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 10, 2022**

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 Capital 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 10, 2022, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the quarter ended September 30, 2022. 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 10, 2022
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 10, 2022

By: /s/ Daniel Dolan
Daniel Dolan
Chief Financial Officer

Exhibit 99.1

Nabriva Therapeutics Pivoting Strategic Focus
Reports Third Quarter Financial Results and Provides Corporate Update

-Shifted Focus to SIVEXTRO to Enable Cost Cutting-

-Cash Runway Extended into Q1 2023-

-Q3 2022 Total Revenue of $9.2 Million-

-Engaged Torreya Capital As Strategic Advisor-

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

Dublin Ireland, November 10, 2022 – 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 it has pivoted its strategic focus towards commercialization efforts, primarily focused on SIVEXTRO, to extend its cash runway, while exploring strategic options. Nabriva also issued financial results for the three months ended September 30, 2022.

"Given the pressures of the macro environment, we believe building on our commercial success with SIVEXTRO, as demonstrated by the continued prescription demand growth, is the most efficient and effective way to extend our cash runway and preserve optionality and value for our shareholders" said Ted Schroeder, Nabriva's CEO.

Mr. Schroeder continued, "Aligned with the shift in our strategic focus, we have suspended early-stage research and development activities and reduced global headcount by approximately 40% as part of the broader initiative to extend our cash runway and maximize the value of the products in our portfolio. As such, we have engaged Torreya Capital to help us explore strategic options."

Torreya Capital will advise Nabriva on its exploration of a range of strategic options, which could include the potential in-licensing or out-licensing of commercial stage assets. This process may not result in any transaction, and the Company does not intend to disclose additional details unless and until it has entered into a specific transaction.

CORPORATE AND DEVELOPMENT UPDATES

- On August 11, 2022, we announced the completion of enrollment in our Phase 1 clinical trial of XENLETA as potential treatment of resistant bacterial infections in patients with Cystic Fibrosis. The Phase 1 trial is an open label, randomized, crossover study to assess the safety and pharmacokinetics following singled doses of oral and intravenous XENLETA in adult patients with Cystic Fibrosis.

- On September 15, 2022, we announced a 1-for-25 reverse stock split which was necessary for us to regain compliance with the minimum $1.00 per share requirement pursuant to Nasdaq Listing Rule 5450(a)(1) (Bid Price Rule). We were notified by Nasdaq on September 30, 2022 that we had regained compliance with the Bid Price Rule.

FINANCIAL RESULTS

Three Months Ended September 30, 2022 and 2021

- Revenues for the three months ended September 30, 2022 were $9.2 million compared to $8.9 million for the three months ended September 30, 2021. The $0.3 million increase was driven by an increase in product revenue, net, offset by a decrease in collaboration revenues.

- Cost of revenues for the three months ended September 30, 2022 was $4.4 million compared to $4.2 million for the three months ended September 30, 2021. The $0.2 million increase was primarily due to SIVEXTRO costs, which were not incurred prior to the launch of our own SIVEXTRO New Drug Code (NDC) in April 2021.

- Research and development expenses for the three months ended September 30, 2022 were $4.0 million compared to $3.2 million for the three months ended September 30, 2021. The $0.8 million increase was primarily due to a $0.5 million increase in consulting fees and a $0.4 million increase in research materials and purchased services driven by our Phase 1 trial to assess the safety and pharmacokinetics of oral and intravenous XENLETA for the treatment of resistant bacterial infections in adult patients with cystic fibrosis.

- Selling, general and administrative expenses for the three months ended September 30, 2022 were $11.9 million compared to $12.3 million for the three months ended September 30, 2021. The $0.3 million decrease was driven by a decrease in personnel costs and a decrease in stock-based compensation expenses.

- Net loss increased by $0.9 million from a $10.7 million net loss for the three months ended September 30, 2021 to a $11.5 million net loss for the three months ended September 30, 2022.

Nine Months Ended September 30, 2022 and 2021

- Revenues for the nine months ended September 30, 2022 were $26.4 million compared to $19.6 million for the nine months ended September 30, 2021. The $6.7 million increase was primarily due to a $8.6 million increase in SIVEXTRO product revenue, net, partly offset by a $2.5 million decrease in collaboration revenues.

- Cost of revenues for the nine months ended September 30, 2022 was $12.2 million compared to $7.9 million for the nine months ended September 30, 2021. The $4.3 million increase was primarily due to SIVEXTRO costs, which were not incurred prior to the launch of our own SIVEXTRO NDC on April 12, 2021.

- Research and development expenses for the nine months ended September 30, 2022 were $11.6 million compared to $10.2 million for the nine months ended September 30, 2021. The $1.4 million

increase was primarily due to a $0.9 million increase in research materials and purchased services driven by our Phase 1 trial to assess the safety and pharmacokinetics of oral and intravenous XENLETA for the treatment of resistant bacterial infections in adult patients with cystic fibrosis, and a $0.4 million increase in advisory and external consultancy expenses.

- Selling, general and administrative expenses for the nine months ended September 30, 2022 were $35.7 million compared to $37.2 million for the nine months ended September 30, 2021. The $1.5 million decrease was primarily due to a decrease in advisory and external consultancy expenses.

- Net loss decreased by $2.0 million from a $36.4 million net loss for the nine months ended September 30, 2021 to a $34.4 million net loss for the nine months ended September 30, 2022.

