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): November 9, 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 November 9, 2022, Verona Pharma plc announced its financial results for the quarter ended September 30, 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 November 9, 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: November 9, 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 Third Quarter 2022 Financial Results and Provides Corporate Update

Access to up to $400 million expected to provide cash runway through at least 2025

Top-line Phase 3 ENHANCE-1 data expected around the end of 2022

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

LONDON and RALEIGH, N.C., November 9, 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 three months ended September 30, 2022, and provides a corporate update.

"We have significantly strengthened our financial position with access up to approximately $400 million, through our cash on hand and recently announced $150 million debt facility from Oxford Finance," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "We expect these funds to extend our cash runway through at least the end of 2025, supporting the ongoing pre-commercialization activities for ensifentrine and the planned commercial launch in the United States.

"Ensifentrine demonstrated consistent positive effects across primary and secondary endpoints of lung function including subgroups in the Phase 3 ENHANCE-2 ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") trial. Additional analyses demonstrated positive effects of ensifentrine in reducing rates of exacerbations across clinically relevant subgroups. We are very encouraged by these data and look forward to reporting our ENHANCE-1 results around the end of the year.

"Alongside our clinical progress, Nuance Pharma, our development partner, received clearance from China's Center for Drug Evaluation ("CDE") to begin Phase 1 and Phase 3 studies with ensifentrine for chronic obstructive pulmonary disease ("COPD") in mainland China. Nuance Pharma is responsible for developing and commercializing ensifentrine in Greater China and we look forward to providing future updates."

Program Updates and Key Milestones

The Company's near-term milestones include:

- Reporting top-line data from ENHANCE-1 around the end of 2022.
- Conditional upon positive results, Verona Pharma expects to submit a New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") in the first half of 2023 for inhaled ensifentrine for the maintenance treatment of COPD.

Third Quarter and Recent Highlights

Clinical

- In October 2022, the Company reported additional positive Phase 3 ENHANCE-2 results demonstrating ensifentrine reduced rates of moderate and severe COPD exacerbations across all subgroups analyzed over 24 weeks. Results of the subgroup analyses confirmed effects consistent with the 42% reduction in the rate of moderate to severe exacerbations observed in the overall population compared to placebo. ENHANCE-2 was not powered for exacerbation rate.
- In August 2022, the Company reported positive top-line Phase 3 data from ENHANCE-2. The trial successfully met its primary endpoint and secondary endpoints evaluating lung function. Ensifentrine also significantly reduced the rate and risk of COPD exacerbations. Ensifentrine was well tolerated with safety results similar to placebo.

Corporate

- During the third and early fourth quarter, Verona Pharma completed financings valued at up to $300 million with an upsized $150 million equity offering in August and a $150 million debt financing facility with Oxford Finance in October. The $150 million debt facility replaces the existing $30 million facility with Silicon Valley Bank and is available upon achievement of certain clinical and regulatory milestones and other conditions. The September 30 cash balances, together with potential draws from the debt facility and expected cash receipts from the UK tax credit program, are expected to finance the planned commercial launch of nebulized ensifentrine for COPD maintenance treatment in the US through at least the end of 2025.
- During the third quarter, Verona Pharma expanded the senior leadership team with appointments across marketing, market access, commercial operations, IT, HR and finance.
- In August 2022, Verona Pharma's development partner, Nuance Pharma, received clearance from the China CDE to begin Phase 1 and Phase 3 studies with ensifentrine for COPD in mainland China. In 2021, Verona Pharma entered into an agreement with Nuance Pharma for exclusive rights to develop and commercialize ensifentrine in Greater China, with future potential milestone payments up to $179 million plus royalties.

Third Quarter 2022 Financial Results

- **Cash position:** Cash and cash equivalents at September 30, 2022, were $231.7 million (June 30, 2022: $111.5 million). The Company believes cash and cash equivalents at September 30, 2022, 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.
- **R&D Expenses:** Research and development ("R&D") expenses were $9.8 million for the third quarter ended September 30, 2022 (Q3 2021: $22.6 million). The decrease of $12.8 million was primarily due to a $12.5 million decrease in clinical trial and other development costs as the Company progressed to the later stages of the Phase 3 ENHANCE program and a $0.6 million decrease in share-based compensation.
- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were $5.3 million for the third quarter ended September 30, 2022 (Q3 2021: $10.9 million). The decrease of $5.6 million was primarily due to a $4.0 million non-recurring expense associated with the Nuance Agreement in 2021 and a $1.6 million decrease in share-based compensation.
- **Net loss:** Net loss was $15.6 million for the third quarter ended September 30, 2022 (Q3 2021: net profit $11.1 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 Wednesday, November 9, 2022, to discuss the third quarter 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:

- +1-866-652-5200 for callers in the United States
- +1-412-317-6060 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 third quarter 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 / Rebecca Noonan / Zoe Bolt	

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. Ensifentrine met the primary endpoint in ENHANCE-2 demonstrating a statistically significant and clinically meaningful improvement in lung function. In addition, ensifentrine significantly reduced the rate of COPD exacerbations in the ENHANCE-2 trial. ENHANCE-1 is expected to report around the end of 2022. 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.

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 the progress and timing of clinical trials and data, the assumptions underlying the Company's models on clinical trial progress, 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 $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 the fully funding of the 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; potential delays in enrolling subjects, 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

(unaudited)

	Three months ended September 30,	
	2022	2021
	($000's)	($000's)
Revenue	$ -	$ 40,000
Gross profit	-	40,000
Operating expenses		
Research and development	$ 9,838	$ 22,560
Selling, general and administrative	5,290	10,883
Total operating expenses	15,128	33,443
Operating (loss)/profit	(15,128)	6,557
Other (expense)/income		
Research and development tax credit	2,127	4,749
Interest income	779	4
Interest expense	(116)	(86)
Fair value movement on warrants	-	40
Foreign exchange loss	(3,245)	(86)
Total other (expense)/income, net	(455)	4,621
(Loss)/profit before income taxes	(15,583)	11,178
Income tax expense	(64)	(127)
Net (loss)/profit	$ (15,647)	$ 11,051
Weighted-average shares outstanding – basic	544,134,136	475,334,354
Weighted-average shares outstanding – diluted	544,134,136	515,819,439
(Loss)/profit per ordinary share – basic	$ (0.03)	$ 0.02
(Loss)/profit per ordinary share – diluted	(0.03)	0.02

	September 30 2022	June 30 2022
Cash and cash equivalents	$ 231,701	$ 111,510
Total assets	$ 274,872	$ 154,856
Equity	$ 237,485	$ 110,880