

---

---

**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 16, 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 2.02 Results of Operations and Financial Conditions.**

On March 16, 2018, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the year ended December 31, 2017. A copy of the press release is being filed as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K, 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 9.01 Financial Statements and Exhibits.**

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit 99.1 [Press release issued by Nabriva Therapeutics plc, dated March 16, 2018.](#)

**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: March 16, 2018

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



## Nabriva Therapeutics Reports 2017 Financial Results and Recent Corporate Highlights

*- Positive topline results from pivotal LEAP 1 trial announced in September 2017, with read-out from second Phase 3 trial, LEAP 2, expected in the spring of 2018 -*

*- \$86.9 million cash and investments as of December 31, 2017 -*

**Dublin, Ireland, March 16, 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, today announced its financial results for the year ended December 31, 2017 and recent corporate highlights.

“We achieved a significant milestone in our clinical development program for lefamulin in 2017 with the announcement of positive topline data from our first global, IV-to-oral Phase 3 clinical trial in adult patients with moderate to severe CABP, known as LEAP 1,” said Dr. Colin Broom, chief executive officer of Nabriva Therapeutics. “Additionally, we started to efficiently build our medical education and commercial organizations to ensure rapid access to this important new treatment option with activity against the pathogens most commonly associated with CABP—including multi-drug resistant strains—should it be approved in the U.S. Looking ahead, we continue to anticipate reporting topline results from our second global Phase 3 clinical trial evaluating an all-oral regimen of lefamulin in adult patients with moderate CABP this spring. We completed enrollment for LEAP 2 in December 2017. Subject to the receipt of positive data from LEAP 2, we plan to file a New Drug Application for lefamulin with the U.S. Food and Drug Administration in the second half of this year and remain focused on commercializing it in the U.S. with our own targeted sales and marketing organization. We will look to identify and potentially secure external collaborators to help advance our efforts to develop and commercialize lefamulin outside the U.S.”

### RECENT CORPORATE AND DEVELOPMENT HIGHLIGHTS

#### RESEARCH AND DEVELOPMENT

- Announced positive topline results from the LEAP 1 global, Phase 3 clinical trial evaluating IV and oral lefamulin for the treatment of CABP. Lefamulin met the U.S. Food and Drug Administration primary endpoint of non-inferiority (NI, 12.5 percent margin) compared to moxifloxacin with or without adjunctive linezolid for early clinical response assessed 72 to 120 hours following initiation of therapy in the intent to treat patient population. Lefamulin also met the co-primary endpoints for the European Medicines Agency of non-inferiority (NI, 10 percent margin) compared to moxifloxacin with or without adjunctive linezolid in the modified intent to treat and clinically evaluable at test of cure populations based on an investigator assessment of clinical response at a test of cure visit (5 to 10 days following the completion of study therapy). Lefamulin was shown to be generally well-tolerated in LEAP 1.
-

- Completed LEAP 2 patient enrollment in December 2017, and based on the company's current estimation of final data collection and analysis timelines, it expects to announce LEAP 2 topline efficacy and safety data in the spring of 2018. LEAP 2 is a Phase 3 global, registrational clinical trial evaluating the safety and efficacy of oral lefamulin in patients with moderate CABP.
- At the 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) that took place in Vienna, Austria from April 22-25, 2017, Nabriva showcased nine abstracts, three of which were selected as oral presentations. These data are part of a growing body of evidence supporting lefamulin's profile as a potential first-line, empiric treatment for the key pathogens, including multi-drug resistant strains, that are known to cause CABP.
- Nabriva presented data at the American Society of Microbiology Microbe 2017 Conference in June 2017, detailing lefamulin's *in vitro* activity against key pathogens that commonly cause respiratory tract infections.
- Presented data detailing *in vitro* activity of lefamulin against key pathogens that commonly cause respiratory tract infections and lefamulin efficacy against *Staphylococcus aureus* bacteremia in an animal infection model at the IDWeek 2017 meeting. These data add to the growing evidence supporting lefamulin's targeted spectrum of activity against the pathogens most commonly associated with CABP, including multi-drug resistant strains.

#### CORPORATE

- Strengthened the company's cash resources with the completion of its public offering of ordinary shares in September 2017. The gross proceeds from the offering were \$80.0 million, before deducting the underwriting discounts and commissions.
- In June 2017, Nabriva Therapeutics plc concluded its tender offer to exchange outstanding common shares and American Depositary Shares of Nabriva Therapeutics AG for ordinary shares of Nabriva Therapeutics plc and thereby completed the Redomiciliation Transaction from Austria to Ireland. Nabriva Therapeutics plc is now the publicly traded parent company of the Nabriva Group with its tax residency in Ireland.
- Bolstered the senior leadership team with the appointment of industry expert Francesco Maria Lavino as Chief Commercial Officer, in July 2017, to lead the preparation for the potential commercialization of lefamulin. Additionally, Robert Crotty was appointed General Counsel and Corporate Secretary in June 2017.
- Appointed Carrie Bourdow, Executive Vice President and Chief Operating Officer of Trevena, Inc., and Colin Broom, M.D., Chief Executive Officer of Nabriva Therapeutics, to the company's Board of Directors in June 2017.

