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): February 27, 2025

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 February 27, 2025, Verona Pharma plc announced its financial results for the year ended December 31, 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 February 27, 2025
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: February 27, 2025

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

Verona Pharma Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

Ohtuvayre™ (ensifentrine) recorded net product sales of $36.6 million in Q4 and $42.3 million in 2024

More prescriptions filled through February 2025 than in Q4 2024

Over 4,600 unique prescribers with ~55% of Tier 1 HCPs prescribing Ohtuvayre through February 2025

Phase 2 programs in bronchiectasis and fixed-dose combination in COPD advance

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

LONDON and RALEIGH, N.C., February 27, 2025 – Verona Pharma plc (Nasdaq: VRNA) ("Verona Pharma" or the "Company"), a biopharmaceutical company focused on respiratory diseases, announces its financial results for the fourth quarter and full year ended December 31, 2024, and provides a corporate update.

"2024 was another transformational year for Verona Pharma with the US approval and launch of Ohtuvayre (ensifentrine), the first novel inhaled therapy available for the maintenance treatment of Chronic Obstructive Pulmonary Disease ("COPD") in over 20 years," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "We are very pleased to report the extremely strong start to the launch continues to build momentum with more prescriptions dispensed through February 2025 than in the entire fourth quarter of 2024.

"More than 4,600 unique healthcare professionals ("HCPs") including approximately 55% of our Tier 1 HCPs have prescribed Ohtuvayre. Additionally, to date, more than 275 HCPs have prescribed Ohtuvayre to over 20 patients in their practice. Ohtuvayre is being prescribed for maintenance therapy across a broad COPD population including those receiving background single, dual and approximately 50% on triple therapy. These data strengthen our belief that ensifentrine's novel bronchodilator and non-steroidal anti-inflammatory activity will redefine the treatment paradigm for COPD.

"Alongside our commercialization efforts, in the third quarter we initiated two Phase 2 clinical trials: a dose-ranging trial with glycopyrrolate, a long-acting muscarinic antagonist ("LAMA"), to support a nebulized fixed-dose combination of ensifentrine and glycopyrrolate for the maintenance treatment of COPD, and a study assessing the safety and efficacy of nebulized ensifentrine in patients with non-cystic fibrosis bronchiectasis ("bronchiectasis"). We are pleased to report the glycopyrrolate dose-ranging trial was successfully completed and we plan to initiate a dose ranging Phase 2b trial with a fixed-dose combination of ensifentrine and glycopyrrolate in the second half of 2025.

"In addition to our successful Ohtuvayre launch, our development partner in Greater China, Nuance Pharma, announced in February 2025 that Ohtuvayre was approved in Macau, the first approval outside of the US, for the maintenance treatment of COPD. In addition, Nuance Pharma has completed enrollment in its own pivotal Phase 3 trial in China to evaluate ensifentrine for the maintenance treatment of COPD and expects to report results in mid-2025.

"In 2025, we will continue to build on the successful commercialization of Ohtuvayre in the US while progressing our Phase 2 programs. We are also initiating activities with regulatory authorities in the European Union and the UK for potential marketing authorization application submissions for Ohtuvayre."

Program Updates and Key Milestones

The Company's near-term milestones include:

- In the second half of 2025, the Company plans to start a dose-ranging Phase 2b trial to assess the safety and efficacy of a fixed-dose nebulized combination of ensifentrine with glycopyrrolate. The Company has successfully completed a Phase 2 dose-ranging trial with glycopyrrolate to support this program.
- The Company continues to enroll subjects in a Phase 2 trial to assess the efficacy and safety of nebulized ensifentrine in patients with bronchiectasis.
- In 2025, the Company plans to progress the regulatory activities for potential marketing authorization application submissions for Ohtuvayre for the maintenance treatment of COPD in the European Union and in the UK.
- In mid-2025, the Company's development partner in Greater China, Nuance Pharma, is expected to report results from its pivotal Phase 3 trial evaluating ensifentrine for the maintenance treatment of COPD in China.

