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): **August 8, 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))

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

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 August 8, 2019, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the quarter ended June 30, 2019. 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 August 8, 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: August 8, 2019

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

Exhibit 99.1

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

Dublin Ireland, August 8, 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 and six months ended June 30, 2019 and recent corporate highlights.

"Nabriva has made significant advances in the second quarter as we prepare for the upcoming PDUFA date 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, in collaboration with one of our third party manufacturers, we had a productive meeting with the U.S. Food and Drug Administration (FDA) related to the CONTEPO Complete Response Letter (CRL), and hope to provide an update to investors in the weeks ahead with the goal of bringing this important treatment to patients as quickly as possible."

RECENT CORPORATE AND DEVELOPMENT HIGHLIGHTS

- 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 adult patients 18 years of age and older to the European Medicines Agency (EMA).

- In June 2019, presented additional data from the Phase 3 clinical trials of lefamulin and the Phase 2/3 clinical trial of CONTEPO that further support efficacy by pathogen for CABP and complicated urinary tract infections (cUTI), respectively, at ASM Microbe, held in San Francisco, CA.

- In July 2019, held a Type A meeting with the FDA to discuss the CRL for the New Drug Application (NDA) seeking marketing approval for CONTEPO™ (fosfomycin) for injection for the treatment of cUTI, including acute pyelonephritis.

FINANCIAL RESULTS

Three Months Ended June 30, 2019 and 2018

- For the three months ended June 30, 2019, Nabriva Therapeutics reported a net loss of $21.7 million, or $0.30 per share, compared to a net loss of $17.8 million, or $0.44 per share, for the three months ended June 30, 2018. Revenues decreased by $0.3 million from $0.8 million for the three months ended June 30, 2018 to $0.5 million for the three months ended June 30, 2019, primarily as a result of a decrease in research and development expenses for which we were eligible to receive grant revenue.

- Research and development expenses decreased by $1.6 million from $9.7 million for the three months ended June 30, 2018 to $8.1 million for the three months ended June 30, 2019. The decrease was primarily due a $1.5 million decrease in research materials and purchased services related to the development of lefamulin.

- General and administrative expense increased by $4.6 million from $8.8 million for the three months ended June 30, 2018 to $13.4 million for the three months ended June 30, 2019. The increase was primarily due to a $1.9 million increase in staff costs due to the addition of employees in preparation for the potential commercial launch of Nabriva Therapeutics' product candidates, a $1.0 million increase in stock-based compensation expense and a $0.8 million increase in external consultancy expenses.

Six Months Ended June 30, 2019 and 2018

- For the six months ended June 30, 2019, Nabriva Therapeutics reported a net loss of $41.9 million, or $0.59 per share, compared to a net loss of $31.1 million, or $0.80 per share, for the six months ended June 30, 2018. Revenues decreased by $6.2 million from $8.4 million for the six months ended June 30, 2018 to $2.2 million for the six months ended June 30, 2019, primarily due to a decrease in collaboration revenue of $5.5 million.

- Research and development expenses decreased by $4.4 million from $20.0 million for the six months ended June 30, 2018 to $15.6 million for the six months ended June 30, 2019. The decrease was primarily due to a $2.6 million refund from the FDA of the NDA filing fee for CONTEPO and a $3.0 million decrease in research materials and purchased services related to the development of lefamulin, partly offset by a $0.8 million increase in staff costs due to the addition of employees.

- General and administrative expense increased by $7.8 million from $19.0 million for the six months ended June 30, 2018 to $26.8 million for the six months ended June 30, 2019. The increase was primarily due to a $3.7 million increase in staff costs due to the addition of employees in preparation for the potential commercial launch of Nabriva Therapeutics' product candidates, a $1.9 million increase in stock-based compensation expense and a $1.4 million increase in external consultancy expenses.

- As of June 30, 2019, Nabriva Therapeutics had $73.9 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 June 30, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 102,003	$ 58,666
Short-term investments	225	15,253
Other receivables	3,871	4,766
Contract asset	1,500	—
Prepaid expenses	1,154	1,403
Total current assets	108,753	80,088
Property, plant and equipment, net	1,139	2,761
Intangible assets, net	98	86
Long-term receivables	428	710
Total assets	**$ 110,418**	**$ 83,645**
Liabilities and Stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,304	$ 2,914
Accrued expense and other current liabilities	14,502	11,202
Total current liabilities	17,806	14,116
Non-current liabilities		
Long-term debt	23,718	24,306
Other non-current liabilities	264	1,818
Total non-current liabilities	23,982	26,124
Total liabilities	**41,788**	**40,240**
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at June 30, 2019; 67,019,094 and 72,906,293 issued and outstanding at December 31, 2018 and June 30, 2019, respectively	670	729
Preferred shares, par value $0.01, 100,000,000 shares authorized at March 31, 2019; None issued and outstanding	—	—
Additional paid in capital	461,911	478,551
Accumulated other comprehensive income	27	27
Accumulated deficit	(393,978)	(435,902)
Total stockholders' equity	68,630	43,405
Total liabilities and stockholders' equity	**$ 110,418**	**$ 83,645**

Consolidated Statements of Operations
(unaudited)

(in thousands, except share and per share data)	Three Months Ended June 30, 2018	Three Months Ended June 30, 2019	Six Months Ended June 30, 2018	Six Months Ended June 30, 2019
Revenues:				
Collaboration revenue	$ —	$ —	$ 6,500	$ 1,000
Research premium and grant revenue	847	525	1,898	1,228
Total revenue	847	525	8,398	2,228
Operating expenses:				
Research and development	(9,717)	(8,074)	(19,996)	(15,612)
General and administrative	(8,837)	(13,427)	(18,973)	(26,836)
Total operating expenses	(18,554)	(21,501)	(38,969)	(42,448)
Loss from operations	**(17,707)**	**(20,976)**	**(30,571)**	**(40,220)**
Other income (expense):				
Other income (expense), net	(141)	56	(118)	126
Interest income	19	72	28	82
Interest expense	(7)	(904)	(11)	(1,803)
Loss before income taxes	**(17,836)**	**(21,752)**	**(30,672)**	**(41,815)**
Income tax benefit (expense)	48	45	(458)	(109)
Net loss	**$ (17,788)**	**$ (21,707)**	**$ (31,130)**	**$ (41,924)**
Loss per share				
Basic and Diluted ($ per share)	$ (0.44)	$ (0.30)	$ (0.80)	$ (0.59)
Weighted average number of shares:				
Basic and Diluted	40,515,920	72,526,441	38,723,718	70,624,583

Condensed Consolidated Statements of Cash Flows
(unaudited)

(in thousands)	Six Months Ended June 30, 2018	2019
Net cash provided by (used in):		
Operating activities	$ (33,360)	$ (41,748)
Investing activities	(283)	(15,057)
Financing activities	22,218	13,428
Effects of foreign currency translation on cash and cash equivalents	(91)	40
Net decrease in cash and cash equivalents	(11,516)	(43,337)
Cash and cash equivalents at beginning of period	86,769	102,003
Cash and cash equivalents at end of period	$ 75,253	$ 58,666