- As of September 30, 2022, Nabriva had $14.8 million in cash, cash equivalents and restricted cash. Based on its current operating plans, Nabriva expects that its existing cash resources will be sufficient to enable it to fund its operating expenses, debt service obligations and capital expenditure requirements into the first quarter of 2023.

Please refer to our Annual Report on Forms 10-K for the fiscal year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 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 (833) 634-2311 for domestic participants and (412) 902-4177 for international participants and ask to join the "Nabriva Therapeutics Conference Call." 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 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. 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.

About SIVEXTRO

SIVEXTRO (tedizolid phosphate) was approved by the U.S. Food and Drug Administration in 2014. It is indicated in adults and pediatric patients 12 years of age and older for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant (MRSA) and methicillin-

susceptible (MSSA) isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus group (including Streptococcus anginosus, Streptococcus intermedius and Streptococcus constellatus), and Enterococcus faecalis. To reduce the development of drug-resistant bacteria and maintain the effectiveness of SIVEXTRO and other antibacterial drugs, SIVEXTRO should be used only to treat ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

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 managed care coverage for XENLETA, the distribution and promotion of SIVEXTRO for the treatment of ABSSSI, the development of CONTEPO for Complicated Urinary Tract Infections (cUTI), the clinical utility of XENLETA for CABP and Cystic Fibrosis, SIVEXTRO for ABSSSI and of CONTEPO for cUTI, the impact of macro events on sales of SIVEXTRO and XENLETA, plans for and timing of the review of regulatory filings for XENLETA and 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 prospects for future sales of SIVEXTRO, the development of XENLETA and CONTEPO for additional indications, plans to pursue research and development of other product candidates, plans to pursue business development initiatives, 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 execute its commercialization plans for SIVEXTRO and whether market demand for SIVEXTRO is consistent with its expectations, Nabriva Therapeutics' ability to build and maintain a sales force for 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.

CONTACT:

For Investors and Media
Kim Anderson
Nabriva Therapeutics plc
ir@nabriva.com

Consolidated Balance Sheets (unaudited)

(in thousands, except share data)	As of September 30, 2022	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 14,647	$ 47,659
Restricted cash	121	175
Short-term investments	—	16
Accounts receivable, net and other receivables	12,388	12,751
Inventory	17,333	14,509
Prepaid expenses	3,074	5,155
Total current assets	47,563	80,265
Property and equipment, net	293	233
Intangible assets, net	7	31
Other non-current assets	377	380
Total assets	**$ 48,240**	**$ 80,909**
Liabilities and stockholders´ equity		
Current liabilities:		
Current portion of long-term debt	$ 5,733	$ 3,765
Accounts payable	3,895	4,372
Accrued expense and other current liabilities	12,012	13,829
Deferred revenue	—	374
Total current liabilities	21,640	22,340
Non-current liabilities:		
Long-term debt	399	4,265
Other non-current liabilities	578	954
Total non-current liabilities	977	5,219
Total liabilities	**22,617**	**27,559**
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 12,000,000 ordinary shares authorized at September 30, 2022; 3,021,368 and 2,268,612 issued and outstanding at September 30, 2022, and December 31, 2021, respectively	30	23
Preferred shares, par value $0.01, 100,000,000 shares authorized at September 30, 2022; None issued and outstanding	—	—
Additional paid in capital	655,649	648,976
Accumulated other comprehensive income	27	27
Accumulated deficit	(630,083)	(595,676)
Total stockholders' equity	**25,623**	**53,350**
Total liabilities and stockholders' equity	**$ 48,240**	**$ 80,909**

Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share data)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Revenues:				
Product revenue, net	$ 8,643	$ 7,858	$ 24,363	$ 14,928
Collaboration revenue	141	562	866	3,377
Research premium and grant revenue	369	442	1,135	1,329
Total revenues	**9,153**	**8,862**	**26,364**	**19,634**
Operating expenses:				
Cost of revenues	(4,416)	(4,199)	(12,232)	(7,882)
Research and development expenses	(4,032)	(3,221)	(11,637)	(10,239)
Selling, general and administrative expenses	(11,907)	(12,256)	(35,654)	(37,157)
Total operating expenses	(20,355)	(19,676)	(59,523)	(55,278)
Loss from operations	**(11,202)**	**(10,814)**	**(33,159)**	**(35,644)**
Other income (expense):				
Other income, net	354	131	570	479
Interest expense, net	(146)	(221)	(559)	(678)
Loss before income taxes	**(10,994)**	**(10,904)**	**(33,148)**	**(35,843)**
Income tax benefit (expense)	(520)	252	(1,259)	(544)
Net loss	**$ (11,514)**	**$ (10,652)**	**$ (34,407)**	**$ (36,387)**
Loss per share				
Basic and diluted ($ per share)	$ (4.21)	$ (5.27)	$ (13.55)	$ (23.17)
Weighted average number of shares:				
Basic and diluted	2,732,749	2,021,070	2,539,408	1,570,389

Condensed Consolidated Statements of Cash Flows (unaudited)

(in thousands)	Nine Months Ended September 30, 2022	2021
Net cash provided by (used in):		
Operating activities	$ (35,086)	$ (53,439)
Investing activities	(256)	(69)
Financing activities	2,510	64,228
Effects of exchange rate changes on the balance of cash held in foreign currencies	(234)	(136)
Net increase (decrease) in cash and cash equivalents and restricted cash	(33,066)	10,584
Cash and cash equivalents and restricted cash at beginning of period	47,834	41,590
Cash and cash equivalents and restricted cash at end of period	$ 14,768	$ 52,174