# 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 9, 2018**

# 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 August 9, 2018, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the quarter ended June 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 August 9, 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: August 9, 2018

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

**Exhibit 99.1**

**Nabriva Therapeutics Reports Second Quarter 2018 Financial Results and Recent Corporate Highlights**

*- Company preparing for potential commercialization of two first-in-class antibiotics, Lefamulin (IV and Oral) and CONTEPO (IV) in the United States in 2019 -*
*- New Drug Application submissions expected in Q4 2018 -*

**Dublin Ireland, August 9, 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 June 30, 2018.

"Nabriva made significant clinical advances in the first half of the year, taking us another step closer to potentially bringing first-in-class antibiotics to patients in need of better treatment options," said Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics. "We reported positive topline results from a global, pivotal Phase 3 clinical study, Lefamulin Evaluation Against Pneumonia (LEAP 2), that demonstrated a short course 5 day oral regimen of our lead therapy, lefamulin, achieved the primary efficacy endpoint of statistical non-inferiority compared to a longer 7 day treatment course of moxifloxacin for the treatment of community-acquired bacterial pneumonia (CABP) in adults and was well-tolerated. In addition, through our strategic combination with Zavante Therapeutics, Inc., we acquired CONTEPO, a novel, potentially first-in-class injectable antibiotic in the United States that met the primary endpoint of statistical non-inferiority to piperacillin/tazobactam in the ZEUS™ clinical trial in patients with complicated urinary tract infections (cUTIs) including acute pyelonephritis. We strongly believe that both lefamulin and CONTEPO have the potential to change the treatment paradigm of CABP and cUTIs, respectively, and we are on track to submit New Drug Applications (NDAs) to the U.S. Food and Drug Administration (FDA) in the fourth quarter of this year. I am proud to be leading the outstanding team at Nabriva as we continue to execute on our shared mission of delivering innovative treatments to patients with infectious diseases and filling an important gap in the current treatment landscape."

**RECENT CORPORATE AND DEVELOPMENT HIGHLIGHTS**

- Nabriva Therapeutics announced positive topline results from its 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. Lefamulin met the FDA primary endpoint of non-inferiority (NI, 10.0% margin) compared to moxifloxacin for early clinical response (ECR) assessed 72 to 120 hours following initiation of therapy in the intent to treat (ITT) patient population. ECR was 90.8% for the 5-day treatment course of lefamulin and 90.8% for the 7-day treatment course of moxifloxacin. Lefamulin also met the European Medicines Agency (EMA) primary endpoint for non-inferiority (NI, 10.0% margin) compared to moxifloxacin based on an investigator assessment of clinical response (IACR) 5 to 10 days following the completion of study drug dosing in the modified intent to treat (mITT) and clinically evaluable at test of cure (CE-TOC) patient populations. IACR rates for the mITT population were 87.5% for lefamulin and 89.1% for moxifloxacin (treatment difference -1.6 [95% CI -6.3, 3.1])

and for the CE-TOC population were 89.7% for lefamulin and 93.6% for moxifloxacin (treatment difference -3.9 [95% CI -8.2, 0.5]). Lefamulin was shown to be generally well-tolerated.

- 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 of $46.1 million, after deducting underwriting discounts and commissions and offering expenses.
- Presented eight abstracts at the American Society for Microbiology Microbe 2018 conference in Atlanta, Georgia in June 2018. The abstracts support lefamulin as a potential first-in-class pleuromutilin antibiotic targeting CABP pathogens, including drug resistant strains.
- At the same conference, seven abstracts were presented regarding CONTEPO (ZTI-01, Zolyd). The abstracts support CONTEPO as a potential first-in-class IV epoxide antibiotic with a broad spectrum of activity, including Gram-negative multi-drug resistant strains, as well as synergistic activity in combination with other antibiotic classes.

**ACQUISITION OF ZAVANTE THERAPEUTICS**

In July 2018, Nabriva Therapeutics strengthened its antibiotics leadership position with the acquisition of Zavante Therapeutics, Inc., 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 Therapeutics' former stockholders. In addition, Zavante Therapeutics' former stockholders are eligible to receive up to $97.5 million in contingent consideration, of which $25.0 million would become payable upon the first approval of an NDA from the FDA for fosfomycin for injection for any indication and an aggregate of up to $72.5 million would become payable upon the achievement of specified sales milestones. Subject to approval by Nabriva Therapeutics' shareholders, the first milestone will be settled in Nabriva Therapeutics' ordinary shares and the net sales milestone payments may be settled in Nabriva Therapeutics ordinary shares or cash.

