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): **September 6, 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))

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 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™ Availability Announcement

On September 9, 2019, Nabriva Therapeutics plc (the "Company") announced that the oral and intravenous formulations of XENLETA™ (lefamulin) are now available in the U.S. through major specialty distributors. XENLETA was approved by the U.S. Food and Drug Administration ("FDA") on August 19, 2019 for the treatment of adults with community-acquired bacterial pneumonia ("CABP"). The related press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Milestone Payment from Sinovant Sciences Ltd.

In addition, on September 6, 2019, the Company announced that the Company has earned a $5 million milestone payment under its licensing agreement with Sinovant Sciences Ltd. related to the FDA approval of XENLETA for the treatment of adults with CABP. The related press release is attached hereto as Exhibit 99.2 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Nabriva Therapeutics plc, dated September 9, 2019.
99.2	Press release issued by Nabriva Therapeutics plc, dated September 6, 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: September 9, 2019

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

Exhibit 99.1

Nabriva's XENLETA™ (lefamulin) for the Treatment of Community-Acquired Bacterial Pneumonia (CABP) Now Available in the U.S.

First IV and oral antibiotic with novel mechanism of action approved by the FDA in nearly two decades, targets the most common CABP pathogens and supports antibiotic stewardship

DUBLIN, Ireland, September 9, 2019 — 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 the oral and intravenous (IV) formulations of XENLETA™ (lefamulin) are now available in the U.S. through major specialty distributors. XENLETA was approved by the U.S. Food and Drug Administration (FDA) on August 19, 2019 for the treatment of adults with community-acquired bacterial pneumonia (CABP).

"The lack of innovative treatment options for CABP over the past two decades has resulted in increasing resistance in the most common bacteria causing CABP to multiple classes of antibiotics", said Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics. "These drug-resistant pathogens are undermining clinicians' ability to fight CABP and we are delighted to announce that XENLETA is now available as a short course, empiric monotherapy treatment option for adults with CABP."

XENLETA is the first oral and IV treatment in the pleuromutilin class of antibiotics. XENLETA has *in vitro* activity and demonstrated clinical efficacy against the most common pathogens that cause CABP. XENLETA has a novel mechanism of action that targets a binding site on bacterial cells that is different from existing antibiotics, resulting in a low propensity for the development of resistance, as well as a lack of cross-resistance with antibiotic classes commonly used for the treatment of CABP.

"XENLETA is now available to healthcare providers for the treatment of CABP patients in the hospital, during transition from the hospital to home, and for patients in the ambulatory care setting," said Francesco Maria Lavino, Nabriva's Chief Commercial Officer. "We are well-prepared for the launch of XENLETA with an experienced sales team that is fully trained and deployed to help make XENLETA available to physicians and their patients in need. Leveraging our thorough account profiling and preparation, our 60 Territory Business Managers will be focusing on those institutions with the greatest unmet need and highest level of readiness to prescribe XENLETA."

Nabriva has efficiently expanded its commercialization, medical affairs, and supply chain infrastructure to help ensure that clinicians are informed of XENLETA's availability and patients have easy access. The company also plans to kick-off a targeted outreach program in the ambulatory care setting, where there is a significant unmet medical need for the treatment of CABP. The program is scheduled to commence in November 2019 in advance of the upcoming 2019-2020 respiratory tract infection season and will focus on educating community-based healthcare professionals on the attributes and availability of XENLETA.

XENLETA is available for oral (600 mg every 12 hours) and IV (150 mg every 12 hours) administration with a short 5-to-7-day course of therapy. Clinicians can initiate patients on IV or oral therapy, allowing for potential avoidance of hospitalization, or can transition from IV to oral therapy, which may expedite discharge from the hospital. The opportunity to avoid a hospital admission or to discharge a patient earlier on oral therapy may benefit patients and could result in significant savings to the health system.

In addition, Nabriva has partnered with International Health Management Associates, Inc. (IHMA) to offer Nabriva's Observational Bacterial Evaluation Program (NOBEL). The NOBEL program will provide microbiology laboratories and clinicians access to Research Use Only (RUO) lefamulin disks and MIC gradient test strips for non-diagnostic, *in vitro* susceptibility testing purposes. For more information about this program or help with enrollment, please contact IHMA, Inc. at 1-800-738-3344 or email nobel-ruo@ihma.com.

XENLETA is available through the major U.S. specialty distributors: McKesson Plasma and Biologics, ASD Healthcare and, by the middle of the week, Cardinal SD. In addition, XENLETA oral tablets are available through Specialty Pharmacy Networks, including Walgreens Community Specialty Pharmacy and Option Care Health.

