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 2, 2023

Verona Pharma plc

(Exact name of registrant as specified in its charter)

United Kingdom	**001-38067**	**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 2, 2023, Verona Pharma plc announced its financial results for the quarter ended September 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 November 2, 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: November 2, 2023

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

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

US FDA accepted NDA filing for ensifentrine for maintenance treatment of COPD

PDUFA Target Action Date of June 26, 2024

Commercial launch preparations supported by strong balance sheet

Conference call today at 9:00 a.m. EDT / 1:00 p.m. GMT

LONDON and RALEIGH, N.C., November 2, 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 third quarter ended September 30, 2023, and provides a corporate update.

"In August, the US Food and Drug Administration ("FDA") accepted for review our New Drug Application ("NDA") seeking 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. "The Agency assigned a Prescription Drug User Fee Act ("PDUFA") target action date of June 26, 2024, and is not currently planning to hold an advisory committee meeting to discuss the application.

"The NDA acceptance brings us a step closer to our goal of delivering ensifentrine to a broad population of patients suffering from COPD and we look forward to working with the FDA during their review. If approved, ensifentrine is expected to be the first novel mechanism available for the treatment of COPD in more than 10 years. We believe the bronchodilator and non-steroidal anti-inflammatory activity of ensifentrine has the potential to change the treatment paradigm for COPD.

"Following the end of the quarter, we hosted an investor meeting during which the Company's senior management team and key opinion leader, Cedric "Jamie" Rutland, MD, FCCP, discussed the COPD treatment landscape and provided an overview of our commercial preparations for the US launch of ensifentrine, if approved. The Company also shared a detailed overview of the current COPD market, unmet treatment needs, launch access, distribution, reimbursement strategies and plans for field deployment.

"The Company recently presented further analyses from the Phase 3 ENHANCE trials at the European Respiratory Society International Congress and at CHEST Annual Meeting. The analyses showed that ensifentrine demonstrated improvements in lung function and symptoms and quality of life endpoints and substantially reduced the rate and risk of COPD exacerbations regardless of background therapy, as well as reduced daily rescue medication use.

"Also at CHEST, we launched the 'unspoken COPD' disease awareness campaign. The campaign highlights the severe impact COPD has on a patient's daily life and encourages healthcare professionals to engage in deeper conversations to fully understand the impact of COPD on each patient in their practice."

Program Updates and Key Milestones

The Company's near-term planned milestones include:

- In the fourth quarter of 2023, the Company plans to continue its commercial preparations across medical affairs, commercial operations, manufacturing and IT as well as other departments to support the planned launch of ensifentrine in 2024, subject to the approval of the NDA.

- The Company is developing a fixed-dose combination formulation with ensifentrine and glycopyrrolate, a long-acting muscarinic antagonist (“LAMA”), for the maintenance treatment of patients with COPD via delivery in a nebulizer. If a feasible formulation is developed, in the second half of 2024, the Company plans to submit an investigational new drug (“IND”) application to the FDA and, if cleared, initiate a Phase 2 clinical trial assessing the safety and efficacy of the fixed-dose combination formulation in COPD patients.
- Also in the second half of 2024, if the FDA approves the Company’s NDA for ensifentrine as a maintenance treatment of COPD, the Company plans to commence a Phase 2 clinical trial to assess the efficacy and safety of nebulized ensifentrine in patients with non-cystic fibrosis bronchiectasis, subject to clearance by the FDA.

Third Quarter and Recent Highlights

- In August 2023, the FDA accepted for review the Company's NDA filing seeking US approval of ensifentrine for the maintenance treatment of patients with COPD. The FDA assigned a PDUFA target action date of June 26, 2024, and is not currently planning to hold an advisory committee meeting to discuss the application.
- In September 2023, Christina Ackermann joined the board as a Non-Executive Director. Ms. Ackermann has over 25 years of legal and management experience across the pharmaceutical, device and consumer products industries. Most recently, she served as Executive Vice President, General Counsel and Global President Ophthalmic Pharmaceuticals at Bausch + Lomb Corporation, where she was responsible for strategic planning and worldwide commercialization of pharmaceutical prescription assets across the portfolio as well as global legal affairs.
- The Company recently presented additional analyses of data from the successful ENHANCE trials evaluating ensifentrine in COPD at ERS International Congress 2023 and CHEST Annual Meeting 2023. Also, at CHEST Annual Meeting, the Company launched a disease awareness campaign highlighting how many COPD patients struggle to talk about their condition.

