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 5, 2022

Verona Pharma plc
(Exact name of registrant as specified in its charter)

United Kingdom	**001-39067**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3 More London Riverside
London SE1 2RE
United Kingdom
(Address of principal executive offices) (Zip Code)

+44 203 283 4200
(Registrant's telephone number, including area code)

N/A
(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:

☐ 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 £0.05 per share*	VRNA	The Nasdaq Global Market

** The ordinary shares are represented by American Depositary Shares (each representing 8 ordinary shares), which are exempt from the operation of Section 12(a) of the Securities Exchange Act of 1934, as amended, pursuant to Rule 12a-8 thereunder.*

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 Condition.

On January 5, 2022, Verona Pharma plc (the "Company") issued a press release in which the Company stated that, although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2021, the Company expects to report that it had approximately $148.4 million in cash and cash equivalents as of December 31, 2021. The Company also reported that management believes that the Company's cash and cash equivalents at December 31, 2021, expected cash receipts from the U.K. tax credit program and funding expected to be available under the $30.0 million financing facility secured in November 2020, will enable the Company to fund its planned operating expenses and capital expenditure requirements through at least the end of 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Form 8-K") and is incorporated herein by reference.

The information contained in this Item 2.02 of this Form 8-K is unaudited and preliminary, and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2021 and its results of operations for the three months and year ended December 31, 2021. The audit of the Company's financial statements for the year ended December 31, 2021 is ongoing and could result in changes to the information set forth above.

The information contained in this Item 2.02 of 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 to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Information.

On January 5, 2022, the Company announced that enrollment completed in the 48-week subset of the ENHANCE-1 trial in December 2021. Additionally, the ENHANCE-2 trial had completed screening with 788 subjects randomized as of January 4, 2022, and full enrollment is expected by the end of January 2022. The Company expects to complete enrollment of the 24-week subset of the ENHANCE-1 trial in the second quarter of 2022. The Company's models predict top-line data from ENHANCE-2 are expected in the third quarter of 2022 and from ENHANCE-1 around the end of 2022. Conditional upon positive results, the Company intends to file a New Drug Application with the U.S. Food and Drug Administration in the first half of 2023.

The information contained in the first two paragraphs of Item 2.02 of this Form 8-K (excluding Exhibit 99.1) is incorporated by reference into this Item 8.01.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the development of ensifentrine and the progress and timing of clinical trials and data, the assumptions underlying the Company's models on clinical trial recruitment and progress, including the potential impact of the COVID-19 pandemic on such progress and on the Company's business and operations and its future financial results, planned regulatory submissions and timing thereof, the Company's expected financial results for the fourth quarter and fiscal year ended December 31, 2021, the funding expected to become available under the $30.0 million debt financing facility and from cash receipts from U.K. tax credits, and the sufficiency of the Company's cash and cash equivalents to fund its operations. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from our expectations expressed or implied by the forward-looking statements, including without limitation: general business, financial and accounting risks; our need for additional funding to complete development and commercialization of ensifentrine, which may not be available and which may force us to delay, reduce or eliminate our development or commercialization efforts; the reliance of our business on the success of ensifentrine, our only product candidate under development; economic, political, regulatory and other risks involved with international operations; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; serious adverse, undesirable or unacceptable side effects associated with ensifentrine, which could adversely affect our ability to develop or commercialize ensifentrine; potential delays in enrolling patients, which could adversely affect our research and development efforts and the completion of our clinical trials; our ability to obtain approval for and commercialize ensifentrine in multiple major pharmaceutical markets; material differences between our "top-line" data and final data; our reliance on third parties, including clinical research organizations, clinical investigators, manufacturers and suppliers, and the risks related to these parties' ability to successfully develop and commercialize ensifentrine; changes in our tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments could affect our profitability, and audits by tax authorities could result in additional tax payments for prior periods; our vulnerability to natural disasters, global economic factors and other unexpected events, including health epidemics or pandemics like the COVID-19 pandemic, which has and may continue to adversely impact our business; and the other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020 and our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, as any such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investors page of our website at www.veronapharma.com/investors. Any such forward-looking statements represent management's estimates as of the date of this Form 8-K. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following Exhibit 99.1 relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release of Verona Pharma plc issued on January 5, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are 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.

