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): **May 29, 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.

XENLETA™ (lefamulin) Announcement

On May 29, 2020, Nabriva Therapeutics plc (the "Company") announced that the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency has adopted a positive opinion recommending approval of XENLETA for the treatment of community-acquired pneumonia ("CAP") in adults when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of CAP or when these have failed.

The full text of the press release announcing the CHMP's opinion to recommend approval of XENLETA is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

CONTEPO New Drug Application

As previously reported, in April 2019, the U.S. Food and Drug Administration (the "FDA") issued a Complete Response Letter to the Company in connection with its new drug application ("NDA") for CONTEPO, the Company's product candidate for the treatment of complicated urinary tract infections, including acute pyelonephritis, stating that it was unable to approve the application in its current form. Specifically, the Complete Response Letter requested that the Company address issues related to facility inspections and manufacturing deficiencies at its active pharmaceutical ingredient contract manufacturer prior to the FDA approving the NDA. In December 2019, the Company resubmitted the NDA for CONTEPO. The FDA accepted its application and scheduled the Prescription Drug User Fee Act ("PDUFA") date for June 19, 2020. The Company has been informed by the FDA that, in connection with its review of the NDA for CONTEPO, the FDA will need to inspect the facilities of its third-party manufacturers in Europe. However, on March 10, 2020, the FDA announced that it would restrict travel of its employees to Europe for inspections as a result of the spread of COVID-19. As a result of these travel restrictions, the Company believes there is a substantial likelihood that the FDA will not be able to complete its review of the Company's NDA for CONTEPO prior to the PDUFA date. If the FDA cannot complete its review of the NDA because of the current travel restriction or otherwise, or if the manufacturing issues that the FDA previously identified are not resolved to the FDA's satisfaction prior to the PDUFA date, the FDA may issue a Complete Response Letter in response to the Company's resubmitted NDA for CONTEPO and the Company may be further delayed in obtaining or ultimately be unable to obtain regulatory approval of CONTEPO.

Forward-Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans and prospects for the Company, including but not limited to statements about the potential outcome of and timing of a decision by the European Commission with respect to regulatory approval for XENLETA in Europe, the development of CONTEPO for complicated urinary tract infections ("cUTIs"), the clinical utility of XENLETA for CABP and of CONTEPO for cUTIs, plans for and timing of the review of regulatory filings for CONTEPO and XENLETA, efforts to bring CONTEPO to market, the market opportunity for and the potential market acceptance of XENLETA for CABP and/or CAP and CONTEPO for cUTIs, the sufficiency of the Company's 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: the content and timing of decisions made by the European Commission, 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 ability to retain and hire key personnel, the extent of business and other interruptions resulting from the infection causing the COVID-19 outbreaks or similar public health crises, the sufficiency of cash resources and need for additional financing and such other important factors as are set forth in the Company's 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 the Company's views as of the date of this Form 8-K. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company 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 the Company's views as of any date subsequent to the date of this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 29, 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: May 29, 2020

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

Exhibit 99.1

Nabriva Therapeutics Receives Positive EU CHMP Opinion for XENLETA™ (lefamulin) for the Treatment of Community Acquired Pneumonia (CAP)

- *If approved, XENLETA has the potential to be a first-in-class pleuromutilin antibiotic for the intravenous (IV) and oral treatment of adult patients with CAP in Europe*
- *CHMP opinion supported by robust safety and efficacy data from two global pivotal Phase 3 trials of XENLETA*
- *European Commission decision anticipated in the second half of 2020*

DUBLIN, Ireland, May XX, 2020 -- Nabriva Therapeutics plc (NASDAQ: NBRV) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of XENLETA™ (lefamulin) for the treatment of community-acquired pneumonia (CAP) in adults when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of CAP or when these have failed. The CHMP opinion will be reviewed by the European Commission (EC), which has the authority to approve medicines for all 28 countries of the European Union, Norway, Iceland, and Liechtenstein. A regulatory decision is anticipated during the second half of 2020.