CONTEPO™ (fosfomycin for injection) is a novel, potentially first-in-class, intravenous investigational antibiotic in the United States. CONTEPO is in development to treat serious infections, including those caused by multi-drug resistant (MDR) Gram-negative and Gram-positive bacteria. CONTEPO was developed by Zavante with the objective of establishing the therapy as a standard of care for hospitalized patients with serious infections caused by suspected or confirmed MDR bacteria. Zavante has completed a pivotal Phase 2/3 clinical trial (ZEUS™) with CONTEPO for the treatment of cUTIs, including acute pyelonephritis (AP), and has initiated a pediatric clinical trial. In April 2017, Zavante announced that CONTEPO met the primary endpoint of statistical non-inferiority to piperacillin/tazobactam in the ZEUS™ trial in patients with cUTI, including AP. CONTEPO has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA in several indications, including cUTI. Nabriva Therapeutics expects to submit an NDA utilizing the FDA's 505(b)(2) pathway in the fourth quarter of 2018.

Upon the closing of the acquisition, Mr. Schroeder was appointed as Chief Executive Officer of Nabriva Therapeutics to succeed Dr. Colin Broom In addition, pursuant to Mr. Schroeder's employment agreement with Nabriva Therapeutics, Mr. Schroeder was appointed to Nabriva Therapeutics' board of directors effective immediately following Nabriva Therapeutics' 2018 Annual General Meeting of Shareholders held on August 1, 2018. Dr. Broom will continue to serve on Nabriva Therapeutics' board of directors and will work closely with Mr. Schroeder and the management team as a consultant.

**FINANCIAL RESULTS**

*Three Months Ended June 30, 2018 and 2017*

- For the three months ended June 30, 2018, Nabriva Therapeutics reported a net loss of $17.8 million, or $0.44 per share, compared to a net loss of $14.6 million, or $0.54 per share, for the three months ended June 30, 2017.
- Research and development expenses decreased by $1.3 million from $11.0 million for the three months ended June 30, 2017 to $9.7 million for the three months ended June 30, 2018. The decrease was primarily due to a $1.5 million decrease in research materials and purchased services related to the development of lefamulin and a $0.5 million decrease in stock-based compensation expense, partly offset by a $0.3 million increase in research consulting fees, a $0.3 million increase in staff costs due to the addition of employees and a $0.1 million increase in travel and infrastructure costs.
- General and administrative expense increased by $3.3 million from $5.6 million for the three months ended June 30, 2017 to $8.8 million for the three months ended June 30, 2018. The increase was primarily due to a $1.1 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a $2.4 million increase in staff costs due to the addition of employees, a $0.2 million increase in infrastructure costs and a $0.4 million increase in travel and other corporate costs, partly offset by a $0.9 million decrease in stock-based compensation expense.

*Six Months Ended June 30, 2018 and 2017*

- For the six months ended June 30, 2018, Nabriva Therapeutics reported a net loss of $31.1 million, or $0.80 per share, compared to a net loss of $29.8 million, or $1.10 per share, for the six months ended June 30, 2017.
- Research and development expenses decreased by $3.7 million from $23.7 million for the six months ended June 30, 2017 to $20.0 million for the six months ended June 30, 2018. The decrease was primarily due to a $5.3 million decrease in research materials and purchased services related to the development of lefamulin, and a $0.3 million decrease in stock-based compensation expense, partly offset by a $0.8 million increase in research consulting fees, a $0.7 million increase in staff costs due to the addition of employees and a $0.4 million increase in travel and infrastructure costs.
- General and administrative expense increased by $9.2 million from $9.8 million for the six months ended June 30, 2017 to $19.0 million for the six months ended June 30, 2018. The increase was primarily due to a $3.9 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a $4.7 million increase in staff costs due to the addition of employees, a $0.5 million increase in infrastructure costs and a $0.7 million increase in travel and other corporate costs, partly offset by a $0.6 million decrease in stock-based compensation expense.
- As of June 30, 2018, Nabriva Therapeutics had $75.5 million in cash, cash equivalents and short-term investments compared to $86.9 million as of December 31, 2017. Following the Company's recently completed public offering of ordinary shares in July 2018, Nabriva Therapeutics' cash balance is expected to fund operations into the first quarter of 2020.

**Please refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and our Quarterly Report on Form 10-Q for the three months ended June 30, 2018, 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 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 systemic administration in humans, and CONTEPO, a potential first-in-class in the United States, hospital-based intravenous, or IV, antibiotic. Nabriva Therapeutics is developing both IV and oral formulations of lefamulin for the treatment of community-acquired bacterial pneumonia, or CABP. Nabriva Therapeutics is developing CONTEPO IV for complicated urinary tract infections, or cUTI. Nabriva Therapeutics may potentially develop lefamulin and CONTEPO for additional indications.