Wholesalers

Wholesaler Telephone, Fax and Web Ordering Information	XENLETA (lefamulin) tablets, 600 mg Item Order Number	XENLETA (lefamulin) Injection, 150 mg Item Order Number	XENLETA diluent, 250 ml Item Order Number
ASD Healthcare Phone: 800-746-6273 Fax: 800-547-9413 Email: asd.customerservice@asdhealthcare.com Web: www.asdhealthcare.com	55560	55561	55559
Cardinal Health Phone: 866-677-4844 Fax: 877-274-9897 Email: GMB-spd-csorderentry@cardinalhealth.com Web: www.cardinalhealth.com	5564711	5564703	5564695
McKesson Plasma and Biologics Phone: 877-625-2566 Fax: 888-752-7626 Email: mpborders@mckesson.com Web: connect.mckesson.com	3980885	3980877	3980893

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

common adverse reactions associated with XENLETA include diarrhea, nausea, reactions at the injection site, elevated liver enzymes, and vomiting.

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), 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.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

XENLETA is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*.

USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of XENLETA and other antibacterial drugs, XENLETA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

XENLETA is contraindicated in patients with known hypersensitivity to XENLETA or pleuromutilins.

XENLETA tablets are contraindicated for use with CYP3A4 substrates that prolong the QT interval.

WARNINGS AND PRECAUTIONS

XENLETA has the potential to prolong the QT interval. Avoid XENLETA in patients with known QT prolongation, ventricular arrhythmias, and patients receiving drugs that may prolong the QT interval.

Based on animal studies, XENLETA may cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception.

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including XENLETA, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

ADVERSE REACTIONS

The most common adverse reactions (≥2%) for (a) XENLETA Injection are administration site reactions, hepatic enzyme elevation, nausea, hypokalemia, insomnia, and headache and (b) XENLETA Tablets are diarrhea, nausea, vomiting, and hepatic enzyme elevation.

USE IN SPECIFIC POPULATIONS

In patients with severe hepatic impairment, reduce the dosage of XENLETA Injection to 150 mg infused over 60 minutes every 24 hours. XENLETA Tablets are not recommended in patients with moderate or severe hepatic impairment due to insufficient information to provide dosing recommendations.

Avoid XENLETA Injection and Tablets with concomitant strong or moderate CYP3A or P-gp inducers. Monitor for reduced efficacy of XENLETA.

Avoid XENLETA Tablets with strong CYP3A or P-gp inhibitors.

Monitor for adverse reactions of sensitive CYP3A substrates administered with XENLETA Tablets.

XENLETA has not been studied in pregnant women. Verify pregnancy status in females prior to initiating XENLETA and advise females to use contraception during treatment and for 2 days after the final dose. Lactating women should pump and discard milk for the duration of treatment with XENLETA and for 2 days after the final dose.

To report SUSPECTED ADVERSE REACTIONS, or administration during pregnancy, contact Nabriva Therapeutics US, Inc. at 1-855-5NABRIVA or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information for XENLETA.

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 launch and commercialization of XENLETA for the treatment of CABP, the availability of and ease of access to XENLETA through major U.S. specialty distributors, 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 XENLETA and 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 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 and prepare for commercial launch of XENLETA on the timeline expected, or at all, 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 or of XENLETA for the treatment of CABP, 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:

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Exhibit 99.2

Nabriva Therapeutics Earns $5 Million Milestone Payment under its License Agreement with Sinovant Sciences

Dublin, Ireland and King of Prussia, PA., September 6, 2019 — Nabriva Therapeutics plc (NASDAQ: NBRV), a biopharmaceutical company engaged in the commercialization and development of innovative anti-infective agents to treat serious infections, today announced that Nabriva has earned a $5 million milestone payment under its licensing agreement with Sinovant Sciences related to the U.S. regulatory approval of XENLETA™ (lefamulin).

Sinovant Sciences has an exclusive license to develop and commercialize lefamulin (SNV001) in the Greater China region. Sinovant Science's application to conduct a clinical trial of lefamulin (SNV001) in China has been approved by China's National Medical Products Administration, and the trial is expected to be initiated in the fourth quarter of 2019.

Under its license agreement with Sinovant Sciences, Nabriva is eligible for up to approximately $85 million in additional milestone payments tied to the successful completion of certain regulatory and commercial milestones related to lefamulin for community-acquired bacterial pneumonia (CABP). In addition, Nabriva will be eligible to receive low double-digit royalties on sales, if any, in the Greater China region.

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), 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 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 the future development or commercialization of lefamulin in the greater China region, the potential benefits under Nabriva's license agreement with Sinovant Sciences, an affiliate of Roivant Sciences Ltd., launch and commercialization of XENLETA for the treatment of CABP, 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 XENLETA and 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 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 and prepare for commercial launch of XENLETA on the timeline expected, or at all, 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 or of XENLETA for the treatment of CABP, 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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