VERONA PHARMA PLC

Date: January 5, 2022

By: /s/ David Zaccardelli, Pharm. D.
Name: David Zaccardelli, Pharm. D.
Title: Chief Executive Officer

Exhibit 99.1

Verona Pharma Completes Enrollment in ENHANCE-1 48-week Subset

ENHANCE-2 Screening Complete with Full Enrollment Expected in January 2022

ENHANCE Phase 3 Program on Track to Report Top-line Data in 2022

LONDON and RALEIGH, N.C., January 5, 2022 – Verona Pharma plc (Nasdaq: VRNA) ("Verona Pharma" or the "Company"), a clinical-stage biopharmaceutical company focused on respiratory diseases, announces enrollment completed in the 48-week subset of the ENHANCE-1 trial in December 2021. The ENHANCE-2 trial has completed screening with 788 subjects randomized as of January 4, 2022, and full enrollment is expected by the end of January 2022. The Phase 3 ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") program is evaluating nebulized ensifentrine for the maintenance treatment of chronic obstructive pulmonary disease ("COPD").

"This is a significant milestone for Verona Pharma on our path to delivering ensifentrine to COPD patients," said David Zaccardelli, Pharm.D., President and Chief Executive Officer. "The fully enrolled 48-week subset of ENHANCE-1 is a critical driver of delivering top-line data and we expect to complete enrollment of the 24-week subset of the ENHANCE-1 trial in the second quarter of 2022.

"Our models predict top-line data from ENHANCE-2 are expected in the third quarter of 2022 and from ENHANCE-1 around the end of 2022. Conditional upon positive results, the Company intends to file a New Drug Application ("NDA") with the US Food & Drug Administration ("FDA") in the first half of 2023. We look forward to reporting top-line data this year and working with the regulatory authorities to bring our first-in-class product candidate to the millions of COPD patients worldwide who remain symptomatic."

Although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2021, the Company expects to report it had approximately $148.4 million in cash and cash equivalents as of December 31, 2021 (December 31, 2020: $188.0 million). Verona believes its cash and cash equivalents at December 31, 2021, expected cash receipts from the U.K. tax credit program and funding expected to be available under the $30.0 million financing facility secured in November 2020, will enable the Company to fund its planned operating expenses and capital expenditure requirements through at least the end of 2023.

Ensifentrine is a first-in-class product candidate that combines bronchodilator and anti-inflammatory activities in one compound. In prior clinical studies in patients with COPD, ensifentrine has shown significant and clinically meaningful improvements in lung function, symptoms and quality of life as a monotherapy or added onto a maintenance bronchodilator. Ensifentrine has been well tolerated in clinical trials involving more than 1,300 subjects to date.

About the ENHANCE program

The two randomized, double-blind, placebo-controlled studies (ENHANCE-1 and ENHANCE-2) will evaluate the efficacy and safety of nebulized ensifentrine as monotherapy and added onto a single bronchodilator, either a LAMA ("long acting muscarinic antagonist") or a LABA ("long acting beta-agonist"), compared to placebo. The two study designs will replicate measurements of efficacy and safety data over 24 weeks and ENHANCE-1 will also evaluate longer-term safety over 48 weeks.

- Patient Population: Each study will enroll approximately 800 moderate to severe, symptomatic, COPD patients at sites primarily in the U.S. and Europe.

- Dose/Duration: Patients will be randomized to receive a 3 mg nebulized dose of ensifentrine or nebulized placebo twice daily for 24 weeks in ENHANCE-2 and 24 or 48 weeks in ENHANCE-1.

- Primary Endpoint: Improvement in lung function as measured by forced expiratory volume* in one second ("FEV_1") over 12 hours with ensifentrine after 12 weeks of treatment.

- Key Secondary Endpoints: COPD symptoms and health-related quality of life through 24 weeks via the validated patient reported outcome tools, SGRQ and E-RS. Additional lung function endpoints including peak and morning trough FEV_1 will also be assessed.

- Safety: Assessed over 24 weeks in both studies and over 48 weeks in approximately 400 patients in ENHANCE-1.

Further information about this study can be found at www.clinicaltrials.gov, NCT04535986 (ENHANCE-1) and NCT04542057 (ENHANCE-2).

* FEV_1: Forced Expiratory Volume in one second, a standard measure of lung function

For further information please contact:

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About Ensifentrine

Ensifentrine (RPL554) is an investigational, first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4 ("PDE3" and "PDE4"). This dual inhibition enables it to combine both bronchodilator and anti-inflammatory effects in one compound. Ensifentrine also activates the Cystic Fibrosis Transmembrane Conductance Regulator ("CFTR"), which is beneficial in reducing mucous viscosity and improving mucociliary clearance. Ensifentrine's mechanism of action has the potential to alleviate respiratory symptoms such as breathlessness and cough and work against inflammation associated with COPD or inflammation triggered by viruses.

Ensifentrine has demonstrated statistically significant and clinically meaningful improvements in both lung function and symptoms, including breathlessness, in Verona Pharma's Phase 2 clinical studies in patients with moderate to severe Chronic Obstructive Pulmonary Disease ("COPD"). In addition, nebulized ensifentrine showed further improved lung function and reduced lung volumes in COPD patients taking standard short- and long-acting bronchodilator therapy, including maximum bronchodilator treatment with dual/triple therapy. Ensifentrine has been well tolerated in clinical trials involving more than 1,300 subjects to date.

