Applicable
(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 (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))

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. ☒

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, nominal value $0.01 per share	NBRV	The Nasdaq Global Market LLC

Item 8.01 Other Events.

On December 20, 2019, Nabriva Therapeutics plc issued a press release announcing the resubmission to the U.S. Food and Drug Administration of the New Drug Application for CONTEPO™ (fosfomycin for injection) to treat complicated urinary tract infections, including acute pyelonephritis.

The full text of the press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Nabriva Therapeutics plc dated December 20, 2019

Forward-Looking Statements

Any statements in this 8-K about future expectations, plans and prospects for Nabriva Therapeutics, including but not limited to statements about its plans for and timing and potential outcome of the review of regulatory filings for CONTEPO, efforts to bring CONTEPO to market, the development of CONTEPO for cUTI, the clinical utility of CONTEPO for cUTI, the market opportunity for and the potential market acceptance of XENLETA for CABP and CONTEPO for cUTI, the development of XENLETA and CONTEPO for additional indications, the development of additional formulations of XENLETA and CONTEPO, plans to pursue research and development of other product candidates, the sufficiency of Nabriva Therapeutics' existing cash resources and its expectations regarding how far into the future its existing cash resources will fund its ongoing operations and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: Nabriva Therapeutics' ability to resolve the matters set forth in the Complete Response Letter it received from the U.S. Food and Drug Administration ("FDA") in connection with its NDA for CONTEPO (fosfomycin for injection); Nabriva Therapeutics' reliance on third-party manufacturers to manufacture the clinical and commercial supply of its product candidates and the ability of such third parties to comply with applicable regulatory requirements; the content and timing of decisions made by the FDA and other regulatory authorities, Nabriva Therapeutics' ability to realize the anticipated benefits, synergies and growth prospects of its acquisition of Zavante Therapeutics, the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or studies in different disease indications will be indicative of the results of ongoing or future trials, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of CONTEPO for the treatment of cUTI, the ability to retain and hire key personnel, the availability of adequate additional financing on acceptable terms or at all and such other important factors as are set forth in Nabriva Therapeutics' annual and quarterly reports and other filings on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this Form 8-K represent Nabriva Therapeutics' views as of the date of this Form 8-K. Nabriva Therapeutics anticipates that subsequent events and developments will cause its views to change. However, while Nabriva Therapeutics may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Nabriva Therapeutics' views as of any date subsequent to the date of this Form 8-K.

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.

NABRIVA THERAPEUTICS PLC

Date: December 20, 2019

By: /s/ Gary Sender
Gary Sender
Chief Financial Officer

Nabriva Therapeutics Resubmits New Drug Application for Intravenous CONTEPO™ (fosfomycin) for Injection

-Nabriva anticipates a six-month review period by the Food and Drug Administration

-CONTEPO is a potential first-in-class intravenous antibiotic in U.S. for the treatment of complicated urinary tract infections

DUBLIN, Ireland, December 20, 2019 -- Nabriva Therapeutics plc (NASDAQ: NBRV), a commercial-stage biopharmaceutical company engaged in the development of innovative anti-infective agents to treat serious infections, announced today that it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for CONTEPO™ (fosfomycin) for injection for the treatment of complicated urinary tract infections (cUTIs), including acute pyelonephritis. Nabriva anticipates a six-month review period by the FDA.

The NDA for CONTEPO was resubmitted based on the outcome and final minutes of a Type A meeting with the FDA, which was conducted to obtain clarity on the Complete Response Letter (CRL) issued by the FDA in April 2019. The CRL stated that the FDA was unable to approve the NDA in its present form based on issues related to facility inspections and manufacturing deficiencies at one of the Company's contract manufacturers. The FDA did not request any new clinical data and did not raise any concerns with regard to the safety of CONTEPO.

"We are pleased to have received input from the FDA on the required information to include in the CONTEPO NDA resubmission to address the CRL," said Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics. "With the rising prevalence of extended spectrum beta-lactamases (ESBL) and carbapenem resistance (CRE), CONTEPO has the potential to be an important new treatment option for patients with cUTI caused by Gram-negative pathogens. We look forward to continuing to work with the FDA to bring this important treatment option to patients in the United States."

