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 7, 2023

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 7, 2023, Verona Pharma plc announced its financial results for the quarter and year ended December 31, 2022. 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 7, 2023
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 7, 2023

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

Verona Pharma Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

Transformational results in Phase 3 ENHANCE program for COPD

NDA submission expected Q2 2023

Strong balance sheet to support planned US commercial launch

Conference call today at 9:00 a.m. EST / 2:00 p.m. GMT

LONDON and RALEIGH, N.C., March 7, 2023 – 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, 2022, and provides a corporate update.

"2022 was a momentous year for Verona Pharma and most importantly for the millions of patients suffering from chronic obstructive pulmonary disease ("COPD")," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "Supported by the groundbreaking results from our Phase 3 ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") trials, we believe ensifentrine, if approved, has the potential to change the treatment paradigm for COPD.

"With about 50% of patients experiencing symptoms for more than 24 days per month, physicians are in need of new and effective COPD therapies. The success of the ENHANCE trials advances us closer to providing ensifentrine to COPD patients, with its novel mechanism of action delivering bronchodilation and non-steroidal anti-inflammatory effects in one compound. The totality of data from clinical trials, in particular our top-line data from the ENHANCE program including improvements in lung function, symptoms and quality of life measures, and remarkable reduction in the rate and risk of COPD exacerbations, combined with ensifentrine's favorable safety profile, support our belief in the pioneering potential of ensifentrine.

"Our clinical success enabled us to significantly strengthen our financial position through an upsized $150 million equity offering in August and a $150 million debt financing facility in October. We expect these funds to extend our cash runway through at least the end of 2025.

"Alongside our progress in 2022, our development partner Nuance Pharma received clearance from China's Center for Drug Evaluation to begin Phase 1 and Phase 3 studies with ensifentrine for COPD in mainland China. Nuance Pharma are developing and commercializing ensifentrine in Greater China and we look forward to providing future updates.

"2023 is expected to be another pivotal year for Verona Pharma as we continue preparing for the planned commercial launch of ensifentrine in the US in 2024, if approved. We expect to submit a New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") in the second quarter of 2023 and to release additional information from the ENHANCE trials at upcoming scientific conferences."

Program Updates and Key Milestones

The Company's near-term milestones include:

- Submitting an NDA to the US FDA in the second quarter of 2023 for inhaled ensifentrine for the maintenance treatment of patients with COPD.

Fourth Quarter and Recent Highlights

Clinical

- In December 2022, the Company reported positive top-line Phase 3 data from its ENHANCE-1 trial. The trial successfully met its primary and key secondary endpoints demonstrating significant improvements in lung function, symptoms and quality of life measures. In addition, ensifentrine substantially reduced the rate and risk of COPD exacerbations. Ensifentrine was well tolerated over 24 and 48 weeks.

  Pooled exacerbation data from ENHANCE-1 and ENHANCE-2 trials demonstrated that ensifentrine treatment resulted in a statistically significant 40% reduction in the rate of moderate to severe COPD exacerbations over 24 weeks compared to placebo. Additionally, ensifentrine significantly decreased the risk of a moderate/severe exacerbation by 41%.

Corporate

- In October 2022, the Company completed a $150 million debt financing facility with Oxford Finance. This replaced the $30 million facility with Silicon Valley Bank and is available upon achievement of certain clinical and regulatory milestones and other conditions.

Fourth Quarter 2022 Financial Results

- **Cash position:** Cash and cash equivalents at December 31, 2022, were $227.8 million (December 31, 2021: $148.4 million). Between January 1, 2023 and March 3, 2023, the Company sold 2,540,173 ADS's under its ATM facility receiving net proceeds of $56.9 million. After giving effect to these proceeds, our pro forma cash and equivalents at December 31, 2022, was $284.7 million. The Company believes cash and cash equivalents at December 31, 2022, the proceeds from the recent ATM sales, expected cash receipts from the UK tax credit program and funding expected to become available under the $150.0 million debt facility, will enable Verona Pharma to fund planned operating expenses and capital expenditure requirements through at least the end of 2025 including the commercial launch of ensifentrine in the US, if approved.
- **R&D Expenses:** Research and development ("R&D") expenses were $6.8 million for the fourth quarter ended December 31, 2022 (Q4 2021: $22.7 million). This decrease of $15.9 million was primarily due to a $16.7 million decrease in clinical trial and other development costs as the Company progressed to the later stages of the Phase 3 ENHANCE program.
- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were $8.3 million for the fourth quarter ended December 31, 2022 (Q4 2021: $5.8 million). The increase of $2.5 million was primarily due to a $1.4 million increase in people-related costs and $0.5 million in commercial preparation costs.
- **Net loss:** Net loss was $10.5 million for the fourth quarter ended December 31, 2022 (Q4 2022: net loss $23.3 million).