Fourth Quarter and Recent Highlights

- In October 2024, the Company gave four oral presentations and presented two posters on analyses from the ENHANCE studies at CHEST Annual Meeting 2024. These included subgroup data supporting improvements in lung function, symptoms and quality of life, as well as reductions in the rate of exacerbations, regardless of COPD severity (moderate or severe), smoking status (current or former) and chronic bronchitis (with or without). An analysis of Ohtuvayre's impact on reducing exacerbation rates and COPD-related healthcare resource utilization was also presented.
- In November 2024, the 2025 GOLD report added Ohtuvayre to the COPD treatment algorithm.
- Also in November 2024, the Company completed enrollment in a Phase 2 dose-ranging trial with glycopyrrolate, a LAMA, supporting a fixed-dose combination program for the maintenance treatment of COPD via a nebulizer.
- On January 1, 2025, Ohtuvayre's product specific J-code became effective.
- In February 2025, the Company's development partner in Greater China, Nuance Pharma, announced Ohtuvayre has been approved in Macau for the maintenance treatment of COPD in adult patients. This is the first regulatory approval outside of the US.

Fourth Quarter 2024 Financial Results

- **Cash position:** Cash and cash equivalents at December 31, 2024, were $399.8 million (December 31, 2023: $271.8 million).
- **Product sales:** Net sales of Ohtuvayre were $36.6 million for the fourth quarter ended December 31, 2024 (Q4 2023: $0 million). 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 $2.0 million for the fourth quarter ended December 31, 2024 (Q4 2023: $0 million), which included Ohtuvayre manufacturing costs incurred after US approval, inventory overhead costs and sales-based royalties.
- **R&D Expenses:** Research and development ("R&D") expenses were $7.9 million for the fourth quarter ended December 31, 2024 (Q4 2023: $4.1 million). This increase of $3.8 million was primarily due to an increase of $3.2 million in clinical trial and other development costs as we initiated two Phase 2 studies in the third quarter of 2024 related to the combination of nebulized ensifentrine and glycopyrrolate and for Ohtuvayre in patients with bronchiectasis, and an increase of $1.1 million in share-based compensation.
- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were $45.1 million for the fourth quarter ended December 31, 2024 (Q4 2023: $15.0 million). The

increase of $30.1 million was driven primarily by an increase of $9.8 million in marketing and other commercial related activities, including travel, primarily related to the launch of Ohtuvayre, and an increase of $2.6 million in professional and consulting fees, information technology costs and other support costs due to the continued buildout of our commercial organization. Additionally, we had an increase of $8.8 million in people-related costs as we built out our commercial organization including much of the field sales team as well as an increase of $7.8 million related to share-based compensation.

- **Net loss:** Net loss was $33.8 million for the fourth quarter ended December 31, 2024 (Q4 2023: Net loss $14.1 million).

Full Year 2024 Financial Results

- **Product sales:** Net sales were $42.3 million for the year ended December 31, 2024 (2023: $0 million) related to product sales of Ohtuvayre.
- **Cost of sales:** Cost of sales was $2.6 million for the year ended December 31, 2024 (2023: $0 million), which included Ohtuvayre manufacturing costs incurred after US approval, inventory overhead costs and sales-based royalties.
- **R&D Expenses:** R&D expenses were $44.6 million for the year ended December 31, 2024 (full year 2023: $17.2 million), an increase of $27.4 million. This increase was primarily due to an increase of $17.5 million in clinical trial and other development costs we incurred related to the two Phase 2 studies which were initiated in the third quarter of 2024 related to the combination of nebulized ensifentrine and glycopyrrolate and for Ohtuvayre in patients with bronchiectasis, the $6.3 million approval milestone, $3.1 million increase in share-based compensation, $2.0 million increase for people-related costs and $1.1 million related to pre-launch manufacturing costs for commercial supply. This was partially offset by a decrease of $1.3 million in consultant and professional fee costs which were higher in the prior year due to service costs associated with our New Drug Application and the related approval process.
- **SG&A Expenses:** SG&A expenses were $149.8 million for the year ended December 31, 2024 (full year 2023: $50.4 million), an increase of $99.4 million. This increase was driven primarily by an increase of $29.7 million in marketing and other commercial related activities, including travel, primarily related to the launch of Ohtuvayre, a charge of $15.0 million for the first sale milestone and an increase of $7.3 million in professional and consulting fees, information technology costs and other support costs due to the continued buildout of our commercial organization. Additionally, we had an increase of $26.8 million in people-related costs as we built out our commercial organization including much of the field sales team as well as an increase of $18.8 million related to share-based compensation.
- **Net loss:** Net loss was $173.4 million for the year ended December 31, 2024 (full year 2023: $54.4 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 Thursday, February 27, 2025, to discuss the fourth quarter and full year 2024 financial results and the corporate update.

