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): March 3, 2022

Verona Pharma plc

(Exact name of registrant as specified in its charter)

United Kingdom	**001-39067**	**98-1489389**
(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 March 3, 2022, Verona Pharma plc announced its financial results for the quarter and year ended December 31, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Form 8-K (including Exhibit 99.1 attached hereto) 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 provided 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 No.	Description
99.1	Press Release issued on March 3, 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: March 3, 2022

By: /s/ David Zaccardelli, Pharm. D.

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

Verona Pharma
Breath of Innovation™

Verona Pharma Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

Phase 3 ENHANCE program on track to report top-line COPD data in 2022
Conference call today at 9:00 a.m. EST / 2:00 p.m. GMT

LONDON and RALEIGH, N.C., March 3, 2022 – Verona Pharma plc (Nasdaq: VRNA) ("Verona Pharma" or the "Company"), a clinical-stage biopharmaceutical company focused on respiratory diseases, announces its financial results for the fourth quarter and full year ended December 31, 2021, and provides a corporate update.

"In 2021, we made substantial progress towards completing enrollment in our Phase 3 ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") clinical program," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "In December, we completed enrollment of approximately 400 subjects in the 48-week subset of ENHANCE-1 and, in January 2022, we completed enrollment of more than 800 subjects in ENHANCE-2. Achieving our recruitment targets is a significant accomplishment during the ongoing pandemic and brings us closer to delivering ensifentrine to patients with chronic obstructive pulmonary disease ("COPD").

"Additionally, we successfully completed a thorough QT ("TQT") study where ensifentrine met all safety objectives and was shown not to impact the TQT interval or measures of cardiac conduction. The FDA requires a TQT study for most New Drug Applications and these data will support the planned submission for ensifentrine in the first half of 2023. Assisting future development for ensifentrine, we reported positive Phase 2 results with the pressurized metered-dose inhaler ("pMDI") formulation of ensifentrine in moderate to severe COPD patients.

"Alongside our clinical progress in 2021, we advanced our global partnering strategy through a strategic collaboration with Nuance Pharma, a Shanghai-based specialty pharmaceutical company. This provides a tiered double digit royalty and potential milestone payments of up to $179 million in addition to the $40 million in cash and equity received at execution of the agreement. Nuance Pharma is responsible for developing and commercializing ensifentrine in Greater China and we look forward to providing future updates on progress.

"2022 is expected to be a pivotal year for Verona Pharma. We are close to completing enrollment in the ENHANCE program and excited about reporting top-line data. We expect to complete enrollment in the 24-week subset of ENHANCE-1 around the end of the second quarter of 2022, which is the final step in completing enrollment in the program. Top-line data is expected from ENHANCE-2 in the third quarter of 2022 and from ENHANCE-1 around the end of the year."

Program Updates and Key Milestones

As of March 2, 2022, ENHANCE-1 had approximately 80% of subjects randomized into the study.

Based on current models of forecasted recruitment and study progress, the Company's near-term milestones include:

- Completing enrollment of approximately 400 subjects randomized in the 24-week subset of ENHANCE-1 around the end of the second quarter of 2022. This would complete enrollment in the Phase 3 ENHANCE program.
- Reporting top-line data from ENHANCE-2 in the third quarter of 2022 and from ENHANCE-1 around the end of 2022.
- Conditional upon positive results, the Company expects to submit a New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") in the first half of 2023.

With the recent sanctions and other restrictions imposed on Russia and the COVID-19 pandemic and government and other measures continuing to impact a number of clinical trial activities, the Company continues to closely monitor these timelines.

Fourth Quarter and Recent Highlights

Clinical

- In January 2022, the Company completed enrollment in ENHANCE-2 with more than 800 subjects randomized.
- In December 2021, the Company completed enrollment in the 48-week subset of ENHANCE-1 with approximately 400 subjects randomized.
- In December 2021, the Company reported ensifentrine successfully met all safety objectives in a TQT study designed to evaluate the effect, if any, of ensifentrine on measures of the TQT interval and cardiac conduction in 32 healthy volunteers. Ensifentrine was shown not to prolong the QT interval or impact other cardiac conduction parameters.

Fourth Quarter 2021 Financial Results

- **Cash position:** Cash and cash equivalents at December 31, 2021, were $148.4 million (December 31, 2020: $188.0 million). We believe our cash and cash equivalents at December 31, 2021, expected cash receipts from the U.K. tax credit program and funding expected to become available under our $30.0 million debt facility, will enable us to fund our planned operating expenses and capital expenditure requirements through at least the end of 2023.
- **R&D Expenses:** Research and development ("R&D") expenses were $22.7 million for the fourth quarter ended December 31, 2021 (Q4 2020: $16.2 million). The increase of $6.5 million was primarily due to a $10.5 million increase in costs associated with the Phase 3 ENHANCE program partially offset by a $4 million reduction in share-based compensation charges.
- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were $5.8 million for the fourth quarter ended December 31, 2021 (Q4 2020: $11.5 million). The decrease of $5.7 million was primarily driven by a decrease in share-based compensation charges.
- **Net loss:** Net loss was $23.3 million for the fourth quarter ended December 31, 2021 (Q4 2020: net loss $24.8 million).

