
**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 6, 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 November 6, 2018, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the quarter ended September 30, 2018. 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 6, 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: November 6, 2018

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



Nabriva Therapeutics Reports Third Quarter 2018 Financial Results and Recent Corporate Highlights

*- New Drug Application for CONTEPO™ submitted to FDA in October 2018 -
- Company preparing for potential commercialization of two, first-in-class antibiotics,
Lefamulin (IV and Oral) and CONTEPO (IV) in the United States in 2019 -*

Dublin Ireland, November 6, 2018 — Nabriva Therapeutics plc (NASDAQ: NBRV), a clinical stage biopharmaceutical company engaged in the research and development of innovative anti-infective agents to treat serious infections, today provided a business and clinical development update and reported its financial results for the quarter ended September 30, 2018.

“Nabriva has continued to make significant progress in potentially bringing two first-in-class antibiotics to patients in need of better treatment options here in the United States,” said Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics. “We have completed our NDA submission for CONTEPO to treat complicated-urinary tract infections (cUTI), including acute pyelonephritis, and remain on track for our NDA submission for lefamulin for the treatment of community-acquired bacterial pneumonia (CABP) by both intravenous and oral routes in the fourth quarter of 2018. We remain focused on commercializing both lefamulin and CONTEPO in the United States with our own targeted sales, marketing and medical affairs organizations and continue to identify and potentially secure external collaborators to help advance our efforts to develop and commercialize lefamulin outside the United States”

RECENT CORPORATE AND DEVELOPMENT HIGHLIGHTS

- Submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Intravenous CONTEPO in the fourth quarter of 2018 to treat cUTIs, including acute pyelonephritis. CONTEPO has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of several serious infections, including cUTI, which enables Priority Review of the NDA, following acceptance.
 - Completed the acquisition of Zavante Therapeutics (“Zavante”) in July 2018, a biopharmaceutical company focused on developing novel therapies to improve the outcomes of hospitalized patients, for upfront consideration of approximately 8.2 million of Nabriva Therapeutics’ ordinary shares (which includes an indemnity holdback) to Zavante’s former stockholders upon completion of the acquisition. In addition, Zavante’s former stockholders are eligible to receive up to \$97.5 million upon the achievement of specified regulatory and commercial milestones, which subject to specified limitations, may be settled in Nabriva Therapeutics’ ordinary shares.
 - Bolstered the senior leadership team with the appointment of Ted Schroeder, former Chief Executive Officer of Zavante, as Chief Executive Officer of Nabriva Therapeutics to succeed Dr. Colin Broom, who remains on the Board of Directors of Nabriva Therapeutics. In addition, Dr. Steven Gelone was named President and Chief Operating Officer of Nabriva Therapeutics.
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- Strengthened the Company's cash resources with the completion of its public offering of ordinary shares in July 2018. The gross proceeds from the offering were \$50.0 million and net proceeds to the Company were \$46.1 million, after deducting underwriting discounts and commissions and offering expenses. The Company ended the third quarter of 2018 with \$100.7 million of cash, cash equivalents and short-term investments which the Company expects to fund operations into the first quarter of 2020.
- At the Infectious Diseases Society of America (IDSA) IDWeek™ 2018, the Company made three poster presentations and an oral platform presentation for LEAP 2, the pivotal, Phase 3 clinical trial of lefamulin, which demonstrated non-inferiority of 5 days of oral lefamulin to 7 days of oral moxifloxacin which featured both clinical and *in vitro* microbiological data that supports lefamulin as a potential IV and oral treatment for CABP.
- At the same conference, one poster presentation featuring CONTEPO focused on clinical and microbiological response at test of cure in secondary efficacy populations from the pivotal Phase 2/3 clinical trial.

FINANCIAL RESULTS

Three Months Ended September 30, 2018 and 2017

- For the three months ended September 30, 2018, Nabriva Therapeutics reported a net loss of \$52.8 million, or \$0.90 per share, compared to a net loss of \$22.3 million, or \$0.79 per share, for the three months ended September 30, 2017.
- Research and development expenses increased by \$28.1 million from \$12.7 million for the three months ended September 30, 2017 to \$40.8 million for the three months ended September 30, 2018. The increase was primarily due to a \$31.9 million in-process research and development charge associated with the acquisition of Zavante, a \$3.3 million increase in research consulting fees, partly offset by a \$5.4 million decrease in research materials and purchased services related to the development of lefamulin and a \$1.4 million decrease in stock-based compensation expense.
- General and administrative expense increased by \$3.1 million from \$9.5 million for the three months ended September 30, 2017 to \$12.6 million for the three months ended September 30, 2018. The increase was primarily due to a \$3.4 million increase in staff costs due to the addition of employees and a \$1.2 million increase in stock-based compensation expense, partly offset by a \$1.2 million decrease in legal fees.

Nine Months Ended September 30, 2018 and 2017

- For the nine months ended September 30, 2018, Nabriva Therapeutics reported a net loss of \$84.0 million, or \$1.85 per share, compared to a net loss of \$52.1 million, or \$1.89 per share, for the nine months ended September 30, 2017.
 - Research and development expenses increased by \$24.4 million from \$36.4 million for the nine months ended September 30, 2017 to \$60.8 million for the nine months ended September 30, 2018. The increase was primarily due to a \$31.9 million in-process research and development charge associated with the acquisition of Zavante, a \$4.1 million increase in research consulting fees, a \$0.5 million increase in staff costs due to the addition of employees, partly offset by a \$10.7 million decrease in research materials and purchased services related to the development of lefamulin and a \$1.7 million decrease in stock-based compensation expense.
 - General and administrative expense increased by \$12.3 million from \$19.3 million for the nine months ended September 30, 2017 to \$31.6 million for the nine months ended September 30, 2018. The increase was primarily due to a \$8.1 million increase in staff costs due to the addition of employees, a
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\$4.7 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees and a \$0.6 million increase in stock-based compensation expense, partly offset by a \$1.8 million decrease in legal fees.