Full Year 2022 Financial Results

- **Revenue:** Revenue of $0.5 million for the year ended December 31, 2022 is related to sales of clinical supply materials to Nuance (full year 2021: $40.0 million).
- **R&D Expenses:** R&D expenses were $49.3 million for the year ended December 31, 2022 (full year 2021: $79.4 million), a decrease of $30.1 million. This decrease was primarily driven by a decrease in clinical trial and other development costs of $27.9 million as the ENHANCE studies were nearing completion in 2022 and a $4.2 million decrease in share-based compensation charges.
- **SG&A Expenses:** SG&A expenses were $26.6 million for the year ended December 31, 2022 (full year 2021: $33.9 million), a decrease of $7.3 million. This decrease was driven primarily by a $7.1 million decrease in share-based compensation charges.
- **Net loss:** Net loss was $68.7 million for the year ended December 31, 2022 (full year 2021: $55.6 million).

Conference Call and Webcast Information

Verona Pharma will host an investment community webcast and conference call at 9:00 a.m. EST / 2:00 p.m. GMT on Tuesday, March 7, 2023, to discuss the fourth quarter and full year 2022 financial results and the corporate update.

To participate, please dial one of the following numbers and ask to be placed into the Verona Pharma third quarter earnings call:

- +1-833-816-1396 for callers in the United States
- +1-412-317-0489 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 2022 results press release will also be made available today on the Company's website.

For further information please contact:

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Mary Clark / Richard Staines / Zoe Bolt	

About Verona Pharma

Verona Pharma is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of chronic 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 has evaluated nebulized ensifentrine in its Phase 3 clinical program ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") for COPD maintenance treatment. Ensifentrine met the primary endpoint in both ENHANCE-1 and ENHANCE-2 trials demonstrating statistically significant and clinically meaningful improvements in lung function. In addition, ensifentrine significantly reduced the rate and risk of COPD exacerbations in pooled analysis from ENHANCE-1 and ENHANCE-2. Two additional formulations of ensifentrine have been evaluated in Phase 2 studies 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.

Forward-Looking Statements

This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding our operational review, outlook and financial review, the development of ensifentrine and plans to release data from the ENHANCE trials at future scientific conferences, planned regulatory submissions and timing thereof, including the timing of submission of an NDA for ensifentrine, the planned US commercial launch of ensifentrine in 2024, the potential for ensifentrine to be the first therapy for the treatment of respiratory diseases to combine bronchodilator and non-steroidal anti-inflammatory benefits in one compound, the potential of ensifentrine to change the treatment paradigm for COPD patients, and the potential of ensifentrine in the treatment of cystic fibrosis, asthma and other respiratory diseases, as well as the potential of the DPI and pMDI formulations of ensifentrine, ensifentrine's compelling benefit risk profile, the funding we expect to become available under the $150.0 million debt financing facility and from cash receipts from UK tax credits, and the sufficiency of cash and cash equivalents, and the cash runway period provided by the sources of financing through to at least the end of 2025 and expected to fully fund the planned commercial launch.

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; 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, 2022, 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,	
	2022	2021	2022	2021
Revenue	$ 458	$ -	$ 458	$ 40,000
Cost of sales	(346)	-	(346)	-
Gross profit	112	-	112	40,000
Operating expenses				
Research and development	6,838	22,709	49,283	79,406
Selling, general and administrative	8,323	5,757	26,579	33,907
Total operating expenses	15,161	28,466	75,862	113,313
Operating loss	(15,049)	(28,466)	(75,750)	(73,313)
Other income / (expense)				
Research & development tax credit	796	4,975	9,634	15,630
Loss on extinguishment of debt	(815)	-	(815)	-
Interest income	1,862	3	2,821	14
Interest expense	(230)	(85)	(521)	(340)
Fair value movement on warrants	-	2	-	2,246
Foreign exchange gain / (loss)	3,013	59	(3,817)	176
Total other income, net	4,626	4,954	7,302	17,726
Loss before income taxes	(10,423)	(23,512)	(68,448)	(55,587)
Income tax income / (expense)	(28)	250	(253)	18
Net loss	$ (10,451)	$ (23,262)	$ (68,701)	$ (55,569)
Weighted average shares outstanding – basic and diluted	604,204,929	479,210,145	529,071,526	473,188,457
Net loss per ordinary share – basic and diluted	$ (0.02)	$ (0.05)	$ (0.13)	$ (0.12)

	2022	2021
Cash and cash equivalents	$ 227,827	$ 148,380
Total assets	259,468	186,587
Shareholders' equity	$ 230,466	$ 148,005

* Unaudited