
**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): **March 26, 2018**

NABRIVA THERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction of
incorporation)

001-37558
(Commission File Number)

Not Applicable
(I.R.S. Employer Identification
No.)

**25-28 North Wall Quay,
IFSC, Dublin 1, Ireland**
(Address of principal executive offices)

Not Applicable
(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 1.01. Entry into a Material Definitive Agreement.

On March 26, 2018, Nabriva Therapeutics Ireland Designated Activity Company (the “Company”), a wholly owned subsidiary of Nabriva Therapeutics plc (“Nabriva Therapeutics”), entered into a license agreement (the “License Agreement”) with Sinovant Sciences Ltd. (“Sinovant”), an affiliate of Roivant Sciences, Ltd. (“Roivant”). Under the License Agreement, the Company and its affiliate, Nabriva Therapeutics GmbH, granted Sinovant an exclusive (subject to certain retained rights of the Company) license under certain patent rights and know-how to develop and commercialize, and a non-exclusive license to manufacture, certain products containing lefamulin in the forms clinically developed by the Company or any of its affiliates (“Licensed Products”), in the human indications specified by the Company (the “Field”), in the People’s Republic of China, Hong Kong, Macau and Taiwan (the “Licensed Territory”).

The Company retains development and commercialization rights in the rest of the world. Under the License Agreement, Sinovant granted to the Company various exclusive and non-exclusive licenses under certain patent rights and know-how relating to lefamulin to develop, manufacture and commercialize lefamulin and related products, which license does not, prior to any termination of the License Agreement, extend to the development or commercialization of lefamulin or products containing lefamulin in the Licensed Territory. These licenses are royalty-free, except that the Company is obligated to pay a low-to-mid single digit royalty on net sales of Licensed Products in the Licensed Territory if Sinovant terminates the License Agreement for the Company’s uncured material breach.

Under the terms of the License Agreement, the Company is entitled to receive an upfront payment of \$5 million and is entitled to receive up to an additional \$91.5 million in milestone payments upon the achievement of certain regulatory and sales milestone events, plus an additional \$4 million in milestone payments if any Licensed Product receives a second or any subsequent regulatory approval in the People’s Republic of China. There can be no guaranty that any of these milestone events will be met. The Company will also be entitled to receive low double-digit royalties on sales, if any, of Licensed Products in the Licensed Territory. In addition, the due and punctual payment of all of Sinovant’s financial obligations under the License Agreement have been guaranteed by Roivant, provided that such guarantee will terminate upon the occurrence of certain specified event related to Sinovant’s financial condition.

Sinovant is responsible for all costs related to developing, obtaining regulatory approval of, and commercializing Licensed Products in the Field in the Licensed Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Licensed Products in the Field in the Licensed Territory. The Company is obligated to use commercially reasonable efforts to supply, pursuant to supply agreements to be negotiated by the parties, to Sinovant sufficient supply of lefamulin for Sinovant to manufacture finished drug products for development and commercialization of the Licensed Products in the Field in the Licensed Territory.

Unless earlier terminated, the License Agreement will expire upon the expiration of the last royalty term for the last Licensed Product in the Field in the Licensed Territory. The License Agreement may be terminated in its entirety by Sinovant upon 180 days’ prior written notice at any time. Either party may, subject to specified cure periods, terminate the License Agreement in the event of the other party’s uncured material breach. Either party may also terminate the License Agreement under specified circumstances relating to the other party’s insolvency. The Company has the right to terminate the License Agreement immediately if Sinovant does not make the upfront payment within five business days of its entry into the License Agreement, or if Sinovant does not reach certain development milestones by certain specified dates (subject to specified cure periods).

The License Agreement contemplates that the Company will enter in ancillary arrangements with Sinovant, including clinical and commercial supply agreements and a pharmacovigilance agreement.

The foregoing description of certain terms of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement that the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018.

Item 7.01 Regulation FD Disclosure.

On March 27, 2018, Nabriva Therapeutics announced the entry into the License Agreement with Sinovant. The related press release is attached hereto as Exhibit 99.1 and incorporated by reference herein. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

As previously reported, on March 16, 2018, Nabriva Therapeutics entered into a Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co., as agent (“Cantor Fitzgerald”), pursuant to which Nabriva Therapeutics may offer and sell ordinary shares (the “Ordinary Shares”), nominal value \$0.01 per share, for aggregate gross sale proceeds of up to \$50,000,000 from time to time through Cantor Fitzgerald under an “at-the-market” offering program (the “ATM Program”).

Nabriva Therapeutics expects that the net proceeds received to date under its ATM Program and the \$5 million upfront payment it received pursuant to the terms of the License Agreement described above, together with its other cash, cash equivalents and short-term investments, will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2019. Nabriva Therapeutics has based this estimate on assumptions that may prove to be wrong, and it could use its capital resources sooner than it currently expects. This estimate assumes, among other things, that Nabriva Therapeutics does not obtain any additional funding through grants and clinical trial support, collaboration agreements or equity or debt financings, including the ATM Program and the License Agreement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 27, 2018.