About Verona Pharma

Verona Pharma is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of respiratory diseases with significant unmet medical needs. If successfully developed and approved, Verona Pharma's product candidate, ensifentrine, has the potential to be the first therapy for the treatment of respiratory diseases that combines bronchodilator and anti-inflammatory activities in one compound. The Company is evaluating nebulized ensifentrine in its Phase 3 clinical program ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") for COPD maintenance treatment. Two additional formulations of ensifentrine are in Phase 2 development for the treatment of COPD: dry powder inhaler ("DPI") and pressurized metered-dose inhaler ("pMDI"). Ensifentrine has potential applications in cystic fibrosis, asthma and other respiratory diseases. For more information, please visit www.veronapharma.com.

COVID-19 Impact

Verona Pharma is closely monitoring the potential impact of the COVID-19 pandemic on its operations and clinical trials, in particular the timelines and costs of its Phase 3 ENHANCE clinical program. The pandemic and government and other measures in response continue to impact a number of clinical trial activities and the Company will provide an update if it becomes aware of any meaningful disruption caused by the pandemic to its clinical trials.

To help protect the health and safety of the patients, caregivers and healthcare professionals involved in its clinical trials, as well as its employees and independent contractors, the Company continues to follow guidance from the FDA and other health regulatory authorities regarding the conduct of clinical trials during the COVID-19 pandemic to ensure the safety of study participants, minimize risks to study integrity, and maintain compliance with good clinical practice (GCP).

The COVID-19 pandemic is disrupting supply chains, and employee retention and recruitment, globally and the Company is closely monitoring this situation and will provide an update if it becomes aware of any meaningful disruption caused by the pandemic to the supply of ensifentrine and drug-related products, equipment and services for its clinical trials.

Financial Disclosure Advisory

The expected financial results discussed in this press release are unaudited and preliminary and do not present all information necessary for an understanding of the Company's financial condition as of December 31, 2021 and its results of operations for the three months and year ended December 31, 2021. The audit of the Company's financial statements for the year ended December 31, 2021, is ongoing and could result in changes to the information set forth herein.

Forward-Looking Statements

This press release contains forward-looking statements. All statements contained in this press release with respect to our operational review, outlook and financial review that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the development of ensifentrine and the progress and timing of clinical trials and data, the goals and design of clinical trials, the assumptions underlying the Company's models on clinical trial recruitment and progress, including the potential impact of the COVID-19 pandemic on such progress and on our business and operations and the Company's future financial results, planned regulatory submissions and timing thereof, the potential for ensifentrine to be the first therapy for the treatment of respiratory diseases to combine bronchodilator and anti-inflammatory effects in one compound, the potential of ensifentrine in the treatment of COPD, cystic fibrosis, asthma and other respiratory diseases, as well as the potential of the DPI and pMDI formulations of ensifentrine, expected financial results, the funding we expect to become available under the $30.0 million debt financing facility and from cash receipts from U.K. tax credits, and the sufficiency of cash and cash equivalents.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from our expectations expressed or implied by the forward-looking statements, including, but not limited to, the following: our limited operating history; our need for additional funding to complete development and commercialization of ensifentrine, which may not be available and which may force us to delay, reduce or eliminate our development or commercialization efforts; the reliance of our business on the success of ensifentrine, our only product candidate under development; economic, political, regulatory and other risks involved with international operations; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; serious adverse, undesirable or unacceptable side effects associated with ensifentrine, which could adversely affect our ability to develop or commercialize ensifentrine; potential delays in enrolling patients, which could adversely affect our research and development efforts and the completion of our clinical trials; we may not be successful in developing ensifentrine for multiple indications; our ability to obtain approval for and commercialize ensifentrine in multiple major pharmaceutical markets; misconduct or other improper activities by our employees, consultants, principal investigators, third-party service providers and licensees; our inability to realize the anticipated benefits under licenses granted by us to third parties to develop and commercialize ensifentrine, our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel; material differences between our “top-line” data and final data; our reliance on third parties, including clinical research organizations, clinical investigators, manufacturers and suppliers, and the risks related to these parties’ ability to successfully develop and commercialize ensifentrine; lawsuits related to patents covering ensifentrine and the potential for our patents to be found invalid or unenforceable; lawsuits related to our licensing of patents and know-how with third parties for the development and commercialization of ensifentrine; changes in our tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments could affect our profitability, and audits by tax authorities could result in additional tax payments for prior periods; and our vulnerability to natural disasters, global economic factors and other unexpected events, including health epidemics or pandemics like the COVID-19 pandemic, which has and may continue to adversely impact our business. These and other important factors under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020, our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.