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): May 9, 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 May 9, 2023, Verona Pharma plc announced its financial results for the quarter ended March 31, 2023. 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 May 9, 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: May 9, 2023

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

Verona Pharma Reports First Quarter 2023 Financial Results and Provides Corporate Update

NDA submission on schedule for Q2 2023

12 abstracts and one symposium expanding on successful Phase 3 ENHANCE data to be presented at American Thoracic Society 2023

Strong balance sheet to support commercial launch preparations

Conference call today at 9:00 a.m. EDT / 2:00 p.m. BST

LONDON and RALEIGH, N.C., May 9, 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 first quarter ended March 31, 2023, and provides a corporate update.

"We recently had a pre-New Drug Application ("NDA") meeting with the US Food and Drug Administration ("FDA") and are on schedule to submit the NDA in the second quarter of 2023," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "We believe we are aligned on the content of the NDA for ensifentrine for the maintenance treatment of Chronic Obstructive Pulmonary Disease ("COPD"), which will comprise data from the successful Phase 3 ENHANCE studies and other completed ensifentrine clinical studies including data from approximately 3,000 subjects.

"As announced earlier this month, we are looking forward to presenting additional analyses from the ENHANCE studies at the American Thoracic Society International Conference ("ATS") taking place May 19-24. We will present 12 abstracts and a clinical trials symposium on subgroup data and pooled analyses from ENHANCE-1 and ENHANCE-2 covering exacerbations, symptoms, quality of life, use of rescue medication, healthcare utilization and safety. An overview of the ENHANCE trial results will be presented as part of the clinical trials symposium reserved for highlighting new breakthroughs. The abstracts are published on the ATS website and in the publication, *American Journal of Respiratory and Critical Care Medicine*. We will be hosting a webcast and conference call on Tuesday, May 23, to discuss these data.

"Alongside our progress, Nuance Pharma, our development partner in Greater China, enrolled the first subject in its Phase 3 trial evaluating ensifentrine for the maintenance treatment of COPD in China. This is a significant milestone and we are excited about the potential of ensifentrine to address the urgent global need for a novel therapy for COPD. We look forward to updating you on their progress."

Program Updates and Key Milestones

The Company's near-term planned milestones include:

- Presentation of 12 abstracts and one symposium demonstrating positive efficacy, symptom, quality of life and safety data from the ENHANCE Phase 3 clinical studies with nebulized ensifentrine in COPD at ATS in May 2023. The Company is holding an investment community webcast and conference call at 4:00 p.m. EDT / 9:00 p.m. BST on Tuesday, May 23, 2023, to discuss these data. To participate, please dial one of the following numbers and ask to join the Verona Pharma 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.
- Submission of an NDA to the US FDA in the second quarter of 2023 for inhaled ensifentrine for the maintenance treatment of patients with COPD.

First Quarter and Recent Highlights

Corporate

- In April 2023, the Company held a pre-NDA meeting with the FDA. The submission, comprising data from the Phase 3 ENHANCE studies and other completed ensifentrine clinical studies including data from approximately 3,000 subjects, is on schedule for the second quarter of 2023.
- Also in April 2023, the Company's development partner in Greater China, Nuance Pharma, enrolled the first subject in its pivotal Phase 3 clinical trial evaluating ensifentrine for the maintenance treatment of COPD in 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.

First Quarter 2023 Financial Results

- **Cash position:** Cash and cash equivalents at March 31, 2023, were $291.4 million (December 31, 2022: $227.8 million). The Company believes cash and cash equivalents at March 31, 2023, 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 $12.6 million for the first quarter ended March 31, 2023 (Q1 2022: $17.6 million). This decrease was primarily due to a $5.1 million decrease in clinical trial and other development costs as the Phase 3 ENHANCE program is in the final stages of completing data analysis whereas in the same period in the prior year significant costs were incurred associated with active enrollment.
- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were $9.6 million for the first quarter ended March 31, 2023 (Q1 2022: $7.4 million). This increase was primarily due to a $2.7 million increase in people related costs, inclusive of share-based compensation, as well as an increase of $0.8 million for costs related to the build out of commercial infrastructure in preparation for a potential commercial launch. The increases were partially offset by a non-recurring $2.0 million charge related to the modification of the assignment and license agreement with Ligand UK Development Limited, which was incurred in the three months ended March 31, 2022.
- **Net loss:** Net loss was $16.7 million for the first quarter ended March 31, 2023 (Q1 2022: net loss $24.8 million).

Conference Call and Webcast Information

Verona Pharma will host an investment community webcast and conference call at 9:00 a.m. EDT / 2:00 p.m. BST on Tuesday, May 9, 2023, to discuss the first quarter 2023 financial results and the corporate update.

To participate, please dial one of the following numbers and ask to be placed into the Verona Pharma first 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 first quarter 2023 results press release will also be made available today on the Company's website.

For further information please contact:

Verona Pharma plc	US Tel: +1-833-417-0262 UK Tel: +44 (0)203 283 4200
Victoria Stewart, Senior Director of Investor Relations and Communications	IR@veronapharma.com
Argot Partners (US Investor Enquiries)	Tel: +1-212-600-1902 verona@argotpartners.com
Optimum Strategic Communications (International Media and European Investor Enquiries)	Tel: +44 (0)203 882 9621 verona@optimumcomms.com
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, upcoming events and presentations, planned regulatory submissions and timing thereof, including the timing of submission of an NDA for ensifentrine and our expectations regarding the content of the submission, the planned US commercial launch of ensifentrine, 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, as updated in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 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)

(in thousands, except per share amounts)

	Three months ended March 31,	
	2023	2022
Operating expenses		
Research and development	$ 12,610	$ 17,625
Selling, general and administrative	9,589	7,440
Total operating expenses	22,199	25,065
Operating loss	(22,199)	(25,065)
Other income/(expense)		
Research and development tax credit	2,313	1,302
Interest income	2,677	15
Interest expense	(293)	(84)
Foreign exchange gain/(loss)	932	(923)
Total other income, net	5,629	310
Loss before income taxes	(16,570)	(24,755)
Income tax expense	(173)	(82)
Net loss	$ (16,743)	$ (24,837)
Weighted-average shares outstanding – basic and diluted	621,451	481,942
Loss per ordinary share – basic and diluted	$ (0.03)	$ (0.05)

	Mar-31 2023	Mar-31 2022
Cash and cash equivalents	$ 291,415	$ 132,764
Total assets	$ 323,146	$ 169,315
Shareholders' equity	$ 276,749	$ 126,307