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): August 3, 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 August 3, 2023, Verona Pharma plc announced its financial results for the quarter ended June 30, 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 August 3, 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: August 3, 2023

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

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

NDA submitted to US FDA for ensifentrine for maintenance treatment of COPD

Phase 3 ENHANCE data published in the American Journal of Respiratory and Critical Care Medicine

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., August 3, 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 second quarter ended June 30, 2023, and provides a corporate update.

"In June, we submitted a New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") for approval of ensifentrine for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD")," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "This brings us an important step closer towards providing this novel compound to the millions of symptomatic COPD patients in need of a new effective treatment approach. The FDA is expected to make a decision on acceptance of the NDA in the third quarter."

"Also in June, the *American Journal of Respiratory and Critical Care Medicine ("AJRCCM"),* published results from the successful Phase 3 ENHANCE trials. The data demonstrated ensifentrine improved lung function, symptoms and quality of life and substantially reduced the rate and risk of COPD exacerbations with a favorable safety profile. We are looking forward to presenting additional analyses from the ENHANCE program at the European Respiratory Society International Congress and at CHEST Annual Meeting later this year."

Program Updates and Key Milestones

The Company's near-term planned milestones include:

- In the third quarter of 2023, the US FDA is expected to make a decision on acceptance of the Company's NDA for inhaled ensifentrine for the maintenance treatment of patients with COPD.
- Also in the third quarter of 2023, the Company plans to continue to advance its commercialization efforts across medical affairs, marketing, commercial operations, IT and CMC as well as other departments to support the planned launch of ensifentrine in 2024, subject to the approval of the NDA.
- In the second half of 2023, the Company plans to present further analyses from the Phase 3 ENHANCE trials at the European Respiratory Society International Congress 2023 and at CHEST Annual Meeting 2023.
- Also in the second half of 2023, the Company plans to host an analyst meeting providing an overview of its commercial launch plans.

Second Quarter and Recent Highlights

- In June 2023, the Company submitted a NDA to the US FDA for ensifentrine for the maintenance treatment of patients with COPD.
- Also in June 2023, the *American Journal of Respiratory and Critical Care Medicine ("AJRCCM")* published results from the successful Phase 3 ENHANCE trials evaluating ensifentrine in COPD.
- In May 2023, the Company presented 12 abstracts and a symposium on expanded analyses of the ENHANCE studies with ensifentrine for the treatment of COPD at the American Thoracic Society International Conference ("ATS") 2023. The abstracts are published on the ATS website and in the *AJRCCM*.

Second Quarter 2023 Financial Results

- **Cash position:** Cash and cash equivalents at June 30, 2023, were $270.7 million (December 31, 2022: $227.8 million). The Company believes cash and cash equivalents at June 30, 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 a net reversal of $2.5 million for the second quarter ended June 30, 2023 (Q2 2022: costs of $15.0 million). R&D expenses were significantly lower in 2023 versus in 2022 as study conduct in the Phase 3 ENHANCE program completed late in 2022 with data analysis and wind-down expenses in Q2 2023. In addition, the Company favorably resolved a matter with a supplier, as well as certain disputed invoices, in Q2 2023 resulting in the reversal of approximately $6.3 million of costs accrued in prior periods, which resulted in net negative R&D expense for the three months ended June 30, 2023.
- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were $12.4 million for the second quarter ended June 30, 2023 (Q2 2022: $5.5 million). This increase was primarily due to a $5.0 million increase in people related costs, inclusive of share-based compensation, as well as an increase of $1.7 million for costs related to the build out of commercial and information technology infrastructure in preparation for a potential commercial launch. The Company expects SG&A expenses to continue to be the main driver of expense as Verona Pharma prepares for a potential commercial launch in 2024.
- **Net loss:** Net loss was $8.8 million for the second quarter ended June 30, 2023 (Q2 2022: net loss $17.8 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 Thursday, August 3, 2023, to discuss the second 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 second 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 second 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
Ten Bridge Communications International / US Media Enquiries	Tel: +1-312-523-5016 tbcverona@tenbridgecommunications.com
Leslie Humbel	

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 non-sterodial 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 substantially reduced the rate and risk of COPD exacerbations in pooled analysis from ENHANCE-1 and ENHANCE-2. In the second quarter of 2023, Verona Pharma submitted a New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") for ensifentrine for the maintenance treatment of patients with COPD. 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 timing of the FDA's decisions on the acceptance and approval of the NDA for ensifentrine, the development of ensifentrine and plans to release data from the ENHANCE trials at future scientific conferences, upcoming events and presentations, the planned US commercial launch of ensifentrine and timing thereof and the advancement of commercialization efforts in support of the launch, 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, 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, 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 Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 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 June 30,	
	2023	2022
Operating expenses		
Research and development	$ (2,474)	$ 14,982
Selling, general and administrative	12,439	5,526
Total operating expenses	9,965	20,508
Operating loss	(9,965)	(20,508)
Other income/(expense)		
Research and development tax credit	(1,934)	5,409
Interest income	3,402	165
Interest expense	(740)	(91)
Foreign exchange gain/(loss)	740	(2,662)
Total other income, net	1,468	2,821
Loss before income taxes	(8,497)	(17,687)
Income tax expense	(310)	(79)
Net loss	$ (8,807)	$ (17,766)
Weighted-average shares outstanding – basic and diluted	634,469	484,778
Loss per ordinary share – basic and diluted	$ (0.01)	$ (0.04)

	Jun-30 2023	Mar-31 2023
Cash and cash equivalents	$ 270,727	$ 291,415
Total assets	$ 303,929	$ 323,146
Shareholders' equity	$ 273,093	$ 276,749