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 12, 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))

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 12, 2019, Nabriva Therapeutics plc issued a press release announcing its financial results for the year ended December 31, 2018. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 12, 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: March 12, 2019

By: /s/ Theodore Schroeder
Theodore Schroeder
Chief Executive Officer

Exhibit 99.1

Nabriva Therapeutics Reports 2018 Financial Results and Recent Corporate Highlights

- Two PDUFA dates in 2019: April 30, 2019 for CONTEPO and August 19, 2019 for Lefamulin -
- 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, March 12, 2019 — Nabriva Therapeutics plc (NASDAQ: NBRV), a biopharmaceutical company engaged in the development of innovative anti-infective agents to treat serious infections, today announced its financial results for the year ended December 31, 2018 and recent corporate highlights.

"2018 was a year of tremendous progress for Nabriva. We acquired Zavante, submitted New Drug Applications (NDAs) for CONTEPO for the treatment of complicated-urinary tract infections (cUTIs), including acute pyelonephritis (AP), and for both intravenous and oral formulations of lefamulin for the treatment of community-acquired bacterial pneumonia (CABP)," said Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics. "We look forward to working with the U.S. Food and Drug Administration (FDA) during their reviews of CONTEPO and lefamulin and potentially bringing two first-in-class antibiotics to patients in the United States with serious infections. We remain focused on commercializing both CONTEPO and lefamulin with our own targeted sales and marketing organizations in the U.S., while continuing to identify partners to advance our efforts to develop and commercialize lefamulin outside the U.S."

RECENT CORPORATE AND DEVELOPMENT HIGHLIGHTS

RESEARCH AND DEVELOPMENT

- Submitted NDAs to the FDA in the forth quarter of 2018 for:
    - Intravenous (IV) CONTEPO for the treatment of cUTIs, including AP. 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. In January 2019, Nabriva Therapeutics announced that the FDA accepted the NDA and granted a Priority Review for CONTEPO, with a Prescription Drug User Fee Act (PDUFA) action date for completion of the FDA's review of April 30, 2019.
    - Oral and IV formulations of lefamulin, a potentially first-in-class, pleuromutilin antibiotic, for the treatment of CABP. Both formulations of lefamulin were granted QIDP and Fast Track designation by the FDA, enabling potential Priority Review of the NDAs by the FDA. In February 2019, Nabriva Therapeutics announced the FDA accepted the NDAs and granted Priority Review for lefamulin with a PDUFA action date for completion of the FDA's review of August 19, 2019.
- Announced positive topline results from the **L**efamulin **E**valuation **A**gainst **P**neumonia (LEAP) 2 clinical trial, the second of two global, pivotal Phase 3 clinical trials evaluating the safety and efficacy of oral lefamulin for the treatment of CABP. In this trial, lefamulin met the FDA and EMA primary endpoints and was shown to be generally well-tolerated.

CORPORATE

- In January, 2019, hosted an Investor/Analyst Event featuring discussions with leading clinicians and researchers who addressed current and potential new treatments for CABP and cUTIs. Nabriva management also discussed the commercial strategy for the Company's investigational antibiotics, lefamulin and CONTEPO. Presentations from the event can be found under the "Events and Presentations" tab http://investors.nabriva.com until April 15, 2019.

- Business Development

    - Completed the acquisition of Zavante Therapeutics Inc. ("Zavante") in July 2018 for upfront consideration of approximately 8.2 million of Nabriva Therapeutics' ordinary shares (which includes an indemnity holdback) to Zavante's former stockholders.

    - 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 our Management Team

    - Appointed Ted Schroeder, former Chief Executive Officer of Zavante, as Chief Executive Officer of Nabriva Therapeutics who succeeded Dr. Colin Broom. Dr. Broom, remains on the Board of Directors of Nabriva Therapeutics.

    - Appointed Jennifer Schranz, M.D., as Chief Medical Officer to lead clinical development and medical affairs.

    - Named Dr. Steven Gelone President and Chief Operating Officer of Nabriva Therapeutics.

- Strengthened our Balance Sheet

    - Closed up to a $75.0 million term loan with Hercules Capital, Inc. in December 2018, $25.0 million of which was funded on the day of closing with up to an additional $45.0 million that is available at Nabriva Therapeutics option, subject to the achievement of certain regulatory and commercial milestones.

    - Completed a 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.

- Partnering

    - In March 2018, announced the initiation of a license agreement with Sinovant Sciences, an affiliate of Roivant Sciences, pursuant to which it granted Sinovant Sciences a license to develop and commercialize lefamulin in greater China.

    - Received $6.5 million to date from Sinovant Sciences and will be eligible for up to approximately $90.0 million in additional milestone payments tied to the successful completion of certain regulatory and commercial milestones related to lefamulin for CABP, plus an additional $4.0 million in milestone payments if lefamulin is approved for a second indication in China.

    - In addition, Nabriva Therapeutics will be eligible to receive low double-digit royalties on sales upon approval in the covered territories. Sinovant Sciences is solely responsible for all clinical development and regulatory filings necessary to secure approval in the covered territories, as well as commercialization activities.

