
**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): **November 9, 2017**

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 November 9, 2017, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the quarter ended September 30, 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 November 9, 2017.](#)

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 AG

Date: November 9, 2017

By: /s/ Colin Broom

Colin Broom
Chief Executive Officer



Nabriva Therapeutics Reports Third Quarter 2017 Financial Results and Recent Corporate Highlights

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

- \$112.7 million cash and investments as of September 30, 2017 -

Dublin Ireland, November 9, 2017 — 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 provided a business and clinical development update and reported its financial results for the quarter ended September 30, 2017.

In September, Nabriva Therapeutics delivered positive topline results from the lefamulin evaluation against pneumonia (LEAP 1) Phase 3 trial. The company remains on track to complete patient enrollment for its second Phase 3 trial, LEAP 2, before year end 2017, and expects topline results in the spring of 2018. Lefamulin is being investigated for the treatment of community-acquired bacterial pneumonia (CABP).

“The growing problem of bacterial resistance to commonly prescribed antibiotics continues to be one of the single greatest threats to public health,” said Dr. Colin Broom, chief executive officer of Nabriva Therapeutics. “We are excited about the progress our team continues to make as we advance lefamulin toward our ultimate goal—bringing a new class of antibiotics to patients with CABP. Following the positive results from LEAP 1, we began building our commercial and medical affairs teams and have attracted extremely talented and experienced individuals. Over the coming months, our commercial team will focus on market development activities, while our medical affairs team will educate physician and hospital communities on the significant medical needs in the management of CABP.”

RECENT CORPORATE AND DEVELOPMENT HIGHLIGHTS

- 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.
 - Strengthened the company’s cash resources with the completion of its public offering. The gross proceeds from the offering were approximately \$80.0 million, before deducting the underwriting discounts and commissions.
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- 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.
- Bolstered the senior leadership team with the appointment of industry expert Francesco Maria Lavino as chief commercial officer to lead the preparation for the potential commercialization of lefamulin.

FINANCIAL RESULTS

Three Months Ended September 30, 2017 and 2016

- For the three months ended September 30, 2017, Nabriva reported a net loss of \$22.3 million or \$0.79 per share, compared to a net loss of \$14.0 million or \$0.66 per share for the three months ended September 30, 2016.
- Research and development expenses increased by \$0.6 million from \$12.1 million for the three months ended September 30, 2016 to \$12.7 million for the three months ended September 30, 2017. The change was primarily due to a \$0.9 million increase in staff costs due to the addition of employees and a \$0.3 million increase in stock-based compensation expense, partially offset by a \$0.6 million decrease in research consulting fees.
- General and administrative expense increased by \$6.5 million from \$3.0 million for the three months ended September 30, 2016 to \$9.5 million for the three months ended September 30, 2017. The increase was primarily due to a \$1.9 million increase in advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a \$1.5 million increase in legal fees mainly related to the redomiciliation of our parent company from Austria to Ireland, a \$1.0 million increase in stock-based compensation expense, a \$0.6 million increase in staff costs due to the addition of employees, a \$0.6 million increase in VAT tax expenses and a \$0.4 million increase in support, infrastructure and other corporate costs.

Nine Months Ended September 30, 2017 and 2016

- For the nine months ended September 30, 2017, Nabriva reported a net loss of \$52.1 million or \$1.89 per share, compared to a net loss of \$39.7 million or \$1.87 per share for the nine months ended September 30, 2016.
 - Research and development expenses increased by \$1.3 million from \$35.0 million for the nine months ended September 30, 2016 to \$36.4 million for the nine months ended September 30, 2017. The change was primarily due to a \$1.7 million increase in staff costs due to the addition of employees and a \$1.0 million increase in stock-based compensation expense, partially offset by a \$0.8 million decrease in research materials and purchased services related to the development of lefamulin and a \$0.5 million decrease in research consulting fees.
 - General and administrative expense increased by \$9.9 million from \$9.4 million for the nine months ended September 30, 2016 to \$19.3 million for the nine months ended September 30, 2017. The increase was primarily due to a \$3.1 million increase in legal fees mainly related to the redomiciliation of our parent company from Austria to Ireland, a \$2.6 million increase in advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a \$1.6 million increase in stock-based compensation expense, a \$1.0 million increase in staff costs due to the addition of employees, a \$0.6 million increase in VAT tax expenses, and a \$0.7 million increase in support, infrastructure and other corporate costs.
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- As of September 30, 2017, Nabriva had \$112.7 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, 2016 and our Quarterly Report on Form 10-Q for the three and nine months ended September 30, 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 intends to further pursue development of lefamulin for additional indications, including the treatment of acute bacterial skin and skin structure infections (ABSSSI), and is developing a formulation of lefamulin appropriate for pediatric use.

