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): **April 30, 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. ☒

Item 8.01. Other Events.

On April 30, 2019, 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 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 April 30, 2019

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: May 1, 2019

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

Exhibit 99.1

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

Issues related to facility inspections and manufacturing deficiencies at one contract manufacturer

Conference call and webcast tomorrow at 8:00 a.m. EDT

DUBLIN, Ireland, April 30, 2019 — Nabriva Therapeutics plc (NASDAQ: NBRV), a clinical-stage biopharmaceutical company engaged in the 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) seeking marketing approval of CONTEPO™ (fosfomycin) for injection for the treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis.

The CRL requests that Nabriva address issues related to facility inspections and manufacturing deficiencies at one of Nabriva's contract manufacturers prior to the FDA approving the NDA. Nabriva plans to request a "Type A" meeting to discuss the FDA's findings. The FDA did not request any new clinical data and did not raise any concerns with regard to the safety of CONTEPO.

"We will be working with the FDA in the coming weeks to gain a full understanding of the FDA's comments, with the goal of bringing this important treatment to patients as quickly as possible," said Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics.

Conference Call and Webcast

Nabriva Therapeutics will host a conference call and webcast at 8:00 a.m. EDT tomorrow, May 1, 2019. The live webcast can be accessed under "Events and Presentations" in the Investors section of Nabriva Therapeutics' website at www.nabriva.com and will be accessible for 90 days. The conference call can also be accessed by dialing (866) 811-8671 (U.S./Canada) or (409) 981-0874 (international) and providing the passcode 8537966.

About CONTEPO

CONTEPO (fosfomycin) for injection, (previously referred to as ZTI-01 and ZOLYD) 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 ESBL-producing Enterobacteriaceae. Intravenous (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. CONTEPO utilizes a new dosing approach, originally developed by Zavante (which Nabriva Therapeutics acquired), to optimize its pharmacokinetics and pharmacodynamics. 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 development of innovative anti-infective agents to treat serious infections. Nabriva Therapeutics has two product candidates that are in late stage development: lefamulin, potentially the first systemic pleuromutilin antibiotic for CABP and CONTEPO (fosfomycin) for injection, a potential first-in-class epoxide antibiotic in the United States for complicated urinary tract infections (cUTIs) including acute pyelonephritis (AP). 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 Nabriva Therapeutics' plans for further interactions with the FDA; the development of Nabriva Therapeutics' product candidates, such as the future development or commercialization of lefamulin and CONTEPO, the clinical utility of lefamulin for CABP and of CONTEPO for cUTI, plans for and timing of the review of regulatory filings, efforts to bring lefamulin and CONTEPO to market, the market opportunity for and the potential market acceptance of lefamulin for CABP and CONTEPO for cUTI, the potential benefits under its license agreement with Sinovant Sciences, the development of lefamulin and CONTEPO for additional indications, the development of additional formulations of lefamulin and CONTEPO, plans to pursue research and development of other product candidates, its ability to achieve any of the specified regulatory or performance milestones under its loan agreement with Hercules Capital, the sufficiency of Nabriva Therapeutics' existing cash resources 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, whether results of ZEUS will be indicative of results for any ongoing or future clinical trials and studies of CONTEPO, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates including lefamulin for use as a first-line empiric monotherapy for the treatment of CABP and CONTEPO for the treatment of cUTI, the ability to retain and hire key personnel, the sufficiency of cash resources and need for additional financing 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
Dave Garrett
Nabriva Therapeutics plc
david.garrett@nabriva.com
610-816-6657

For Media
Mike Beyer
Sam Brown Inc.
mikebeyer@sambrown.com
312-961-2502