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): **May 10, 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. ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Ordinary Shares, nominal value $0.01 per share	NBRV	The Nasdaq Global Market LLC

Item 2.02 Results of Operations and Financial Conditions.

On May 10, 2019, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the quarter ended March 31, 2019. 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 May 10, 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: May 10, 2019

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

Exhibit 99.1

Nabriva Therapeutics Reports First Quarter 2019 Financial Results and Recent Corporate Highlights

Dublin Ireland, May 10, 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 three months ended March 31, 2019 and recent corporate highlights.

"This will be a transformational year for Nabriva as we look forward to the upcoming PDUFA dates for both the intravenous and oral formulations of lefamulin for the treatment of community-acquired bacterial pneumonia (CABP)," said Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics. "Additionally, we will be working with the FDA in the coming weeks to gain a full understanding of the FDA's comments related to the CONTEPO Complete Response Letter (CRL), with the goal of bringing this important treatment to patients as quickly as possible."

RECENT CORPORATE AND DEVELOPMENT HIGHLIGHTS

RESEARCH AND DEVELOPMENT

- In May 2019, submitted a marketing authorization application for both the intravenous and oral formulations of lefamulin for the treatment of community-acquired pneumonia in adults 18 years of age and older to the European Medicines Agency (EMA).
- In April 2019, received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) seeking marketing approval of CONTEPO™ (fosfomycin) for injection for the treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis, due to issues related to facility inspections and manufacturing deficiencies at one contract manufacturer. The FDA did not request any new clinical data and did not raise any concerns with regard to the safety of CONTEPO.
- In February 2019, announced the FDA accepted the NDAs and granted Priority Review for both formulations of lefamulin with a Prescription Drug User Fee Act (PDUFA) action date for completion of the FDA's review of August 19, 2019.
- At the 29th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) that took place in Amsterdam, the Netherlands from April 13-16, 2019, Nabriva Therapeutics presented new data that continue to support lefamulin and CONTEPO as potential first-in-class antibiotics in the United States that target the most common causative pathogens of CABP and cUTI, including multi-drug resistant (MDR) strains.

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.
- Partnering

- In March 2019, announced entry into a license and commercialization agreement with Sunovion Pharmaceutics Canada, Inc. (Sunovion), pursuant to which Sunovion will be responsible for developing, obtaining regulatory approval of and commercializing lefamulin in Canada, and Nabriva Therapeutics received an upfront payment, potential milestone payments upon the achievement of certain regulatory and sales milestone events and royalties on net sales of lefamulin, if any, in Canada.

FIRST QUARTER 2019 FINANCIAL RESULTS

- For the three months ended March 31, 2019, Nabriva Therapeutics reported a net loss of $20.2 million, or $0.29 per share, compared to a net loss of $13.3 million, or $0.36 per share, for the three months ended March 31, 2018. Revenues decreased by $5.8 million from $7.6 million for the three months ended March 31, 2018 to $1.7 million for the three months ended March 31, 2019, primarily due to a decrease in collaboration revenue of $5.5 million.
- Research and development expenses decreased by $2.7 million from $10.3 million for the three months ended March 31, 2018 to $7.5 million for the three month ended March 31, 2019. The decrease was primarily due to a $2.6 million refund of payment of the NDA fees to the FDA for CONTEPO, and a $1.5 million decrease in research materials and purchased services related to the development of lefamulin, partly offset by a $0.7 million increase in research consulting fees and a $0.6 million increase in staff costs due to the addition of employees.
- General and administrative expense increased by $3.3 million from $10.1 million for the three months ended March 31, 2018 to $13.4 million for the three month ended March 31, 2019. The increase was primarily due to a $1.8 million increase in staff costs due to the addition of employees, a $0.8 million increase in stock-based compensation expense and a $0.6 million increase in external consultancy expenses.
- As of March 31, 2019, Nabriva Therapeutics had $91.3 million in cash, cash equivalents and short-term investments compared to $102.2 million as of December 31, 2018. Existing cash resources are expected to fund operations into the second quarter of 2020.