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, 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:

INVESTOR RELATIONS

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MEDIA

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CONSOLIDATED BALANCE SHEETS
(unaudited)

| (in thousands, except per share data) | As of December 31, 2016 | As of September 30, 2017 |
|---|-------------------------------|--------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 32,778 | \$ 112,158 |
| Short-term investments | 51,106 | 531 |
| Other receivables | 5,561 | 3,673 |
| Prepaid expenses | 1,176 | 1,510 |
| Total current assets | 90,621 | 117,872 |
| Property, plant and equipment, net | 519 | 1,405 |
| Intangible assets, net | 270 | 199 |
| Long-term receivables | 420 | 420 |
| Deferred tax assets | 1,410 | — |
| Total assets | \$ 93,240 | \$ 119,896 |
| Liabilities and equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,551 | \$ 5,319 |
| Accrued expense and other current liabilities | 13,326 | 11,014 |
| Total current liabilities | 15,877 | 16,333 |
| Non-current liabilities: | | |
| Long-term debt | — | 227 |
| Other non-current liabilities | 107 | 198 |
| Total non-current liabilities | 107 | 425 |
| Total liabilities | 15,984 | 16,758 |
| 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 September 30, 2017; 36,691,490 issued and outstanding at September 30, 2017 | — | 367 |
| Preferred shares, par value \$0.01, 100,000,000 shares authorized at September 30, 2017; None issued and outstanding at September 30, 2017 | — | — |
| Additional paid in capital | 279,149 | 359,680 |
| Accumulated other comprehensive income | 10 | 27 |
| Accumulated deficit | (204,842) | (256,936) |
| Total stockholders' equity | 77,256 | 103,138 |
| Total liabilities and stockholders' equity | \$ 93,240 | \$ 119,896 |

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(unaudited)

| (in thousands, except share and per share data) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|--------------------|------------------------------------|--------------------|
| | 2016 | 2017 | 2016 | 2017 |
| Revenues: | | | | |
| Research premium and grant revenue | \$ 971 | \$ 1,468 | \$ 4,175 | \$ 4,197 |
| Operating expenses: | | | | |
| Research and development | (12,058) | (12,668) | (35,037) | (36,371) |
| General and administrative | (2,992) | (9,525) | (9,445) | (19,313) |
| Total operating expenses | (15,050) | (22,193) | (44,482) | (55,684) |
| Loss from operations | (14,079) | (20,725) | (40,307) | (51,487) |
| Other income (expense): | | | | |
| Other income (expense), net | 50 | 301 | 404 | 391 |
| Interest income | 92 | 69 | 234 | 302 |
| Interest expense | (35) | (42) | (35) | (46) |
| Loss before income taxes | (13,972) | (20,397) | (39,704) | (50,840) |
| Income tax benefit (expense) | (28) | (1,872) | 1 | (1,254) |
| Net loss | (14,000) | (22,269) | (39,703) | (52,094) |
| Other comprehensive income (loss), net of tax | | | | |
| Unrealized gains on available-for-sale securities | 34 | 69 | 67 | 43 |
| Other comprehensive income, net of tax | 34 | 69 | 67 | 43 |
| Comprehensive loss | \$ (13,966) | \$ (22,200) | \$ (39,636) | \$ (52,051) |
| | | | | |
| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
| | 2016 | 2017 | 2016 | 2017 |
| Loss per share | | | | |
| Basic and Diluted | \$ (0.66) | \$ (0.79) | \$ (1.87) | \$ (1.89) |
| | | | | |
| Weighted average number of shares: | | | | |
| Basic and Diluted | 21,276,610 | 28,147,226 | 21,236,260 | 27,517,267 |

CONSOLIDATED STATEMENT OF CASH FLOWS
(unaudited)

| (in thousands) | Nine Months Ended September 30, | |
|---|------------------------------------|-------------|
| | 2016 | 2017 |
| Cash flows from operating activities | | |
| Net loss | \$ (39,703) | \$ (52,094) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Non-cash other expense, net | (283) | (1,356) |
| Non-cash interest income | (102) | — |
| Depreciation and amortization expense | 172 | 295 |
| Stock-based compensation | 1,983 | 4,538 |
| Deferred income taxes | (428) | 1,410 |
| Other, net | 36 | 147 |
| Changes in operating assets and liabilities: | | |
| Changes in long-term receivables | (8) | — |
| Changes in other receivables and prepaid expenses | (4,418) | 1,554 |
| Changes in accounts payable | (234) | 2,632 |
| Changes in accrued expenses and other liabilities | 5,251 | (2,419) |
| Changes in other non-current liabilities | 13 | 27 |
| Net cash used in operating activities | (37,721) | (45,266) |
| Cash flows from investing activities | | |
| Purchases of plant and equipment and intangible assets | (456) | (1,141) |
| Purchases of available-for-sale securities | (14,000) | — |
| Purchase of term deposits | (10) | — |
| Proceeds from sales of property, plant and equipment | — | 2 |
| Proceeds from maturities of term deposits | 15,000 | — |
| Proceeds from sales of available-for-sale securities | 25,000 | 50,500 |
| Net cash provided by investing activities | 25,534 | 49,361 |
| Cash flows from financing activities | | |
| Proceeds from sale of ordinary shares | — | 80,000 |
| Proceeds from long-term debt | — | 228 |
| Proceeds from exercise of stock options | 243 | 83 |
| Equity offering costs | — | (6,382) |
| Net cash provided by financing activities | 243 | 73,929 |
| Effects of foreign currency translation on cash and cash equivalents | 282 | 1,356 |
| Net increase (decrease) in cash and cash equivalents | (11,662) | 79,380 |
| Cash and cash equivalents at beginning of period | 36,446 | 32,778 |
| Cash and cash equivalents at end of period | \$ 24,784 | \$ 112,158 |