Full Year 2021 Financial Results

- **Revenue:** Revenue of $40.0 million for the year ended December 31, 2021 is related to upfront consideration received under the Nuance Agreement. There was no revenue for the year ended December 31, 2020.
- **R&D Expenses:** Research and development costs were $79.4 million for the year ended December 31, 2021 (full year 2020: $44.5 million), an increase of $34.9 million. This increase was primarily driven by an increase in clinical costs of $35.0 million as the majority of enrollment relating to the ENHANCE program occurred in 2021.
- **SG&A Expenses:** SG&A expenses were $33.9 million for the year ended December 31, 2021 (full year 2020: $29.8 million), an increase of $4.1 million. This increase was driven primarily by a $2.9 million increase in share-based compensation charges, $4.0 million related to transaction advisory fees on the Nuance Agreement, $0.9 million related to increased Directors' and Officers' insurance, partially offset by a $2.1 million decrease related to severance incurred in 2020, and $1.9 million decrease of expenses relating to our private placement in 2020.
- **Net loss:** Net loss was $55.6 million for the year ended December 31, 2021 (full year 2020: $65.1 million). The decrease in net loss was primarily the result of the revenue from the Nuance Agreement offset by an increase in operating costs and the increase in other income, net, discussed above.

Conference Call and Webcast Information

Verona Pharma will host an investment community conference call at 9:00 a.m. EST / 2:00 p.m. GMT on Thursday, March 3, 2022 to discuss the fourth quarter and full year 2021 financial results and the corporate update.

Analysts and investors may participate by dialing one of the following numbers and reference conference ID 5113060:

- +1-888-317-6003 for callers in the United States
- +1-412-317-6061 for international callers

A live webcast will be available on the Events and Presentations link on the Investors page of the Company's website, www.veronapharma.com, and the audio replay will be available for 90 days. An electronic copy of the fourth quarter and full year 2021 results press release will also be made available today on the Company's website. This press release does not constitute an offer to sell or the solicitation of an offer to buy any of the Company's securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

For further information please contact:

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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 clinical program ENHANCE. 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.

Russia-Ukraine Conflict

Verona Pharma is conducting its ENHANCE-1 program at a number of clinical trial sites in Russia. If the U.S. or other countries impose further sanctions or other restrictions as a result of the current conflict between Russia and Ukraine, we may encounter problems transferring funds into Russia to pay the clinical trial sites, supplying ensifentrine and equipment to trial sites, or validating trial data, which would increase the cost and timelines of our Phase 3 program. The Company is closely monitoring this situation.

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 and the Russia-Ukraine conflict on such progress and on our business and operations and the Company's future financial results, the timing of submission of an NDA for ensifentrine, 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, 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, geo-political actions and unexpected events, including health epidemics or pandemics like the COVID-19 pandemic, and conflicts such as the Russia-Ukraine conflict, 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, 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.

Verona Pharma, plc
Consolidated Financial Summary

	Three months ended December 31,		Years ended December 31,	
	2021	2020	2021	2020
Revenue	$ —	$ —	$ 40,000	$ —
Operating expenses				
Research and development	22,709	16,246	79,406	44,505
Selling general and administrative	5,757	11,454	33,907	29,772
Total operating expenses	28,466	27,700	113,313	74,277
Operating loss	(28,466)	(27,700)	(73,313)	(74,277)
Other income / (expense)				
Benefit from R&D tax credit	4,975	2,458	15,630	8,267
Interest income	3	5	14	121
Interest expense	(85)	(35)	(340)	(35)
Fair value movement on warrants	2	(389)	2,246	(1,136)
Foreign exchange gain	59	872	176	2,060
Total other income, net	4,954	2,911	17,726	9,277
Loss before income taxes	(23,512)	(24,789)	(55,587)	(65,000)
Income tax credit / (expense)	250	(36)	18	(146)
Net loss	$ (23,262)	$ (24,825)	$ (55,569)	$ (65,146)
Weighted average shares outstanding	479,210,145	462,798,050	473,188,457	262,932,653
Loss per ordinary share — basic and diluted	$ (0.05)	$ (0.05)	$ (0.12)	$ (0.25)

	2021	2020
Cash and cash equivalents	$ 148,380	$ 187,986
Total assets	186,587	204,206
Equity	$ 148,005	$ 184,854