In its 2019 report on Antibiotic Resistance Threats in the United States, the Centers for Disease Control and Prevention (CDC) designated CRE and ESBL resistance as urgent and serious threats in the United States. According to the CDC, both CRE and ESBL resistance are major concerns for patients in healthcare facilities, with some Enterobacteriaceae resistant to nearly all antibiotics, leaving more toxic or less effective treatment options.

About CONTEPO

CONTEPO (fosfomycin) for injection is a novel, potentially first-in-class in the United States, intravenous investigational antibiotic with a broad spectrum of Gram-negative and Gram-positive activity, including activity against most contemporary multi-drug resistant (MDR) strains such as extended spectrum β-lactamase (ESBL)-producing Enterobacteriaceae. ESBL enzymes break down and destroy some commonly used antibiotics such as Carbapenem therapy, leading to an increase in Carbapenem resistance.

CONTEPO has a differentiated mechanism of action that results in broad spectrum microbiologic activity against MDR pathogens with limited available treatment options; no observed cross-resistance with other antibiotic classes; and demonstrated in vitro synergy or additive effect in combination with other antimicrobial classes. CONTEPO utilizes a new dosing approach, originally developed by Zavante Therapeutics (which Nabriva Therapeutics acquired in 2018), to optimize its pharmacokinetics and pharmacodynamics. IV fosfomycin has been approved for a number of indications and utilized for over 45 years outside the U.S. to treat a variety of infections, including cUTIs and other serious bacterial infections.

Nabriva Therapeutics believes these attributes, along with the positive clinical experience worldwide, support CONTEPO as an early appropriate treatment for cUTIs, including acute pyelonephritis, suspected to be caused by MDR pathogens. An estimated 40 percent of cUTIs are suspected to be caused by MDR bacteria and limited treatment options are available in the U.S. for these patients.

About Nabriva Therapeutics plc

Nabriva Therapeutics is a biopharmaceutical company engaged in the commercialization and development of innovative anti-infective agents to treat serious infections. Nabriva Therapeutics received U.S. Food and Drug Administration approval for XENLETA™ (lefamulin), the first systemic pleuromutilin antibiotic for community-acquired bacterial pneumonia (CABP). Nabriva Therapeutics is also developing CONTEPO™ (fosfomycin) for injection, a potential first-in-class epoxide antibiotic for intravenous use in the United States for complicated urinary tract infections (cUTI), including acute pyelonephritis. For more information, please visit https://www.nabriva.com.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Nabriva Therapeutics, including but not limited to statements about its plans for and timing and potential outcome of the review of regulatory filings for CONTEPO, efforts to bring CONTEPO to market, the development of CONTEPO for cUTI, the clinical utility of CONTEPO for cUTI, the market opportunity for and the potential market acceptance of XENLETA for CABP and CONTEPO for cUTI, the development of XENLETA and CONTEPO for additional indications, the development of additional formulations of XENLETA and CONTEPO, plans to pursue research and development of other product candidates, the sufficiency of Nabriva Therapeutics' existing cash resources and its expectations regarding how far into the future its existing cash resources will fund its ongoing operations and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: Nabriva Therapeutics' ability to resolve the matters set forth in the Complete Response Letter it received from the FDA in connection with its NDA for CONTEPO (fosfomycin) for injection; Nabriva Therapeutics' reliance on third-party manufacturers to manufacture the clinical and commercial supply of its product candidates and the ability of such third parties to comply with applicable regulatory requirements; the content and timing of decisions made by the U.S. Food and Drug Administration and other regulatory authorities, Nabriva Therapeutics' ability to realize the anticipated benefits, synergies and growth prospects of its acquisition of Zavante Therapeutics, the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or studies in different disease indications will be indicative of the results of ongoing or future trials, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of CONTEPO for the treatment of cUTI, the ability to retain and hire key personnel, the availability of adequate additional financing on acceptable terms or at all and such other important factors as are set forth in Nabriva Therapeutics' annual and quarterly reports and other filings on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Nabriva Therapeutics' views as of the date of this press release. Nabriva Therapeutics anticipates that subsequent events and developments will cause its views to change. However, while Nabriva Therapeutics may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Nabriva Therapeutics' views as of any date subsequent to the date of this press release.

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