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 4, 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.

PDUFA Date for CONTEPO™

On January 4, 2019, Nabriva Therapeutics plc (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has accepted for priority review the New Drug Application (the "NDA") for CONTEPO™ (fosfomycin for injection) to treat complicated urinary tract infections ("cUTIs"), including acute pyelonephritis. The CONTEPO application has been given a Prescription Drug User Fee Act ("PDUFA") target action date of June 30, 2019.

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

NDA Submission for Lefamulin

The Company also had previously announced the submission of two NDAs to the FDA for the oral and intravenous formulations of lefamulin, a first-in-class, semi-synthetic pleuromutilin antibiotic for the treatment of community-acquired bacterial pneumonia. In addition, the Company announced that it plans to submit a marketing authorization application for lefamulin in Europe in the first quarter of 2019.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 Press release issued by Nabriva Therapeutics plc, dated January 4, 2019.

Forward-Looking Statements

Any statements in this Form 8-K about future expectations, plans and prospects for Nabriva Therapeutics, including but not limited to statements about the development of Nabriva Therapeutics' product candidates, such as the development or commercialization of lefamulin and CONTEPO, conduct and timelines of clinical trials, 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 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, 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: 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 moderate to severe 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 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: January 4, 2019

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

Exhibit 99.1

Nabriva Therapeutics Announces Acceptance of the New Drug Application for Intravenous CONTEPO™ to Treat Complicated Urinary Tract Infections by FDA

-PDUFA action date set for June 30, 2019-

Dublin Ireland, January 4, 2019 — Nabriva Therapeutics plc (NASDAQ: NBRV), a clinical-stage biopharmaceutical company engaged in the research and development of innovative anti-infective agents to treat serious infections, announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) and granted a priority review for CONTEPO™ (fosfomycin for injection) to treat complicated urinary tract infections (cUTIs), including acute pyelonephritis. The acceptance of the NDA indicates that the FDA has deemed the application sufficiently complete to allow a substantive review. The PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA's review of the CONTEPO NDA is June 30, 2019. In addition to priority review, CONTEPO has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of several serious infections, including cUTI.

"The acceptance of the CONTEPO NDA marks another major milestone for Nabriva Therapeutics, demonstrating our commitment to bring novel anti-infective agents that address the urgent, unmet medical need in patients with serious infections," said Dr. Jennifer Schranz, chief medical officer of Nabriva Therapeutics. "CONTEPO, if approved in the United States, represents a first-in-class intravenous antibiotic with broad spectrum activity against Gram-negative and Gram-positive organisms, including ESBL-producing Enterobacteriaceae and other contemporary multi-drug resistant (MDR) organisms."

The NDA submission is utilizing the 505(b)(2) regulatory pathway and is supported by a robust data package, including 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.

In the NDA acceptance letter, the FDA stated that no filing or potential review issues were identified. In addition, the Agency stated that it has not referred CONTEPO to an advisory committee meeting at this time.

About cUTIs

Urinary tract infections (UTIs) are a significant health problem in both the community- and hospital-based treatment settings. It is estimated that 150 million UTIs occur yearly worldwide, accounting for $6 billion in health care expenditures, according to the American Urological Association. Patients who fail to respond to an initial course of antibiotics can go on to develop a cUTI, which occurs when the bacteria are embedded in the bladder wall where they can multiply more slowly and are much harder to address with antibiotics. In most cases, cUTIs occur following treatment for a normal UTI because antibiotics were given too late, for too short a period of time, at too low of a dose course or the wrong antibiotic was used and did not provide adequate spectrum of coverage. An estimated three million cases of cUTIs are treated in the hospital setting in the

United States each year for Gram-negative infections. Enterobacteriaceae are the most common pathogens causing cUTIs and, currently, widespread antibiotic resistance limits the effective treatment options for cUTI. Ineffectively managed cUTI can lead to increased treatment failure rates, recurrence of infection, increased re-hospitalization, and increased morbidity and mortality.

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 (I.V.) fosfomycin has been approved for a number of indications and utilized for over 45 years in Europe 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 a first-line treatment for cUTIs, including acute pyelonephritis, suspected to be caused by MDR pathogens. At least 20 percent of cUTIs are caused by MDR bacteria and limited treatment options are available in the U.S. In addition, non-clinical data have shown that CONTEPO acts in combination with certain other antibiotics to improve bacterial killing.

About Nabriva Therapeutics plc

Nabriva Therapeutics is a clinical-stage biopharmaceutical company engaged in the research and 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

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