FULL YEAR 2018 FINANCIAL RESULTS

- For the year ended December 31, 2018, Nabriva Therapeutics reported a net loss of $114.8 million, or $2.26 per share, which includes a $32.0 million in-process research and development charge

associated with the acquisition of Zavante, compared to a net loss of $74.4 million, or $2.49 per share, for the year ended December 31, 2017.

- Research and development expenses increased by $32.7 million from $49.6 million for the year ended December 31, 2017 to $82.3 million for the year ended December 31, 2018. The increase was primarily due to a $32.0 million in-process research and development charge associated with the acquisition of Zavante, a $6.5 million increase in research consulting fees, a $6.5 million increase associated with the payment of the new drug application fees to the FDA and a $1.9 million increase in staff costs due to the addition of employees, partly offset by a $13.9 million decrease in research materials and purchased services related to the development of lefamulin.

- General and administrative expense increased by $12.3 million from $29.5 million for the year ended December 31, 2017 to $41.7 million for the year ended December 31, 2018. The increase was primarily due to a $9.6 million increase in staff costs due to the addition of employees, a $2.6 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees and a $1.0 million increase in other corporate costs, partly offset by a $2.2 million decrease in legal fees.

- As of December 31, 2018, Nabriva Therapeutics had $102.2 million in cash, cash equivalents and short-term investments compared to $86.9 million as of December 31, 2017. Existing cash resources are expected to fund operations into the second quarter of 2020.

Please refer to the Annual Report on Form 10-K of Nabriva Therapeutics for the fiscal year ended December 31, 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 biopharmaceutical company engaged in the development of innovative anti-infective agents to treat serious infections. Nabriva Therapeutics has two product candidates that are in late stage development: lefamulin, potentially the first systemic pleuromutilin antibiotic for CABP and CONTEPO (fosfomycin for injection), a potential first-in-class epoxide antibiotic in the United States for complicated urinary tract infections (cUTIs) including acute pyelonephritis (AP). 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, 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 potential benefits under its license agreement with Sinovant Sciences, 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, its ability to achieve any of the specified regulatory or performance milestones under its loan agreement with Hercules Capital, 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 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.

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Consolidated Balance Sheets

(in thousands, except share data)	As of December 31, 2017	As of December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 86,769	$ 102,003
Short-term investments	110	225
Other receivables	5,402	3,871
Contract asset	—	1,500
Prepaid expenses	1,558	1,154
Total current assets	93,839	108,753
Property, plant and equipment, net	1,327	1,139
Intangible assets, net	172	98
Long-term receivables	425	428
Total assets	**$ 95,763**	**$ 110,418**
Liabilities and Stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,136	$ 3,304
Accrued expense and other current liabilities	8,124	14,502
Total current liabilities	13,260	17,806
Non-current liabilities		
Long-term debt	232	23,718
Other non-current liabilities	203	264
Total non-current liabilities	435	23,982
Total liabilities	**13,695**	**41,788**
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at December 31, 2018; 36,707,685 and 67,019,094 issued and outstanding at December 31, 2017 and 2018, respectively	367	670
Preferred shares, par value $0.01, 100,000,000 shares authorized at December 31, 2018; None issued and outstanding	—	—
Additional paid in capital	360,872	461,911
Accumulated other comprehensive income	27	27
Accumulated deficit	(279,198)	(393,978)
Total stockholders' equity	82,068	68,630
Total liabilities and stockholders' equity	**$ 95,763**	**$ 110,418**

Consolidated Statements of Operations

(in thousands, except share and per share data)	Year Ended December 31, 2017	2018
Revenues:		
Collaboration revenue	$ —	$ 6,500
Research premium and grant revenue	5,319	3,156
Total revenues	5,319	9,656
Operating expenses:		
Research and development	(49,615)	(82,288)
General and administrative	(29,472)	(41,743)
Total operating expenses	(79,087)	(124,031)
Loss from operations	**(73,768)**	**(114,375)**
Other income (expense):		
Other income (expense), net	492	(272)
Interest income	318	49
Interest expense	(43)	(133)
Loss before income taxes	**(73,001)**	**(114,731)**
Income tax expense	(1,355)	(49)
Net loss	$ **(74,356)**	$ **(114,780)**
Loss per share		
Basic and diluted	$ **(2.49)**	$ **(2.26)**
Weighted average number of shares:		
Basic and diluted	**29,830,669**	**50,795,768**

Condensed Consolidated Statements of Cash Flows

(in thousands)	Year ended December 31, 2017	2018
Net cash provided by (used in):		
Operating activities	$ (69,348)	$ (72,723)
Investing activities	49,749	(4,604)
Financing activities	72,219	92,923
Effects of foreign currency translation on cash and cash equivalents	1,371	(362)
Net increase in cash and cash equivalents	53,991	15,234
Cash and cash equivalents at beginning of year	32,778	86,769
Cash and cash equivalents at end of year	$ 86,769	$ 102,003