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): **January 8, 2020**

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))

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, nominal value $0.01 per share	NBRV	The Nasdaq Global Market

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.

CONTEPO™ PDUFA Date Announcement

On January 8, 2020, Nabriva Therapeutics plc (the "Company") issued a press release announcing that in a letter acknowledging the receipt of its resubmitted New Drug Application for marketing approval of CONTEPO™ (fosfomycin for injection) to treat complicated urinary tract infections, the U.S. Food and Drug Administration (the "FDA") stated that the Company's filing was a complete, class 2 response to the complete response letter the FDA issued on April 30, 2019. As a result, the FDA set a Prescription Drug User Fee Act (PDUFA) goal date of June 19, 2020 for the completion of its review of the NDA. 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 January 8, 2020.

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: January 8, 2020

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

Exhibit 99.1

Nabriva Therapeutics Receives FDA Acknowledgement of New Drug Application Resubmission for Intravenous CONTEPO™ (fosfomycin) for Injection

-PDUFA action date set for June 19, 2020 -

DUBLIN, Ireland, Jan. 8, 2020 --Nabriva Therapeutics plc (NASDAQ: NBRV), a commercial-stage biopharmaceutical company engaged in the development of innovative anti-infective agents to treat serious infections, announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of its New Drug Application (NDA) resubmission for marketing approval of CONTEPO™ (fosfomycin) for injection for the treatment of complicated urinary tract infections (cUTIs).

In the acknowledgement letter for the resubmitted NDA, the FDA stated that Nabriva's filing was a complete, class 2 response to the complete response letter the FDA issued on April 30, 2019. As a result, the FDA set a Prescription Drug User Fee Act (PDUFA) goal date of June 19, 2020 for the completion of its review of the NDA.

CONTEPO is a potential first-in-class intravenous antibiotic in the U.S. for the treatment of cUTIs. The NDA resubmission is supported by data from a pivotal Phase 2/3 clinical trial (known as ZEUS™), which met its primary endpoint of statistical non-inferiority to piperacillin/tazobactam in patients with cUTI, including acute pyelonephritis.

Complicated Urinary Tract Infection

Complicated urinary tract infection (cUTI) occurs when Gram-negative bacteria are embedded in the bladder wall where they can multiply more slowly and are much harder to address with antibiotics. Patients who are being treated for a urinary tract infection and fail to respond to an initial course of antibiotics can go on to develop a cUTI.

Among the causes of cUTI is Enterobacteriaceae, which is a multi-drug resistance (MDR) strain of Gram-negative bacteria. Enterobacteriaceae produces extended spectrum beta-lactamases (ESBL), a chemical that can cause some antibiotics to be ineffective in treating bacterial infections such as cUTI. As a result, cUTI poses a serious and rapidly emerging health threat for hospitalized patients, especially those in intensive care units.

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. 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.

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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