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): **February 19, 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 February 19, 2019, Nabriva Therapeutics plc issued a press release announcing that the U.S. Food and Drug Administration has accepted for priority review the two New Drug Applications (NDAs) for the intravenous (IV) and oral formulations of lefamulin, a potentially first-in-class, semi-synthetic pleuromutilin antibiotic, for the treatment of community-acquired bacterial pneumonia (CABP). Both NDAs have been given a Prescription Drug User Fee Act (PDUFA) target action date of August 19, 2019.

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 99.1 Press release issued by Nabriva Therapeutics plc, dated February 19, 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: February 19, 2019

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

Exhibit 99.1

Nabriva Therapeutics Announces Acceptance of New Drug Applications by the FDA for Intravenous and Oral Lefamulin to Treat Community-Acquired Bacterial Pneumonia in Adults

-PDUFA action date set for August 19, 2019-

Dublin Ireland, February 19, 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 Applications (NDAs) and granted a priority review for both the intravenous (IV) and oral formulations of lefamulin, a potentially first-in-class, semi-synthetic pleuromutilin antibiotic, for the treatment of community-acquired bacterial pneumonia (CABP). The acceptance of lefamulin's two NDAs indicates that the FDA has deemed both applications sufficiently complete to allow a substantive review. Both applications have been granted priority review and the Prescription Drug User Fee Act (PDUFA) goal date for the completion of the FDA's review is August 19, 2019. In addition to priority review, lefamulin has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA.

"Lefamulin is the second product candidate with an accepted NDA this year for Nabriva Therapeutics, supporting 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. "We believe lefamulin has the potential to provide a much-needed monotherapy treatment option for adults with CABP. As demonstrated in our clinical program, the ability to switch from IV to oral administration and the short-course oral regimen has the potential to position lefamulin, if approved, as a monotherapy option for patients in the hospital, transition of care and ambulatory care settings."

The NDAs are supported by two pivotal, Phase 3 clinical trials (known as LEAP 1 and LEAP 2) that evaluated the safety and efficacy of IV and oral lefamulin compared to moxifloxacin in the treatment of adults with CABP. LEAP 1 was designed with the option to switch from IV to oral administration and LEAP 2 was designed as a short course, 5-day, oral only treatment with lefamulin. In both LEAP 1 and LEAP 2, lefamulin was demonstrated to be non-inferior to moxifloxacin, and met both the FDA and European Medicines Agency (EMA) primary and secondary efficacy endpoints for the treatment of CABP. Lefamulin was also shown to be generally well-tolerated when administered either orally or intravenously.

In the acceptance letter for the NDAs, the FDA stated that no filing or potential review issues were identified. In addition, the Agency stated that it is not currently planning to hold an advisory committee meeting to discuss these applications.

About CABP

Based on Nabriva Therapeutics' combined analysis of the U.S. Centers for Disease Control and Prevention's 2007 National Ambulatory Medical Care Survey, the National Hospital Ambulatory Medical Care Survey and 2013 data from the Healthcare Cost and Utilization Project, Nabriva

Therapeutics estimates that more than five million adults are treated annually for CABP in the United States. Additionally, based on 2013 data from the Healthcare Cost and Utilization Project, Nabriva Therapeutics estimates that approximately three million of these adult CABP patients are diagnosed in an in-patient hospital and/or emergency department setting, where most are then treated with in-patient IV and oral antibiotics or out-patient oral antibiotics prescribed for use following hospital discharge or release.

About Lefamulin

Lefamulin is a semi-synthetic pleuromutilin antibiotic with potential to be first-in-class for systemic administration in humans discovered and developed by the Nabriva Therapeutics team. It is designed to inhibit the synthesis of bacterial protein, which is required for bacteria to grow. Lefamulin's binding occurs with high affinity, high specificity and at molecular sites that are different than other antibiotic classes. Based on results from its two global, Phase 3 clinical trials, Nabriva Therapeutics believes lefamulin is well-positioned for use as a first-line monotherapy for the treatment of CABP due to its novel mechanism of action, targeted spectrum of activity, resistance profile, achievement of substantial drug concentration in lung tissue and fluid, availability of oral and IV formulations and a generally well-tolerated safety profile. Nabriva Therapeutics believes lefamulin represents a potentially important new treatment option for the approximately five to six million adults in the United States diagnosed with CABP each year.

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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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.

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