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): **June 19, 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 Select 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.

On June 19, 2020, Nabriva Therapeutics plc issued a press release announcing that it received a Complete Response Letter from the U.S. Food and Drug Administration regarding its New Drug Application resubmission for CONTEPO™ (fosfomycin) for injection for the treatment of complicated urinary tract infections, including acute pyelonephritis.

The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated June 19, 2020

SIGNATURES

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.

NABRIVA THERAPEUTICS PLC

Date: June 22, 2020

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

Exhibit 99.1

Nabriva Therapeutics Receives Complete Response Letter from FDA on NDA for CONTEPO™ (fosfomycin) for injection

Agency Cited Travel Restrictions and Inability to Conduct Onsite Inspections to Resolve Observations at Manufacturing Partner Facilities

DUBLIN, Ireland, June 19, 2020 -- Nabriva Therapeutics plc (NASDAQ: NBRV), a biopharmaceutical company engaged in the commercialization and development of innovative anti-infective agents to treat serious infections, announced today that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) resubmission seeking marketing approval of CONTEPO™ (fosfomycin) for injection for the treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis.

Although Nabriva's European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cites observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. In general, previously identified product quality and facility inspection related observations at our contract manufacturing partners are required to be satisfactorily resolved before the NDA may be approved. The FDA did not request any new clinical data and did not raise any other concerns with regard to the safety or efficacy of CONTEPO in the CRL. Nabriva plans to request a Type A meeting with the FDA to discuss appropriate next steps and the FDA's plans for completing foreign facility inspections. CONTEPO has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of serious infections, including cUTI.

Complicated Urinary Tract Infection

Complicated urinary tract infections represent a serious infection in patients with underlying functional or structural abnormality of the urinary tract or in the presence of catheterization, and includes patients with acute pyelonephritis, regardless of underlying abnormalities of the urinary tract. An estimated three million cases of Gram-negative cUTIs are treated in the U.S. hospital setting annually, where approximately 40 percent of cases are suspected to be caused by resistant strains. Ineffectively managed cUTIs can lead to increased treatment failure rates, which in turn, can result in prolonged hospital stays, recurrence, re-hospitalization, and mortality – each of which poses a substantial resource and economic burden on the healthcare and payer systems.

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 injection, lefamulin tablets), 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 complicated urinary tract infections (cUTIs), including acute pyelonephritis. For more information, please visit 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 Nabriva Therapeutics' plans for further interactions with the FDA, the development of CONTEPO for cUTI, the clinical utility of XENLETA for CABP and of CONTEPO for cUTI, plans for and timing of the review of regulatory filings for CONTEPO, efforts to bring CONTEPO to market, 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 anticipated revenues from product sales and 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 resubmission 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, 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 extent of business interruptions resulting from the infection causing the COVID-19 outbreak or similar public health crises, 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.

CONTACTS:

For Investors

Gary Sender

Nabriva Therapeutics plc

ir@nabriva.com

For Media

Mike Beyer

Sam Brown Inc.

mikebeyer@sambrown.com

312-961-2502