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 5, 2020**

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 Select 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 November 5, 2020, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the quarter ended September 30, 2020. 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 November 5, 2020.
Exhibit 104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

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 5, 2020

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

Nabriva Therapeutics Reports Third Quarter 2020 Financial Results and Provides Corporate Updates

-Relaunch of Xenleta® and Sivextro® commenced in late September-

- Type A Meeting with FDA for Contepo™ held on October 30th -

-Conference call today at 4:30 p.m. Eastern Time-

Dublin Ireland, November 5, 2020 – Nabriva Therapeutics plc (NASDAQ: NBRV), a biopharmaceutical company engaged in the commercialization and development of innovative anti-infective agents to treat serious infections, today announced its financial results for the three months ended September 30, 2020 and provided a corporate update.

"Nabriva started the third quarter by completing an important business development transaction with Merck & Co., Inc. to promote and distribute SIVEXTRO in the U.S. It was one of several key components in our plan towards re-establishing our community-focused sales effort, along with continuing to expand our strong managed care coverage and deploying the Amplity sales force," said Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics. "Since late September, there have been 15 Amplity representatives in the field promoting both SIVEXTRO and XENLETA. Initial indications are promising with better than expected access to physicians due to SIVEXTRO's brand recognition. We are leveraging Amplity's experience by targeting the most accessible health care providers (HCPs) during the pandemic which is also enabling increased promotion of XENLETA. Given the favorable experience to date, an additional 45 professional representatives are expected to be placed in select territories in November. We estimate that the expanded team will be able to call on almost 8,000 HCPs in total and reach approximately 60% of historical SIVEXTRO prescribers and about 57% of estimated XENLETA prescribers. With an estimated 50% of these physicians being potential prescribers of both brands, we believe Nabriva will be in a position to efficiently establish a right-sized organization to drive demand for both products."

CORPORATE AND DEVELOPMENT UPDATES

- On October 30th, Nabriva participated in a Type A meeting with the U.S. Food and Drug Administration (FDA) to obtain any new information related to the FDA's pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including the CONTEPO (fosfomycin for injection) New Drug Application (NDA). The FDA informed us that it has not yet determined how it will conduct international inspections during the COVID-19 pandemic. As a result, next steps and specific timing of the CONTEPO NDA resubmission cannot be finalized until the agency issues industry guidance. We and the industry await future communication from the FDA as it continues to assess the options available under existing regulations and laws to conduct these foreign facility inspections. It is noteworthy that the FDA has not requested any new non-clinical or clinical data and did not raise any other concerns with regard to the safety or efficacy of CONTEPO.

- In September 2020, the Centers for Medicare & Medicaid Services (CMS) granted a new technology add-on payment (NTAP) for XENLETA (lefamulin) for injection when administered in the hospital inpatient setting. Both the intravenous (IV) and oral formulations of XENLETA were granted Qualified Infectious Disease Product (QIDP) and Fast Track designation by the FDA. CONTEPO was granted an NTAP making it the first QIDP antibiotic to be granted conditional NTAP approval prior to receiving FDA approval. CONTEPO was granted QIDP and Fast Track Designation by the FDA for the treatment of complicated urinary tract infections (cUTIs), including acute pyelonephritis.

- On July 28, 2020, Nabriva announced that the European Commission (EC) approved the Marketing Authorization Application (MAA) for XENLETA for the treatment of community-acquired pneumonia (CAP) in adults in the European Union following a review by the European Medicines Agency (EMA).

- On July 16, 2020, Nabriva announced that Sunovion Pharmaceuticals Canada Inc. received approval from Health Canada to market oral and IV formulations of XENLETA for the treatment of community-acquired pneumonia in adults in Canada. Nabriva entered into a license and commercialization agreement with Sunovion Pharmaceuticals Canada Inc. in March 2019 for XENLETA in Canada. In the third quarter of 2020, Nabriva received a milestone payment of $500,000 from Sunovion due to the approval of XENLETA in Canada.