Third Quarter 2023 Financial Results

- **Cash position:** Cash and cash equivalents at September 30, 2023, were $257.4 million (December 31, 2022: $227.8 million). The Company believes cash and cash equivalents at September 30, 2023, expected cash receipts from the UK tax credit program and the remaining $130.0 million funding expected to become available under the 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 $3.0 million for the third quarter ended September 30, 2023 (Q3 2022: $9.8 million). This decrease was primarily due to a $7.9 million decrease in clinical trial and other development costs as all study conduct and analysis of the Phase 3 ENHANCE program was complete, whereas in the same period in the prior year significant costs were incurred associated with the then ongoing study conduct. The third quarter 2023 clinical trial and other development costs also include the impact of $2.2 million of credits received related to the final financial reconciliation of a Phase 3 ENHANCE program supplier. This decrease was partially offset by an increase of $0.7 million in people related costs, inclusive of share-based compensation.
- **SG&A Expenses:** Selling, general and administrative expenses (“SG&A”) were $13.4 million for the third quarter ended September 30, 2023 (Q3 2022: $5.3 million). This increase was primarily due to a $4.7 million increase in people related costs,

inclusive of share-based compensation, as well as an increase of $2.9 million for costs primarily related to preparations for a potential commercial launch including the build out of the distribution network and work related to payer and disease education as well as advancing the commercial and information technology infrastructure of the Company.

- **Net loss:** Net loss was $14.7 million for the third quarter ended September 30, 2023 (Q3 2022: $15.6 million).

Conference Call and Webcast Information

Verona Pharma will host an investment community webcast and conference call at 9:00 a.m. EDT / 1:00 p.m. GMT on Thursday, November 2, 2023, to discuss the third 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 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 third quarter 2023 results press release will also be made available today on the Company's website.

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 chronic respiratory diseases with significant unmet medical needs. If successfully developed and approved, Verona Pharma's product candidate, ensifentrine, has the potential to become the first non-steroidal therapy for the treatment of respiratory diseases that combines bronchodilator and anti-inflammatory activities in one molecule. 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 third quarter of 2023, the US Food and Drug Administration accepted for review the Company's NDA for ensifentrine for the maintenance treatment of patients with COPD and assigned a PDUFA target action date of June 26, 2024. Two additional formulations of ensifentrine have been evaluated in Phase 2 trials for the treatment of COPD: dry powder

inhaler (“DPI”) and pressurized metered-dose inhaler (“pMDI”). Ensifentrine has potential applications in non-cystic fibrosis bronchiectasis, 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 decision on the approval of the NDA for ensifentrine and the assigned PDUFA target action date, the planned US commercial launch of ensifentrine and timing thereof and the advancement of commercialization preparations in support of the launch, the potential for ensifentrine to be the first novel mechanism available for the treatment of COPD in more than 10 years and the first therapy for the treatment of respiratory diseases to combine bronchodilator and non-steroidal anti-inflammatory benefits in one compound, the planned development of a fixed-dose combination formulation of ensifentrine and glycopyrrolate for the treatment of COPD and the planned development and potential of ensifentrine in the treatment of non-cystic fibrosis bronchiectasis 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 remaining $130 million funding we expect to become available under the debt facility and from cash receipts from UK tax credits, and the sufficiency of our 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 fund our operations.

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, June 30, 2023 and September 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 September 30,	
	2023	2022
Operating expenses		
Research and development	$ 2,958	$ 9,838
Selling, general and administrative	13,353	5,290
Total operating expenses	16,311	15,128
Operating loss	(16,311)	(15,128)
Other income/(expense)		
Research and development tax credit	(309)	2,127
Interest income	3,390	779
Interest expense	(401)	(116)
Foreign exchange (loss)/gain	(1,012)	(3,245)
Total other income/(expense), net	1,668	(455)
Loss before income taxes	(14,643)	(15,583)
Income tax expense	(44)	(64)
Net loss	$ (14,687)	$ (15,647)
Weighted-average shares outstanding – basic and diluted	638,239	544,134
Loss per ordinary share – basic and diluted	$ (0.02)	$ (0.03)

	Sep-30 2023	Jun-30 2023
Cash and cash equivalents	$ 257,366	$ 270,727
Total assets	$ 292,470	$ 303,929
Shareholders' equity	$ 263,533	$ 273,093