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 5, 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 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 May 5, 2022, Nabriva Therapeutics plc issued a press release announcing its consolidated financial results for the quarter ended March 31, 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 May 5, 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: May 5, 2022

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

Exhibit 99.1

Nabriva Therapeutics Reports First Quarter 2022 Financial Results and Provides a Corporate Update

-SIVEXTRO Distribution and Promotion Agreement with Merck Formally Extended Through at Least 2026-

-SIVEXTRO Prescription Demand Grew 10% Versus Q1 2021-

-Phase 1 XENLETA Cystic Fibrosis Trial Enrollment Progressing-

-Conference Call Today at 4:30 p.m. Eastern Time-

Dublin Ireland, May 5, 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 its financial results for the three months ended March 31, 2022 and provided a corporate update.

"We continued to execute on our near-term strategy in the first quarter of 2022. We extended our agreement with Merck to promote and distribute SIVEXTRO, by three years, through at least December 2026. We are seeing consistent growth in SIVEXTRO sales from our commercial efforts, highlighted by the 10% growth in SIVEXTRO prescription demand in the first quarter of 2022 versus the first quarter of 2021. With historically higher demand quarters still in front of us this year, we are confident in our goal to return SIVEXTRO to historical peak run rate sales by the third quarter of 2022. We anticipate SIVEXTRO to be a significant contributor to the business and plan to leverage this momentum to continue to grow Nabriva's commercial business."

Mr. Schroeder added, "We also continue to educate the medical community, especially pulmonologists, about the differentiated profile of XENLETA for the treatment of community-acquired bacterial pneumonia in adults. We are encouraged by our targeted life cycle management activities focused on significant unmet medical needs that may be addressed by XENLETA. In particular, we are pleased to report enrollment in our Phase 1 clinical trial in patients with cystic fibrosis has commenced and we expect to report results from the trial in the first half of 2023."

CORPORATE AND DEVELOPMENT UPDATES

- On May 5, 2022, we announced that we signed an agreement to officially extend our SIVEXTRO Distribution and Promotion Agreement with Merck through at least December 2026.

- On April 11, 2022, we announced that the first patient in our Phase 1 clinical trial of XENLETA for the treatment of resistant bacterial infections in patients with Cystic Fibrosis was randomized and dosed. The Phase 1 trial is an open-label, randomized, crossover study to assess the safety and pharmacokinetics following single doses of oral and intravenous XENLETA in adult patients with cystic fibrosis.

FINANCIAL RESULTS

Three Months Ended March 31, 2022 and 2021

- Revenues for the three months ended March 31, 2022 were $8.0 million compared to $2.5 million for the three months ended March 31, 2021. The $5.5 million increase was primarily due to $7.2 million in SIVEXTRO product revenue, net for the three months ended March 31, 2022, partially offset by a $1.4 million decrease in collaboration.

- Cost of revenues for the three months ended March 31, 2022 was $3.4 million compared to $62 thousand for the three months ended March 31, 2021. The $3.3 million increase was primarily due to the launch of our own SIVEXTRO National Drug Code on April 12, 2021.

- Research and development expenses for the three months ended March 31, 2022 were $3.5 million compared to $3.9 million for the three months ended March 31, 2021. The $0.4 million decrease was primarily due to a $0.2 million decrease in research consulting fees, and a $0.2 million decrease in research materials and purchased services.

- Selling, general and administrative expenses for the three months ended March 31, 2022 were $12.7 million compared to $12.0 million for the three months ended March 31, 2021. The $0.7 million increase was primarily due to a $0.4 million increase in staff costs, a $0.2 million increase in stock-based compensation, and a $0.1 million increase in advisory and external consultancy expenses primarily related to commercialization activities.

- Net loss decreased by $2.2 million from a $14.0 million net loss for the three months ended March 31, 2021, to a $11.8 million net loss for the three months ended March 31, 2022.

- As of March 31, 2022, Nabriva had $33.8 million in cash and cash equivalents. 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 well into the fourth quarter of 2022.

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 March 31, 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 (800) 579-2543 for domestic participants and (203) 518-9708 for international participants, with Conference ID # NBRVQ122. 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, 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, 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 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.

CONTACT:

For Investors and Media
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Consolidated Balance Sheets (unaudited)

(in thousands, except share data)	As of March 31, 2022	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 33,784	$ 47,659
Restricted cash	174	175
Short-term investments	—	16
Accounts receivable, net and other receivables	11,007	12,751
Inventory	15,632	14,509
Prepaid expenses	4,602	5,155
Total current assets	65,199	80,265
Property and equipment, net	181	233
Intangible assets, net	21	31
Other non-current assets	379	380
Total assets	**$ 65,780**	**$ 80,909**
Liabilities and stockholders´ equity		
Current liabilities:		
Current portion of long-term debt	$ 4,196	$ 3,765
Accounts payable	1,578	4,372
Accrued expense and other current liabilities	10,496	13,829
Deferred revenue	—	374
Total current liabilities	16,270	22,340
Non-current liabilities:		
Long-term debt	3,917	4,265
Other non-current liabilities	968	954
Total non-current liabilities	4,885	5,219
Total liabilities	**21,155**	**27,559**
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 300,000,000 ordinary shares authorized at March 31, 2022; 61,725,236 and 56,715,306 issued and outstanding at March 31, 2022, and December 31, 2021, respectively	617	567
Preferred shares, par value $0.01, 100,000,000 shares authorized at March 31, 2022; None issued and outstanding	—	—
Additional paid in capital	651,476	648,432
Accumulated other comprehensive income	27	27
Accumulated deficit	(607,495)	(595,676)
Total stockholders' equity	**44,625**	**53,350**
Total liabilities and stockholders' equity	**$ 65,780**	**$ 80,909**

Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share data)	Three Months Ended March 31, 2022	2021
Revenues:		
Product revenue, net	$ 7,040	$ 130
Collaboration revenue	629	2,002
Research premium and grant revenue	351	397
Total revenues	8,020	2,529
Operating expenses:		
Cost of revenues	(3,361)	(62)
Research and development expenses	(3,517)	(3,868)
Selling, general and administrative expenses	(12,700)	(12,047)
Total operating expenses	(19,578)	(15,977)
Loss from operations	**(11,558)**	**(13,448)**
Other income (expense):		
Other income (expense), net	308	(122)
Interest income (expense), net	(215)	(221)
Loss before income taxes	**(11,465)**	**(13,791)**
Income tax benefit (expense)	(354)	(190)
Net loss	**$ (11,819)**	**$ (13,981)**
Loss per share		
Basic and diluted ($ per share)	$ (0.20)	$ (0.53)
Weighted average number of shares:		
Basic and diluted	58,794,142	26,413,590

Condensed Consolidated Statements of Cash Flows (unaudited)

(in thousands)	Three Months Ended March 31, 2022	2021
Net cash provided by (used in):		
Operating activities	$ (15,870)	$ (21,626)
Investing activities	(36)	(120)
Financing activities	2,194	34,930
Effects of exchange rate changes on the balance of cash held in foreign currencies	(164)	244
Net increase (decrease) in cash and cash equivalents and restricted cash	(13,876)	13,428
Cash and cash equivalents and restricted cash at beginning of quarter	47,834	41,590
Cash and cash equivalents and restricted cash at end of quarter	$ 33,958	$ 55,018