- On July 15, 2020, Nabriva announced that it entered into an exclusive agreement with subsidiaries of Merck & Co. Inc., Kenilworth, N.J., USA to market, sell and distribute SIVEXTRO (tedizolid phosphate) in the United States and certain of its territories. SIVEXTRO is an oxazolidinone-class antibacterial indicated for acute bacterial skin and skin structure infections (ABSSSI). In addition, Nabriva engaged Amplity Health, a leading pharmaceutical contract commercial organization, to provide community-based commercial and sales services for SIVEXTRO and XENLETA in the United States.

FINANCIAL RESULTS

Three Months Ended September 30, 2019 and 2020

- Revenues decreased by $5.6 million from $6.9 million for the three months ended September 30, 2019 to $1.3 million for the three months ended September 30, 2020, primarily due to a $4.4 million decrease in collaboration revenue and a $1.5 million decrease in product revenues, net. Collaboration revenues in 2019 included a $5.0 million milestone payment from Sinovant. For the three months ended September 30, 2020, we recorded $5 thousand of product revenue, net of gross-to-net accruals. In addition, we recorded a $0.1 million adjustments for returns from mail order specialty pharmacies, resulting in $47 thousand of negative product revenue, net for the three months ended September 30, 2020. For the three months ended September 30, 2019, we recorded $1.4 million of product revenue, net upon the initial launch of XENLETA.

- Research and development expenses decreased by $2.1 million from $5.6 million for the three months ended September 30, 2019 to $3.5 million for the three months ended September 30, 2020. The decrease was primarily due to a $0.8 million decrease in stock-based compensation expense, a $0.3 million decrease in staff costs, a $0.5 million decrease in research materials and purchased services, a $0.2 million decrease in consulting fees, and a $0.2 million decrease in travel costs.

- Selling, general and administrative expense decreased by $7.5 million from $18.5 million for the three months ended September 30, 2019 to $11.0 million for the three months ended September 30, 2020. The decrease was primarily due to a $3.5 million decrease in advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees in 2019, a $2.3 million decrease in staff costs due to the reduction of headcount, and a $2.2 million decrease in stock-based compensation expense, partly offset by a $0.3 million increase in legal fees, and a $0.1 million increase in tax and audit related fees.

Nine Months Ended September 30, 2019 and 2020

- Revenues decreased by $6.6 million from $9.1 million for the nine months ended September 30, 2019 to $2.5 million for the nine months ended September 30, 2020, primarily due a $5.3 million decrease in collaboration revenue and a $1.4 million decrease in product revenue, net associated with the launch of XENLETA in 2019, offset by a $0.1 million increase in research premium and grant revenue. Collaboration revenues in 2019 included $6.5 million for two milestone payments from Sinovant. For the nine months ended September 30, 2020 we recorded $0.3 million of product revenue, net of gross-to-net accruals. In addition, we recorded a $0.4 million returns reserve adjustment for slow moving inventory, representing 50% of XENLETA IV inventory held at our Specialty Distributors and adjustments for returns from mail order specialty pharmacies, partly offset by a favorable $0.2 million gross-to-net adjustment, resulting in $61 thousand product revenue, net for the nine months ended September 30, 2020.

- Research and development expenses decreased by $6.3 million from $21.2 million for the nine months ended September 30, 2019 to $14.9 million for the nine months ended September 30, 2020. The decrease was primarily due to a $3.5 million decrease in research materials and purchased services, a $1.9 million decrease in research consulting fees, a $2.2 million decrease in staff costs, a $0.7 million decrease in stock-based compensation expense, and a $0.3 million decrease in travel and infrastructure costs, partly offset by a $2.6 million refund of NDA filing fees for our product candidate, CONTEPO, in 2019.

- Selling, general and administrative expense decreased by $10.2 million from $45.3 million for the nine months ended September 30, 2019 to $35.1 million for the nine months ended September 30, 2020. The decrease was primarily due to a $6.0 million decrease in advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees in 2019, a $2.9 million decrease in stock-based compensation expense, a $0.8 million decrease in travel, a $0.1 million decrease infrastructure costs, and a $0.1 million decrease in other corporate costs.

- As previously disclosed, Nabriva's distribution partners continue to primarily utilize their existing inventory to satisfy product demand, which in turn impacted sales in the third quarter of 2020. In light of the COVID-19 pandemic and the associated disruption to the healthcare industry, future sales amounts in 2020 are uncertain.