- As of September 30, 2018, Nabriva Therapeutics had \$100.7 million in cash, cash equivalents and short-term investments compared to \$86.9 million as of December 31, 2017.

Please refer to the Annual Report on Form 10-K of Nabriva Therapeutics for the fiscal year ended December 31, 2017 and Nabriva Therapeutics' Quarterly Report on Form 10-Q for the three months ended September 30, 2018, filed with the U.S. Securities and Exchange Commission, for additional information regarding the Company's business and financial results.

About Nabriva Therapeutics plc

Nabriva Therapeutics is a clinical-stage biopharmaceutical company engaged in the research and development of innovative anti-infective agents to treat serious infections. Nabriva Therapeutics has two product candidates that are in late stage development: lefamulin, under development to potentially be the first pleuromutilin antibiotic available for I.V. and oral administration in humans, and CONTEPO, a potential first-in-class in the United States I.V. antibiotic for cUTI. Nabriva Therapeutics is developing both I.V. and oral formulations of lefamulin for the treatment of community-acquired bacterial pneumonia (CABP) and CONTEPO I.V. for cUTIs, including acute pyelonephritis. Nabriva Therapeutics may potentially develop lefamulin and CONTEPO for additional indications. 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 development of Nabriva Therapeutics' product candidates, such as the future development or commercialization of lefamulin and CONTEPO, conduct and timelines of clinical trials, the clinical utility of lefamulin for CABP and of CONTEPO for cUTI, plans for and timing of the review of regulatory filings, efforts to bring lefamulin and CONTEPO to market, the market opportunity for and the potential market acceptance of lefamulin for CABP and CONTEPO for cUTI, the development of lefamulin and CONTEPO for additional indications, the development of additional formulations of lefamulin 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: the content and timing of decisions made by the U.S. Food and Drug Administration and other regulatory authorities, Nabriva Therapeutics' ability to realize the anticipated benefits, synergies and growth prospects of its acquisition of Zavante Therapeutics, 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, whether results of ZEUS will be indicative of results for any ongoing or future clinical trials and studies of CONTEPO, 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 and CONTEPO for the treatment of cUTI, 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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Consolidated Balance Sheets
(unaudited)

(in thousands, except share data)	As of December 31, 2017	As of September 30, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 86,769	\$ 100,331
Short-term investments	110	326
Other receivables	5,402	7,362
Contract asset	—	1,500
Prepaid expenses	1,558	1,163
Total current assets	93,839	110,682
Property, plant and equipment, net	1,327	1,226
Intangible assets, net	172	109
Long-term receivables	425	428
Total assets	\$ 95,763	\$ 112,445
Liabilities and equity		
Current liabilities:		
Accounts payable	\$ 5,136	\$ 4,765
Accrued expense and other current liabilities	8,124	10,300
Total current liabilities	13,260	15,065
Non-current liabilities:		
Long-term debt	232	710
Other non-current liabilities	203	244
Total non-current liabilities	435	954
Total liabilities	13,695	16,019
Stockholders' Equity:		
Ordinary shares, nominal value \$0.01, 1,000,000,000 ordinary shares authorized at September 30, 2018; 36,707,685 and 66,484,159 issued and outstanding at December 31, 2017 and September 30, 2018, respectively	367	665
Preferred shares, par value \$0.01, 100,000,000 shares authorized at September 30, 2018; None issued and outstanding	—	—
Additional paid in capital	360,872	458,887
Accumulated other comprehensive income	27	27
Accumulated deficit	(279,198)	(363,153)
Total stockholders' equity	82,068	96,426
Total liabilities and stockholders' equity	\$ 95,763	\$ 112,445

Consolidated Statements of Operations
(unaudited)

(in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2018	2017	2018
Revenues:				
Collaboration revenue	\$ —	\$ —	\$ —	\$ 6,500
Research premium and grant revenue	1,468	461	4,197	2,359
Total Revenue:	1,468	461	4,197	8,859
Operating expenses:				
Research and development	(12,668)	(40,804)	(36,371)	(60,800)
General and administrative	(9,525)	(12,582)	(19,313)	(31,555)
Total operating expenses	(22,193)	(53,386)	(55,684)	(92,355)
Loss from operations	(20,725)	(52,925)	(51,487)	(83,496)
Other income (expense):				
Other income (expense), net	301	(54)	391	(172)
Interest income	69	11	302	39
Interest expense	(42)	(8)	(46)	(19)
Loss before income taxes	(20,397)	(52,976)	(50,840)	(83,648)
Income tax benefit (expense)	(1,872)	151	(1,254)	(307)
Net loss	\$ (22,269)	\$ (52,825)	\$ (52,094)	\$ (83,955)
Loss per share				
Basic and Diluted	\$ (0.79)	\$ (0.90)	\$ (1.89)	\$ (1.85)
Weighted average number of shares:				
Basic and Diluted	28,147,226	58,442,987	27,517,267	45,369,040

Condensed Consolidated Statements of Cash Flows
(unaudited)

(in thousands)	Nine Months Ended	
	September 30,	
	2017	2018
Net cash provided by (used in):		
Operating Activities	\$ (45,266)	\$ (50,492)
Investing Activities	49,361	(4,375)
Financing Activities	73,929	68,596
Effects of foreign currency translation on cash and cash equivalents	1,356	(167)
Net increase in cash and cash equivalents	79,380	13,562
Cash and cash equivalents at beginning of period	32,778	86,769
Cash and cash equivalents at end of period	\$ 112,158	\$ 100,331