**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 acquisition of Zavante Therapeutics Inc. and the other transactions contemplated by the acquisition and any other statements about future expectations, prospects, estimates and other matters that are dependent upon future events or developments, including statements related to Nabriva Therapeutics' expectations with respect to the potential financial impact and benefits of the acquisition, including Nabriva Therapeutics' expectations with respect to milestone payments and expectations with respect to and potential advantages of CONTEPO as well as any statements with respect to 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 and plans for filing of regulatory approvals and 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: Nabriva Therapeutics' ability to realize the anticipated benefits, synergies and growth prospects of the acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period or at all, negative effects of the announcement of the acquisition on the market price of Nabriva Therapeutics' ordinary shares, significant transaction costs, unknown liabilities, the risk of litigation and/or regulatory actions related to the acquisition, 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, whether regulatory or commercial milestones are achieved, Nabriva Therapeutics' ability to successfully integrate Zavante Therapeutics' business into its business, any challenges associated with Nabriva Therapeutics' chief executive officer transition in connection with the Acquisition, Nabriva Therapeutics' ability to retain and hire key personnel, the risk that disruption resulting from the acquisition may adversely affect Nabriva Therapeutics' business and business relationships, including with employees and suppliers, 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 per share data) | As of December 31, 2017 | As of June 30, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 86,769 | $ 75,253 |
| Short-term investments | 110 | 225 |
| Other receivables | 5,402 | 6,820 |
| Contract asset | — | 1,500 |
| Prepaid expenses | 1,558 | 1,150 |
| Total current assets | 93,839 | 84,948 |
| Property, plant and equipment, net | 1,327 | 1,285 |
| Intangible assets, net | 172 | 127 |
| Long-term receivables | 425 | 428 |
| **Total assets** | **$ 95,763** | **$ 86,788** |
| | | |
| **Liabilities and equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,136 | $ 2,928 |
| Accrued expense and other current liabilities | 8,124 | 8,364 |
| Total current liabilities | 13,260 | 11,292 |
| Non-current liabilities: | | |
| Long-term debt | 232 | 592 |
| Other non-current liabilities | 203 | 236 |
| Total non-current liabilities | 435 | 828 |
| **Total liabilities** | **13,695** | **12,120** |
| | | |
| Stockholders' Equity: | | |
| Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at June 30, 2018; 36,707,685 and 40,959,452 issued and outstanding at December 31, 2017 and June 30, 2018, respectively | 367 | 410 |
| Preferred shares, par value $0.01, 100,000,000 shares authorized at June 30, 2018; None issued and outstanding | — | — |
| Additional paid in capital | 360,872 | 384,557 |
| Accumulated other comprehensive income | 27 | 27 |
| Accumulated deficit | (279,198) | (310,326) |
| **Total stockholders' equity** | **82,068** | **74,668** |
| **Total liabilities and stockholders' equity** | **$ 95,763** | **$ 86,788** |

**Consolidated Statements of Operations and Comprehensive Income (Loss)**
**(unaudited)**

| (in thousands, except share and per share data) | Three Months Ended June 30, 2017 | Three Months Ended June 30, 2018 | Six Months Ended June 30, 2017 | Six Months Ended June 30, 2018 |
|---|---|---|---|---|
| **Revenues:** | | | | |
| Collaboration revenue | $ — | $ — | $ — | $ 6,500 |
| Research premium and grant revenue | 1,051 | 847 | 2,729 | 1,898 |
| **Total Revenue:** | 1,051 | 847 | 2,729 | 8,398 |
| **Operating expenses:** | | | | |
| Research and development | (11,043) | (9,717) | (23,703) | (19,996) |
| General and administrative | (5,570) | (8,837) | (9,788) | (18,973) |
| Total operating expenses | (16,613) | (18,554) | (33,491) | (38,969) |
| **Loss from operations** | **(15,562)** | **(17,707)** | **(30,762)** | **(30,571)** |
| **Other income (expense):** | | | | |
| Other income (expense), net | (116) | (141) | 90 | (118) |
| Interest income | 112 | 19 | 233 | 28 |
| Interest expense | (3) | (7) | (4) | (11) |
| **Loss before income taxes** | **(15,569)** | **(17,836)** | **(30,443)** | **(30,672)** |
| Income tax benefit (expense) | 967 | 48 | 618 | (458) |
| **Net loss** | **$ (14,602)** | **$ (17,788)** | **$ (29,825)** | **$ (31,130)** |
| | | | | |
| **Loss per share** | | | | |
| Basic and Diluted | $ (0.54) | $ (0.44) | $ (1.10) | $ (0.80) |
| | | | | |
| **Weighted average number of shares:** | | | | |
| Basic and Diluted | 27,186,560 | 40,515,920 | 27,197,070 | 38,723,718 |

**Condensed Consolidated Statements of Cash Flows**
**(unaudited)**

| (in thousands) | Six Months Ended June 30, 2017 | 2018 |
|---|---|---|
| **Net cash provided by (used in):** | | |
| Operating Activities | $ (30,219) | $ (33,360) |
| Investing Activities | 17,766 | (283) |
| Financing Activities | (1,244) | 22,218 |
| | | |
| Effects of foreign currency translation on cash and cash equivalents | 1,008 | (91) |
| Net decrease in cash and cash equivalents | (12,689) | (11,516) |
| Cash and cash equivalents at beginning of period | 32,778 | 86,769 |
| Cash and cash equivalents at end of period | $ 20,089 | $ 75,253 |