- As of September 30, 2020, Nabriva Therapeutics had $41.1 million in cash and cash equivalents, compared to $86.0 million as of December 31, 2019.

- Based on its current operating plans, the Company expects that its existing cash resources will be sufficient to enable Nabriva to fund its operating expenses, debt service obligations and capital expenditure requirements substantially through the first quarter of 2021. This estimate assumes,

among other things, that Nabriva remains in compliance with the covenants under its Loan Agreement.

Please refer to our Annual Report on Forms 10-K for the fiscal year ended December 31, 2019 and our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, which are filed with the U.S. Securities and Exchange Commission, for additional information regarding the Company's business and financial results.

Company to Host Conference Call

Nabriva's management will host a conference call today at 4:30 p.m. ET to discuss the financial results and recent corporate highlights. The dial-in number for the conference call is (866) 811-8671 for domestic participants and (409) 981-0874 for international participants, with Conference ID #5564729. A live webcast of the conference call can be accessed through the "Investors" tab on the Nabriva Therapeutics website at www.nabriva.com. A replay will be available on this website shortly after conclusion of the event for 90 days.

About Nabriva Therapeutics plc

Nabriva Therapeutics is a biopharmaceutical company engaged in the commercialization and development of innovative anti-infective agents to treat serious infections. Nabriva Therapeutics received U.S. Food and Drug Administration approval for XENLETA® (lefamulin injection, lefamulin tablets), the first systemic pleuromutilin antibiotic for community-acquired bacterial pneumonia (CABP). Nabriva Therapeutics is also developing CONTEPO™ (fosfomycin) for injection, a potential first-in-class epoxide antibiotic for complicated urinary tract infections (cUTI), including acute pyelonephritis. Nabriva entered into an exclusive agreement with subsidiaries of Merck & Co. Inc., Kenilworth, N.J., USA to market, sell and distribute SIVEXTRO® (tedizolid phosphate) in the United States and certain of its territories.

About XENLETA

XENLETA (lefamulin) is a first-in-class semi-synthetic pleuromutilin antibiotic for systemic administration in humans discovered and developed by the Nabriva Therapeutics team. It is designed to inhibit the synthesis of bacterial protein, which is required for bacteria to grow. XENLETA's binding occurs with high affinity, high specificity and at molecular sites that are different than other antibiotic classes. Efficacy of XENLETA was demonstrated in two multicenter, multinational, double-blind, double-dummy, non-inferiority trials assessing a total of 1,289 patients with CABP. In these trials, XENLETA was compared with moxifloxacin and in one trial, moxifloxacin with and without linezolid. Patients who received XENLETA had similar rates of efficacy as those taking moxifloxacin alone or moxifloxacin plus linezolid. The most common adverse reactions associated with XENLETA included diarrhea, nausea, reactions at the injection site, elevated liver enzymes, and vomiting. For more information, please visit www.XENLETA.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 its ability to successfully commercialize XENLETA for the treatment of CABP, including the availability of and ease of access to XENLETA through major U.S. specialty distributors, marketing exclusivity and patent protection for XENLETA, the distribution and