Please refer to our Annual Report on Forms 10-K for the fiscal year ended December 31, 2018 and our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2019, which are 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 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 Nabriva Therapeutics' plans for further interactions with the FDA and EMA; 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, plans to enter into arrangements with third parties to commercialize lefamulin in

Europe, if approved; the market opportunity for and the potential market acceptance of lefamulin for CABP and CONTEPO for cUTI, the potential benefits under its license agreements with Sinovant Sciences, Ltd. and Sunovion Pharmaceutics Canada, Inc., 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: Nabriva Therapeutics' ability to resolve the matters set forth in the Complete Response Letter it received from the FDA in connection with its NDA for CONTEPO (fosfomycin) for injection; Nabriva Therapeutics' reliance on third-party manufacturers to manufacture the clinical and commercial supply of its product candidates and the ability of such third parties to comply with applicable regulatory requirements; 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
(unaudited)

(in thousands, except share data)	As of December 31, 2018	As of March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 102,003	$ 91,042
Short-term investments	225	225
Other receivables	3,871	7,238
Contract asset	1,500	1,000
Prepaid expenses	1,154	973
Total current assets	108,753	100,478
Property, plant and equipment, net	1,139	2,972
Intangible assets, net	98	99
Long-term receivables	428	438
Total assets	**$ 110,418**	**$ 103,987**
Liabilities and Stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,304	$ 7,562
Accrued expense and other current liabilities	14,502	10,533
Total current liabilities	17,806	18,095
Non-current liabilities		
Long-term debt	23,718	23,945
Other non-current liabilities	264	1,840
Total non-current liabilities	23,982	25,785
Total liabilities	**41,788**	**43,880**
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at March 31, 2019; 67,019,094 and 71,335,980 issued and outstanding at December 31, 2018 and March 31, 2019, respectively	670	713
Preferred shares, par value $0.01, 100,000,000 shares authorized at March 31, 2019; None issued and outstanding	—	—
Additional paid in capital	461,911	473,562
Accumulated other comprehensive income	27	27
Accumulated deficit	(393,978)	(414,195)
Total stockholders' equity	68,630	60,107
Total liabilities and stockholders' equity	**$ 110,418**	**$ 103,987**

Consolidated Statements of Operations
(unaudited)

(in thousands, except share and per share data)	Three Months Ended March 31, 2018	2019
Revenues:		
Collaboration revenue	$ 6,500	$ 1,000
Research premium and grant revenue	1,051	703
Total revenues	7,551	1,703
Operating expenses:		
Research and development	(10,279)	(7,538)
General and administrative	(10,136)	(13,409)
Total operating expenses	(20,415)	(20,947)
Loss from operations	**(12,864)**	**(19,244)**
Other income (expense):		
Other income (expense), net	23	70
Interest income	9	10
Interest expense	(4)	(899)
Loss before income taxes	**(12,836)**	**(20,063)**
Income tax expense	(506)	(154)
Net loss	$ **(13,342)**	$ **(20,217)**
Loss per share		
Basic and diluted	$ **(0.36)**	$ **(0.29)**
Weighted average number of shares:		
Basic and diluted	**36,911,604**	**68,701,599**

Condensed Consolidated Statements of Cash Flows
(unaudited)

(in thousands)	Three Months Ended March 31, 2018	2019
Net cash provided by (used in):		
Operating activities	$ (16,339)	$ (20,625)
Investing activities	(160)	(42)
Financing activities	19,059	9,679
Effects of foreign currency translation on cash and cash equivalents	112	27
Net increase (decrease) in cash and cash equivalents	2,672	(10,961)
Cash and cash equivalents at beginning of year	86,769	102,003
Cash and cash equivalents at end of year	$ 89,441	$ 91,042