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 4, 2024

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 4, 2024, Verona Pharma plc announced its financial results for the quarter ended September 30, 2024. 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 4, 2024
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 4, 2024

By: /s/ David Zaccardelli, Pharm. D.
Name: David Zaccardelli, Pharm. D.
Title: President and Chief Executive Officer

Verona Pharma Reports Third Quarter 2024 Financial Results and Provides Corporate Update

Ohtuvayre™ (ensifentrine) launch recorded Q3 net sales of $5.6 million and October net sales exceeded Q3

Through October more than 2,200 unique prescribers and more than 5,000 prescriptions filled across a broad COPD population

Pipeline expansion continues: Phase 2 programs enrolling

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

LONDON and RALEIGH, N.C., November 4, 2024 – Verona Pharma plc (Nasdaq: VRNA) ("Verona Pharma" or the "Company"), a biopharmaceutical company focused on respiratory diseases, announces its financial results for the third quarter ended September 30, 2024, and provides a corporate update.

"We are pleased to report an exceptionally strong start to the US launch of Ohtuvayre (ensifentrine) with healthcare professionals (HCPs) prescribing treatment across a broad range of chronic obstructive pulmonary disease ("COPD") patients including background single, dual and nearly 50% on triple therapy," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "While it is still very early in the launch, we are extremely encouraged from the initial patient and HCP reports about Ohtuvayre's potential to improve COPD symptoms regardless of COPD severity. This broad utilization across all patient types is consistent with market research and supports our belief that Ohtuvayre's bronchodilator and non-steroidal anti-inflammatory activity is a significant advancement for COPD patients and can re-define the treatment paradigm.

"In the third quarter, through the first seven weeks of launch, we recorded $5.6 million of net sales. We are excited by the continued acceleration as net sales for October exceeded the third quarter. More than 5,000 Ohtuvayre prescriptions were filled and more than 2,200 unique HCPs prescribed Ohtuvayre in just 12 weeks.

"Alongside our successful Ohtuvayre launch, in the third quarter we initiated two Phase 2 clinical trials: a dose-ranging trial with glycopyrrolate, a long-acting muscarinic antagonist ("LAMA"), supporting a nebulized fixed-dose combination program with ensifentrine for the maintenance treatment of COPD, and a trial assessing the efficacy and safety of nebulized ensifentrine in patients with non-cystic fibrosis bronchiectasis ("NCFBE")."

Third Quarter and Recent Highlights

- In August 2024, the Company launched Ohtuvayre for the maintenance treatment of COPD in the US.
- During the third quarter of 2024, the Company began enrollment in two new clinical programs:
  - Phase 2 dose-ranging trial with glycopyrrolate, a LAMA, supporting a fixed-dose combination program for the maintenance treatment of COPD via a nebulizer.
  - Phase 2 trial to assess the efficacy and safety of nebulized ensifentrine in patients with NCFBE.

- Following the end of the third quarter, the Company received notification from the Centers for Medicare & Medicaid Services that its permanent, product-specific J-code for Ohtuvayre, J7601, has been accepted and will be effective January 1, 2025.
- The Company recently presented additional analyses of data from the Phase 3 ENHANCE trials with ensifentrine for the maintenance treatment of COPD at the European Respiratory Society International Congress 2024 and at CHEST Annual Meeting 2024 ("CHEST"). Approximately 1,500 HCPs visited Verona Pharma's medical and commercial booths for Ohtuvayre at CHEST.
- In September 2024, the Company's development partner in Greater China, Nuance Pharma, completed enrollment in its pivotal Phase 3 clinical trial evaluating ensifentrine for the maintenance treatment of COPD in China. Results from the trial are expected in 2025.