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 future development or commercialization of lefamulin in the greater China region, the potential benefits under its license agreement with Sinovant Sciences, an affiliate of Roivant Sciences Ltd., plans for the design, conduct and timelines of Nabriva Therapeutics’ ongoing Phase 3 clinical trial of lefamulin for CABP, the clinical utility of lefamulin for CABP and Nabriva Therapeutics’ plans for filing of regulatory approvals and efforts to bring lefamulin to market, the market opportunity for and the potential market acceptance of lefamulin for CABP, the development of lefamulin for additional indications, the development of additional formulations of lefamulin, 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 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 trials in different

disease indications will be indicative of the results of ongoing or future trials, whether results of Nabriva Therapeutics' first Phase 3 clinical trial of lefamulin will be indicative of the results for its second Phase 3 clinical trial of lefamulin, 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, the sufficiency of cash resources and need for additional financing and such other important factors as are set forth under the caption "Risk Factors" in Nabriva Therapeutics' annual and quarterly reports 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.

Date: March 27, 2018

NABRIVA THERAPEUTICS PLC

By: /s/ Colin Broom
Colin Broom
Chief Executive Officer



Nabriva Therapeutics and Roivant Sciences Enter into License Agreement to Develop and Commercialize Lefamulin in Greater China

DUBLIN, Ireland, and HONG KONG, March 27, 2018 — Nabriva Therapeutics plc (NASDAQ:NBRV), a clinical stage biopharmaceutical company engaged in the research and development of novel anti-infective agents to treat serious infections, with a focus on the pleuromutilin class of antibiotics, and Roivant Sciences, today announced the initiation of a collaboration to develop and commercialize lefamulin in greater China. Lefamulin has completed a pivotal, international Phase 3 clinical trial for the treatment of adults with moderate to severe community-acquired bacterial pneumonia (CABP). Topline data from a second pivotal, international Phase 3 clinical trial are expected in the spring of 2018.

As part of the license agreement, Nabriva has granted a Roivant subsidiary an exclusive license to develop and commercialize lefamulin in the greater China region, specifically the People's Republic of China, Hong Kong, Macau, and Taiwan. The companies will establish a joint development committee to review and oversee all development and commercialization plans. Nabriva will receive a \$5 million upfront payment and will be eligible for up to approximately \$90 million in additional payments tied to the successful completion of certain regulatory and commercial milestones related to lefamulin for CABP. In addition, Nabriva will be eligible to receive low double-digit royalties on sales upon approval in the covered territories. Roivant's affiliate will be solely responsible for all clinical development and regulatory filings necessary to secure approval in the covered territories.

"Our partnership with Roivant underscores our commitment to ensuring rapid access to lefamulin for adults with CABP around the globe," said Dr. Colin Broom, chief executive officer of Nabriva Therapeutics. "Roivant has a broad therapeutic portfolio and deep development and commercialization expertise, making the company an excellent partner as we pursue bringing an important and much-needed new treatment option for CABP—and potentially other serious bacterial infections—to China and surrounding territories. The funding from this agreement will also contribute to our efforts to prepare for a successful launch should lefamulin be approved in the United States."

"This partnership demonstrates our commitment to build out a robust pipeline of products in China in addition to derazantinib," said Vivek Ramaswamy, founder and chief executive officer of Roivant Sciences. "It is also indicative of our desire to develop treatments for infectious diseases beyond hepatitis B virus. Increasing resistance to commonly prescribed anti-infectives represents a significant threat to public health, especially in China, but we believe that lefamulin's novel mechanism of action represents a promising advance. Our partnership with Nabriva is an important step in our contribution to this area of medicine and this region of the world."

Pneumonia is a leading cause of infectious disease mortality worldwide. In China, pneumonia is the fourth leading cause of death in urban areas and the leading cause of death in rural areas.(1) Mortality is expected to rise as bacteria become increasingly resistant to currently prescribed treatments. The incidence of multi-drug resistant pneumonia is rising in China and several other Asian countries.(2),(3),(4)

About Lefamulin

Lefamulin is a semi-synthetic derivative of pleuromutilin that inhibits a key process for bacterial growth. In pre-clinical studies, lefamulin has demonstrated a targeted spectrum of activity against the pathogens that most commonly cause CABP, including multi-drug resistant strains. Due to its novel mechanism of action, low incidence of cross-resistance between other antibacterial agents commonly used to treat CABP, and low propensity for bacterial resistance to develop, lefamulin has the potential to be used as a first-line empiric monotherapy for the treatment of CABP. Furthermore, if approved, the availability of both oral and intravenous (IV) formulations and a favorable tolerability profile make it appropriate for potential use across all three CABP treatment settings, including in-hospital, transition of care, and community-initiated.