“Today’s announcement brings us one step closer to the first approval of a new class of antibiotics for patients with community acquired pneumonia in Europe in almost 20 years,” said Jennifer Schranz, MD, Chief Medical Officer of Nabriva. “XENLETA has a novel mechanism of action and provides an urgently needed short course, empiric monotherapy treatment alternative for adult patients with CAP. We look forward to the European Commission’s decision and the opportunity to bring this important medicine to patients.”

The CHMP recommendation for marketing authorization is based on efficacy data from the Lefamulin Evaluation Against Pneumonia (LEAP) 1 and LEAP 2 studies and a safety database of 1,242 study participants.

In the two Phase 3 clinical trials, the EMA co-primary endpoint was the Investigator Assessment of Clinical Response (IACR) at Test of Cure (TOC) in both the clinically evaluable (CE) and modified intent-to-treat (mITT) populations. Both studies established XENLETA to be non-inferior to the standard-of-care moxifloxacin in the treatment of adults with CAP independently and when the pooled data were analyzed across PORT scores of II-V. In the pooled analysis, the IACR success rate at TOC in the modified Intent-to-Treat (mITT) population was 85 percent in the XENLETA group and 87.1 percent in the moxifloxacin group (treatment difference -2.2 percent; 95 percent confidence interval (CI): -5.9, 1.6), and 88.5 percent in the lefamulin group and 91.8 percent in the moxifloxacin group (treatment difference -3.3 percent; 95 percent CI: -6.8, 0.1) in the Clinically Evaluable population. In these trials, lefamulin was generally well-tolerated. The most frequently reported adverse reactions are administration site reactions, diarrhea, nausea, vomiting, hepatic enzyme elevation, headache, hypokalemia, and insomnia.

The European Commission will review the CHMP recommendation and typically delivers its final decision in approximately two months. The U.S. Food and Drug Administration (FDA) approved XENLETA in August 2019 for the treatment of adult patients with community-acquired bacterial pneumonia (CABP).

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 (cUTI), including acute pyelonephritis. For more information, please visit www.nabriva.com.

About XENLETA

XENLETA (lefamulin) is a first-in-class semi-synthetic pleuromutilin antibiotic 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. XENLETA's binding occurs with high affinity, high specificity and at molecular sites that are different than other antibiotic classes. Efficacy of XENLETA was demonstrated in two multicenter, multinational, double-blind, double-dummy, non-inferiority trials assessing a total of 1,289 patients with CABP. In these trials, XENLETA was compared with moxifloxacin and in one trial, moxifloxacin with and without linezolid. Patients who received XENLETA had similar rates of efficacy as those taking moxifloxacin alone or moxifloxacin plus linezolid. The most frequently reported adverse reactions are administration site reactions (7%), diarrhea (7%), nausea (4%), vomiting (2%), hepatic enzyme elevation (2%), headache (1%), hypokalaemia (1%), and insomnia (1%). Administration site reactions led to discontinuation in <1%; gastrointestinal disorders were predominantly associated with the oral formulation and led to treatment discontinuation in <1%.

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 the potential outcome of and timing of a decision by the European Commission with respect to regulatory approval for XENLETA in Europe, Nabriva Therapeutics' ability to successfully launch and commercialize XENLETA for the treatment of CABP, including the availability of and ease of access to XENLETA through major U.S. specialty distributors, marketing exclusivity and patent protection for XENLETA, 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 for making lefamulin available in China, plans to pursue research and development of other product candidates, expectations regarding the ability of customers to satisfy demand for XENLETA with their existing inventory, 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 successfully implement its commercialization plans for XENLETA and whether market demand for XENLETA is consistent with its expectations, Nabriva Therapeutics' ability to build and maintain a sales force for XENLETA, the content and timing of decisions made by the European Commission, 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 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