Third Quarter 2024 Financial Results

- **Cash position:** Cash and cash equivalents at September 30, 2024 were $336.0 million (December 31, 2023: $271.8 million). The Company believes cash and cash equivalents at September 30, 2024, along with product sales and funding expected to become available under the $650 million strategic financings completed in May 2024, will enable Verona Pharma to fund planned operating expenses and capital expenditure requirements through at least the end of 2026.
- **Product sales:** Net sales were $5.6 million for the third quarter ended September 30, 2024 (Q3 2023: $0 million) related to product sales of Ohtuvayre. The Company received FDA approval on June 26, 2024 and the product was commercially available beginning in August 2024.
- **Cost of sales:** Cost of sales was $0.5 million for the third quarter ended September 30, 2024 (Q3 2023: $0 million), which included Ohtuvayre manufacturing costs incurred after US approval, inventory overhead costs and sales-based royalties due to Ligand.
- **R&D Expenses:** Research and development ("R&D") expenses were $10.6 million for the third quarter ended September 30, 2024 (Q3 2023: $3.0 million). This increase of $7.6 million was primarily due to an $7.8 million increase in clinical trial and other development costs as we initiated two Phase 2 trials in the quarter.
- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were $35.2 million for the third quarter ended September 30, 2024 (Q3 2023: $13.4 million). This increase of $21.8 million was driven primarily by a $9.7 million increase in people-related costs and $2.8 million in share-based compensation primarily related to our field sales team, which was hired in the lead up to the launch of Ohtuvayre. Additionally, marketing and other commercial related activities, including travel, increased by $7.5 million due to the launch. We also had an increase of $1.6 million related to professional and consulting fees, information technology costs and other support costs due to the continued build-out of our commercial organization.
- **Net loss:** Net loss was $43.0 million for the third quarter ended September 30, 2024 (Q3 2023: $14.7 million).

Conference Call and Webcast Information

Verona Pharma will host an investment community webcast and conference call at 9:00 a.m. ET / 2:00 p.m. GMT on Monday, November 4, 2024, to discuss the third quarter 2024 financial results and provide a corporate update.

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. An electronic copy of the third quarter 2024 results press release will also be made available today on the Company's website.

For further information please contact:

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Wendy Ryan	

About Verona Pharma

Verona Pharma is a biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of chronic respiratory diseases with significant unmet medical needs. Ohtuvayre™ (ensifentrine) is the Company's first commercial product and the first inhaled therapy for the maintenance treatment of COPD that combines bronchodilator and non-steroidal anti-inflammatory activities in one molecule. 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 within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements. Words such as "anticipate," "believe," "plan," "expect," "intend," "may," "potential," "prepare," "possible" and similar words and expressions are intended to identify forward-looking statements.These forward-looking statements include, but are not limited to, statements regarding the potential benefits and efficacy of our drug Ohtuvayre to treat adult patients in the US with COPD, as well as the continued growth of sales and adoption by HCPs of Ohtuvayre, and statements regarding our two recently initiated Phase 2 clinical trials.

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 efficacy of Ohtuvayre compared to competing drugs and the other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the period ended September 30, 2024 filed with the Securities and Exchange Commission ("SEC") on November 4, 2024, as such factors may be updated from time to time in our other filings with the SEC. We disclaim any obligation to update or revise any forward-looking statement contained in this press release, even if subsequent events cause our views to change, except as required under applicable law.

Verona Pharma plc

Consolidated Financial Summary

(unaudited)

(in thousands, except share and per share amounts)

	Three months ended September 30,	
	2024	2023
Revenue	$ 5,624	$ —
Operating expenses:		
Cost of sales	543	—
Research and development	10,552	2,958
Selling, general and administrative	35,196	13,353
Total operating expenses	46,291	16,311
Operating loss	(40,667)	(16,311)
Other income/(expense)		
Research and development tax credit	1,612	(309)
Interest income	4,750	3,390
Interest expense	(9,882)	(401)
Foreign exchange gain/(loss)	1,475	(1,012)
Total other (expense)/income, net	(2,045)	1,668
Loss before income taxes	(42,712)	(14,643)
Income tax expense	(250)	(44)
Net loss	$ (42,962)	$ (14,687)
Weighted average shares outstanding – basic and diluted	651,944	638,239
Loss per ordinary share - basic and diluted	$ (0.07)	$ (0.02)

	Sep-30 2024	Jun-30 2024
Cash and cash equivalents	$ 336,040	$ 404,599
Total assets	$ 381,818	$ 434,123
Shareholders' equity	$ 130,491	$ 168,274