In the U.S., Nabriva Therapeutics anticipates filing a New Drug Application in the second half of 2018 contingent on positive results from its second, pivotal Phase 3 clinical trial of lefamulin for CAPB, which is referred to as LEAP 2. Topline data from LEAP 2 is expected in the spring of 2018. LEAP 2 is designed to assess the efficacy and safety of oral lefamulin compared to oral moxifloxacin in adult patients with moderate CABP. In September 2017, Nabriva Therapeutics announced positive topline results from its first Phase 3 clinical trial of lefamulin for CAPB, which is referred to as LEAP 1, which evaluated the efficacy and safety of intravenous (IV) to oral lefamulin in adult patients with moderate to severe CABP compared to moxifloxacin with or without adjunctive linezolid. In LEAP 1, lefamulin met both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) primary endpoints of non-inferiority compared to moxifloxacin with or without adjunctive linezolid. Lefamulin also showed a favorable tolerability profile in the LEAP 1 trial, with no unexpected safety signals or evidence of off-target activity.

About Roivant Sciences

Roivant is dedicated to transformative innovation in healthcare. Roivant focuses on realizing the full potential of promising biomedical research by developing and commercializing novel therapies across diverse therapeutic areas. Roivant partners with innovative biopharmaceutical companies and academic institutions to ensure that important medicines are rapidly developed and delivered to patients.

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- (1) Guan X, Silk B, Li W, et al. Pneumonia incidence and mortality in mainland China: systematic review of Chinese and English literature, 1985-2008
 - (2) Liu Y, Chen M, Zhao T, et al. Causative agent distribution and antibiotic therapy assessment among adult patients with community acquired pneumonia in Chinese urban population. *BMC Infect Dis* 2009;9:31.
 - (3) Cao B, Zhao CJ, Yin YD, et al. High prevalence of macrolide resistance in *Mycoplasma pneumoniae* isolates from adult and adolescent patients with respiratory tract infection in China. *Clin Infect Dis* 2010;51:189—94.
 - (4) Qiao M, Ying GG, Singer A, et al. Review of antibiotic resistance in China and its environment. *Env Intl* 2018;110:160-172
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Roivant advances its drug pipelines through wholly- or majority-owned subsidiary companies, including Myovant (women's health and endocrine diseases), Axovant (neurology), Urovant (urology), Enzyvant (rare diseases), Dermavant (dermatology) and Metavant (cardiometabolic diseases). Roivant also pursues its mission by incubating and launching innovative healthcare companies operating outside of traditional biopharmaceutical development, including Datavant (healthcare analytics). Roivant's long-range mission is to reduce the time and cost of developing and delivering new medicines for patients.

About Nabriva Therapeutics plc

Nabriva Therapeutics is a biopharmaceutical company engaged in the research and development of new medicines to treat serious bacterial infections, with a focus on the pleuromutilin class of antibiotics. Nabriva Therapeutics' medicinal chemistry expertise has enabled targeted discovery of novel pleuromutilins, including both intravenous and oral formulations. Nabriva Therapeutics' lead product candidate, lefamulin, is a novel semi-synthetic pleuromutilin antibiotic with the potential to be the first-in-class available for systemic administration in humans. The company believes that lefamulin is the first antibiotic with a novel mechanism of action to have reached late-stage clinical development in more than a decade. Nabriva has announced positive topline data for lefamulin from the first of its two global, registrational Phase 3 clinical trials evaluating lefamulin in patients with moderate to severe community-acquired bacterial pneumonia (CABP). Nabriva Therapeutics believes lefamulin is well-positioned for use as a first-line empiric monotherapy for the treatment of moderate to severe CABP due to its novel mechanism of action, targeted spectrum of activity, resistance profile, achievement of substantial drug concentration in lung tissue and fluid, oral and IV formulations and a favorable tolerability profile, with the results of the LEAP 1 trial showing a rate of treatment-emergent adverse events comparable to moxifloxacin with or without linezolid. Nabriva Therapeutics is evaluating the continued development of lefamulin for additional indications and is developing a formulation of lefamulin appropriate for pediatric use.

Outside of the greater China region, Nabriva Therapeutics owns exclusive rights to lefamulin, which is protected by composition of matter patents issued in the United States, Europe and Japan.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Nabriva, including but not limited to statements about the development of Nabriva's product candidates, such as the future development or commercialization of lefamulin in the greater China region, the potential benefits under its license agreement with Roivant and its subsidiary, plans for the design, conduct and timelines of Nabriva's ongoing Phase 3 clinical trial of lefamulin for CABP, the clinical utility of lefamulin for CABP and Nabriva's plans for filing of regulatory approvals and efforts to bring lefamulin to market, the market opportunity for and the potential market acceptance of lefamulin for CABP, the development of lefamulin for additional indications, the development of additional formulations of lefamulin, plans to pursue research and development of other product candidates, the sufficiency of Nabriva's 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 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 trials in different disease indications will be indicative of the results of ongoing or future trials, whether results of Nabriva's first Phase 3 clinical trial of lefamulin will be indicative of the results for its second Phase 3 clinical trial of lefamulin, 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, the sufficiency of cash resources and need for additional financing and such other important factors as are set forth under the caption "Risk Factors" in Nabriva's annual and quarterly reports on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Nabriva's views as of the date of this release. Nabriva anticipates that subsequent events and developments will cause its views to change. However, while Nabriva 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's views as of any date subsequent to the date of this release.

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