#### FULL YEAR 2017 FINANCIAL RESULTS

- For the year ended December 31, 2017, Nabriva reported a net loss of \$74.4 million or \$2.49 per share, compared to a net loss of \$54.9 million or \$2.56 per share for the year ended December 31, 2016.
  - Research and development expenses increased by \$1.6 million from \$48.0 million for the year ended December 31, 2016 to \$49.6 million for the year ended December 31, 2017. The increase was primarily due to a \$2.1 million increase in staff costs due to the addition of employees and a \$1.2 million increase in share-based compensation expense due to the inclusion of additional employees in our share-based compensation plan, partially offset by a \$1.5 million decrease in direct costs for purchased services related to the development of lefamulin and a \$0.2 million decrease of advisory and external consultancy, travel and other expenses.
-

- General and administrative expense increased by \$16.0 million from \$13.5 million for the year ended December 31, 2016 to \$29.5 million for the year ended December 31, 2017. The increase was primarily due to a \$6.1 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a \$4.1 million increase in legal fees mainly related to the redomiciliation of our parent company from Austria to Ireland, a \$2.8 million increase in staff costs due to the addition of employees, a \$2.0 million increase in share-based compensation expense due to the inclusion of additional employees in our share-based compensation plan, a \$0.7 million increase in VAT tax expenses, and a \$0.3 million increase in support, infrastructure and other corporate costs.
- As of December 31, 2017, Nabriva had \$86.9 million in cash, cash equivalents and short-term investments compared to \$83.9 million as of December 31, 2016. This cash balance is expected to fund operations into the fourth quarter of 2018.

**Please refer to our Annual Report on Forms 10-K for the fiscal year ended December 31, 2017 filed with the U.S. Securities and Exchange Commission, for additional information regarding our business and financial results.**

#### **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 indications in addition to CABP. Pediatric oral formulation development is ongoing and we anticipate initiating clinical studies in pediatric patients in mid-2018. We believe lefamulin has potential to treat ABSSSI, VABP or HABP and STIs. In addition, we may explore longer duration of treatment with lefamulin to support development of a treatment for osteomyelitis and prosthetic joint infections.

Nabriva Therapeutics owns exclusive, worldwide 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 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 development of lefamulin for additional indications, the development of additional formulations of lefamulin, plans to pursue research and development of other product candidates, Nabriva's plans to enter

---

into arrangements with external collaborators, 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.

CONTACT:

FOR INVESTORS

Dave Garrett  
Nabriva Therapeutics plc  
david.garrett@nabriva.com  
610-816-6657

FOR MEDIA

Benjamin Navon  
W2O Group  
bnavon@w2ogroup.com  
617-337-4166

---

**CONSOLIDATED BALANCE SHEETS**

(in thousands, except share data)	As of December 31, 2016	As of December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 32,778	\$ 86,769
Short-term investments	51,106	110
Other receivables	5,561	5,402
Prepaid expenses	1,176	1,558
<b>Total current assets</b>	<b>90,621</b>	<b>93,839</b>
Property, plant and equipment, net	519	1,327
Intangible assets, net	270	172
Long-term receivables	420	425
Deferred tax assets	1,410	—
<b>Total assets</b>	<b>\$ 93,240</b>	<b>\$ 95,763</b>
<b>Liabilities and equity</b>		
Current liabilities:		
Accounts payable	\$ 2,551	\$ 5,136
Accrued expense and other current liabilities	13,326	8,124
<b>Total current liabilities</b>	<b>15,877</b>	<b>13,260</b>
Non-current liabilities:		
Long-term debt	—	232
Other non-current liabilities	107	203
<b>Total non-current liabilities</b>	<b>107</b>	<b>435</b>
<b>Total liabilities</b>	<b>15,984</b>	<b>13,695</b>
Stockholders' Equity:		
Common shares, no par value, 2,719,695 common shares issued and outstanding at December 31, 2016	2,939	—
Ordinary shares, nominal value \$0.01, 1,000,000,000 ordinary shares authorized at December 31, 2017; 36,707,685 issued and outstanding at December 31, 2017	—	367
Preferred shares, par value \$0.01, 100,000,000 shares authorized at December 31, 2017; None issued and outstanding at December 31, 2017	—	—
Additional paid in capital	279,149	360,872
Accumulated other comprehensive income	10	27
Accumulated deficit	(204,842)	(279,198)
<b>Total stockholders' equity</b>	<b>77,256</b>	<b>82,068</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 93,240</b>	<b>\$ 95,763</b>



**CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share data)	Year ended December 31,	
	2016	2017
<b>Revenues:</b>		
Research premium and grant revenue	\$ 6,482	\$ 5,319
<b>Operating expenses:</b>		
Research and development	(47,994)	(49,615)
General and administrative	(13,535)	(29,472)
Total operating expenses	(61,529)	(79,087)
<b>Loss from operations</b>	<b>(55,047)</b>	<b>(73,768)</b>
<b>Other income (expense):</b>		
Other income (expense), net	(783)	492
Interest income	343	318
Interest expense	(75)	(43)
<b>Loss before income taxes</b>	<b>(55,562)</b>	<b>(73,001)</b>
Income tax (expense) benefit	672	(1,355)
<b>Net loss</b>	<b>\$ (54,890)</b>	<b>\$ (74,356)</b>
<b>Loss per share</b>		
Basic and diluted	\$ (2.56)	\$ (2.49)
<b>Weighted average number of shares:</b>		
Basic and diluted	21,478,320	29,830,669

**Condensed Consolidated Statements of Cash Flows**

<b>(in thousands)</b>	<b>Year ended December 31,</b>	
	<b>2016</b>	<b>2017</b>
<b>Net cash provided by (used in):</b>		
Operating activities	\$ (48,325)	\$ (69,348)
Investing activities	23,352	49,749
Financing activities	22,301	72,219
Effects of foreign currency translation on cash and cash equivalents	(996)	1,371
Net (decrease) increase in cash and cash equivalents	(3,668)	53,991
Cash and cash equivalents at beginning of year	36,446	32,778
Cash and cash equivalents at end of year	\$ 32,778	\$ 86,769

---