promotion of SIVEXTRO for the treatment of ABSSSI, the development of CONTEPO for Complicated Urinary Tract Infections (cUTI), the expansion of its commercial sales force, the clinical utility of XENLETA for CABP, SIVEXTRO for ABSSSI and of CONTEPO for cUTI, plans for and timing of the review of regulatory filings for CONTEPO, efforts to bring CONTEPO to market, the market opportunity for and the potential market acceptance of XENLETA for CABP, SIVEXTRO for ABSSSI and CONTEPO for cUTI, the development of XENLETA and CONTEPO for additional indications, the development of additional formulations of XENLETA and CONTEPO, plans for making lefamulin available in the European Union, Canada and China, plans to pursue research and development of other product candidates, expectations regarding the ability of customers to satisfy demand for XENLETA with their existing inventory, expectations regarding the impact of the interruptions resulting from COVID-19 on its business, the sufficiency of Nabriva Therapeutics' existing cash resources and its expectations regarding anticipated revenues from product sales and how far into the future its existing cash resources will fund its ongoing operations 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 successfully implement its commercialization plans for XENLETA and SIVEXTRO and whether market demand for XENLETA and SIVEXTRO is consistent with its expectations, Nabriva Therapeutics' ability to build and maintain a sales force for XENLETA and SIVEXTRO, the content and timing of decisions made by the U.S. Food and Drug Administration and other regulatory authorities, 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, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of CONTEPO for the treatment of cUTI, the extent of business interruptions resulting from the infection causing the COVID-19 outbreak or similar public health crises, the ability to retain and hire key personnel, the availability of adequate additional financing on acceptable terms or at all 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, 2019	As of September 30, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 86,019	$ 41,122
Restricted cash	392	230
Short-term investments	175	16
Accounts receivable, net and other receivables	2,744	3,385
Inventory	682	5,803
Prepaid expenses	1,158	3,754
Total current assets	91,170	54,310
Property, plant and equipment, net	2,474	2,007
Intangible assets, net	91	84
Long-term receivables	378	369
Total assets	**$ 94,113**	**$ 56,770**
Liabilities and equity		
Current liabilities:		
Accounts payable	$ 4,673	$ 2,041
Accrued expense and other current liabilities	11,966	8,934
Total current liabilities	16,639	10,975
Non-current liabilities		
Long-term debt	34,502	7,610
Other non-current liabilities	1,698	1,956
Total non-current liabilities	36,200	9,566
Total liabilities	**52,839**	**20,541**
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at September 30, 2020; 94,545,116 and 150,006,432 issued and outstanding at December 31, 2019 and September 30, 2020, respectively	945	1,500
Preferred shares, par value $0.01, 100,000,000 shares authorized at September 30, 2020; None issued and outstanding	—	—
Additional paid in capital	517,044	563,095
Accumulated other comprehensive income	27	27
Accumulated deficit	(476,742)	(528,393)
Total stockholders' equity	**41,274**	**36,229**
Total liabilities and stockholders' equity	**$ 94,113**	**$ 56,770**

Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share data)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2020
Revenues:				
Product revenue, net	$ 1,445	(47)	$ 1,445	$ 61
Collaboration revenue	5,051	616	6,051	768
Research premium and grant revenue	424	722	1,652	1,738
Total revenue	6,920	1,291	9,148	2,567
Operating expenses:				
Cost of product sales	(15)	(25)	(15)	(401)
Research and development expenses	(5,601)	(3,486)	(21,213)	(14,930)
Selling, general and administrative expenses	(18,503)	(10,997)	(45,339)	(35,094)
Total operating expenses	(24,119)	(14,508)	(66,567)	(50,425)
Loss from operations	**(17,199)**	**(13,217)**	**(57,419)**	**(47,858)**
Other income (expense):				
Other income (expense), net	(10)	450	116	614
Interest income	94	5	176	85
Interest expense	(709)	(261)	(2,512)	(1,536)
Loss on extinguishment of debt	—	—	—	(2,757)
Loss before income taxes	**(17,824)**	**(13,023)**	**(59,639)**	**(51,452)**
Income tax benefit (expense)	29	72	(80)	(199)
Net loss	**$ (17,795)**	**(12,951)**	**$ (59,719)**	**$ (51,651)**
Loss per share				
Basic and Diluted ($ per share)	$ (0.24)	(0.09)	$ (0.83)	$ (0.44)
Weighted average number of shares:				
Basic and Diluted	75,161,192	144,690,904	72,153,405	117,454,536

Condensed Consolidated Statements of Cash Flows
(unaudited)

(in thousands)	Nine Months Ended September 30, 2019	2020
Net cash provided by (used in):		
Operating activities	$ (56,405)	$ (57,967)
Investing activities	131	(257)
Financing activities	32,680	12,903
Effects of foreign currency translation on cash and cash equivalents	(80)	262
Net decrease in cash and cash equivalents	(23,674)	(45,059)
Cash and cash equivalents and restricted cash at beginning of period	102,003	86,411
Cash and cash equivalents and restricted cash at end of period	$ 78,329	$ 41,352