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): **January 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 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. o

Item 2.02. Results of Operations and Financial Condition.

On January 10, 2022, Nabriva Therapeutics plc (the "Company") issued a press release announcing preliminary financial results for the fourth quarter of 2021. 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 Item 2.02, 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 8.01. Other Events.

Preliminary Financial Results

As described above, on January 10, 2022, the Company announced that, although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2021, it expects to report cash, cash equivalents and short-term investments of approximately $47.7 million as of December 31, 2021. In addition, the Company expects to report that total revenue for the fourth quarter of 2021 grew at a mid-to-high single digit percentage versus third quarter of 2021's reported total revenue of $8.9 million.

These estimated financial results are preliminary and unaudited, represent management's estimates as of the date of this Current Report on Form 8-K and are subject to the completion of the Company's financial closing procedures. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, these estimated financial results.

Cash Runway

As a result of SIVEXTRO sales in the fourth quarter of 2021 and improved operating efficiencies within the business, the Company anticipates that its cash, cash equivalents and short-term investments as of December 31, 2021 will be sufficient to enable it to fund its operations, debt service obligations and capital expenditure requirements well into the fourth quarter of 2022. The Company has based this estimate on assumptions that may prove to be wrong, and it could use its capital resources sooner than it currently expects.

Clinical Update

The Company has initiated a Phase I clinical trial of lefamulin for the treatment of cystic fibrosis patients with bacterial infections and expects to enroll the first patient in the trial in the first quarter of 2022.

Forward-Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans and prospects for the Company, including but not limited to statements about the sufficiency of the Company's existing cash resources, its preliminary financial results for the fourth quarter of 2021, the timing of patient enrollment for its Phase I clinical trial 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: the extent of business and other interruptions resulting from the infection causing the COVID-19 outbreaks or similar public health crises, the sufficiency of cash resources and need for additional financing and such other important factors as are set forth in the Company's annual and quarterly reports and other filings with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this Form 8-K represent the Company's views as of the date of this Form 8-K. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company 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 the Company's views as of any date subsequent to the date of this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated January 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: January 10, 2022

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

Exhibit 99.1

Nabriva Therapeutics Provides Business Update and Announces Preliminary Financial Results for the Fourth Quarter of 2021

-SIVEXTRO® (tedizolid phosphate) remains on track for return to historical peak sales by mid-2022-

-XENLETA® (lefamulin) Phase I Cystic Fibrosis (CF) trial on track to enroll first patient in Q122-

-Cash resources of $47.7 million as of 12/31/21 provides cash runway well into Q422-

DUBLIN, Ireland and Fort Washington, Pa., January 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, announced a business update today and preliminary, unaudited financial results for the fourth quarter of 2021.

"We made excellent progress in 2021 in spite of the COVID pandemic and are poised for continued growth in 2022," commented Ted Schroeder, Chief Executive Officer of Nabriva Therapeutics. "We had a strong close to 2021 for SIVEXTRO, which contributed to extending our cash runway well into the fourth quarter of 2022 and we continue to propel the product back to historical prescription trends through our promotional efforts." Mr. Schroeder continued, "while our commercialization efforts for XENLETA have faced significant headwinds due to the global pandemic, we remain focused on maximizing the value of this novel, first-in-class antibacterial agent in the U.S. through our focused commercial investments, and outside the U.S. by expanding our partnerships globally."

"We have also made significant progress in executing on life-cycle management opportunities for XENLETA with the initiation of a Phase I trial for CF and early-stage work focused on drug-resistant sexually transmitted infections and other unmet medical conditions for this important drug." Mr. Schroeder added, "we stand ready to resubmit our New Drug Application for CONTEPO and potentially bring this important antibiotic to the U.S. market once COVID-related travel restrictions are lifted and the U.S. Food and Drug Administration (FDA) is able to complete inspections of our manufacturing partners in the European Union."

In 2021, we positioned the growth of our business by:

- Launching Nabriva's own National Drug Code (NDC) of SIVEXTRO in April 2021
- Reporting positive Phase III trial results for lefamulin in China in May 2021
- Transitioning lefamulin commercial rights in China to Sumitomo Pharmaceuticals in May 2021
- Receiving approval of lefamulin in Taiwan in September 2021
- Contracting with Vizient Health in September 2021 to enhance access for XENLETA
- Publishing data on anti-inflammatory effects of lefamulin in PLOS ONE in November 2021
- Achieving acceptance of our New Drug Application by the National Medical Products Administration (NMPA) in China in November 2021
- Launching a 10-count blister pack or "X Pack" of XENLETA in November 2021 to improve distribution and customer access

In 2022, we look for continued growth through execution on key milestones including:

- Growing SIVEXTRO sales to historical levels by mid-2022
- Pulling through hospital transition of care opportunity for XENLETA with Vizient Health
- Enrolling the first patient in our Phase I CF trial in the first quarter
- Geographic expansion of commercialization and distribution partnerships for lefamulin in the EU and the rest of the world
- Continuing to work with FDA to bring CONTEPO to market in the U.S.
- Assessing other business development opportunities to add to our product portfolio and leverage current infrastructure

Preliminary Financial Results

The company enters 2022 with $47.7 million of cash, cash equivalents and short-term investments as of December 31, 2021 compared to $52.2 million of cash, cash equivalents and short-term investments as of September 30, 2021. As a result of the strong close to 2021 for SIVEXTRO sales, and improved operating efficiencies within the business, our cash balance as of December 31, 2021 is expected to fund our operations, debt service obligations and capital expenditure requirements well into the fourth quarter of 2022. In addition, we anticipate reporting that total revenue for the fourth quarter of 2021 grew at a mid-to-high single digit percentage versus third quarter of 2021's reported total revenue of $8.9 million.

These estimated financial results are preliminary and unaudited, represent management's estimates as of the date of this press release and are subject to completion of Nabriva's financial closing procedures. Nabriva's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, these estimated financial results.

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.

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.

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 preliminary financial results for the fourth quarter of 2021, the timing of patient enrollment for its planned Phase I clinical trial of lefamulin for CF, the potential for, and timing of, SIVEXTRO's return to historical peak sales, 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, 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 development of XENLETA and CONTEPO for additional indications, 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 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.

CONTACTS:

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