To participate, please dial one of the following numbers and ask to join the Verona Pharma call:

- +1-800-836-8184 for callers in the United States
- +1-646-357-8785 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 fourth quarter and full year 2024 results press release will also be made available today on the Company’s website.

Important Safety Information

Indication

Ohtuvayre is a prescription medicine used to treat COPD in adults. COPD is a chronic (long-term) lung disease that includes chronic bronchitis, emphysema, or both.

What is the most important information I should know about Ohtuvayre?

Ohtuvayre can cause serious side effects, including:

- Sudden breathing problems immediately after inhaling your medicine. If you have sudden breathing problems immediately after inhaling your medicine, stop using Ohtuvayre and call your healthcare provider right away or go to the nearest hospital emergency room right away.
- Mental health problems including suicidal thoughts and behavior. You may experience mood or behavior changes when taking Ohtuvayre. Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you: thoughts of suicide or dying, attempt to commit suicide, trouble sleeping (insomnia), new or worse anxiety, new or worse depression, acting on dangerous impulses, and/or other unusual changes in your behavior or mood.

Do not use Ohtuvayre to treat sudden breathing problems. Always have a rescue inhaler with you.

Who Should Not use Ohtuvayre?

Do not use Ohtuvayre if you have had an allergic reaction to ensifentrine or any of the ingredients in Ohtuvayre.

What should I tell my healthcare provider before using Ohtuvayre?

Before you use Ohtuvayre, tell your healthcare professional if you have or have had a history of mental health problems including depression and suicidal behavior; have liver problems; are pregnant or plan to become pregnant; are breastfeeding. It is not known if Ohtuvayre may harm your unborn baby. It is not known if the medicine in Ohtuvayre passes into your breast milk and if it can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the most common side effects of Ohtuvayre?

The most common side effects of Ohtuvayre include back pain, high blood pressure, bladder infection and diarrhea.

These are not all the possible side effects of Ohtuvayre. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

This summary does not include all the information about Ohtuvayre and is not meant to take the place of a discussion with your healthcare provider about your treatment.

For further information, please see the full Prescribing Information, including the Patient Information Leaflet.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For further information please contact:

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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, statements regarding our two recently initiated Phase 2 clinical trials, the Company's plans to initiate a Phase 2b clinical trial, potential regulatory approvals in the EU and UK, and Nuance Pharma's results from its pivotal Phase 3 trial, and the timing of any of the foregoing.

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: risks related to our limited operating history; our need for additional funding to complete development and commercialization of Ohtuvayre which may not be available and which may force us to delay, reduce or eliminate our development or commercialization efforts; our reliance on the success of Ohtuvayre, our only commercial product; our reliance on third-party manufacturers and suppliers; the efficacy of Ohtuvayre compared to competing drugs; our ability to successfully commercialize Ohtuvayre; serious adverse, undesirable or unacceptable side effects associated with Ohtuvayre which could adversely affect our ability to commercialize Ohtuvayre; failure to develop Ohtuvayre for additional indications, alternate delivery methods, or as a combination therapy; failure to obtain approval for and commercialize Ohtuvayre in multiple major pharmaceutical markets; our commercial capabilities and infrastructure, including sales, marketing, operations, distribution, and reimbursement infrastructure, may not be adequate to successfully commercialize Ohtuvayre; lawsuits related to patents covering Ohtuvayre and the potential for our patents to be found invalid or unenforceable; lawsuits related to our licensing of patents and know-how from third parties for the commercialization of Ohtuvayre; changes in our tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments that could affect our profitability, and audits by tax authorities that could result in additional tax payments for prior periods; the terms of our credit agreement and the revenue interest purchase and sale agreement ("RIPSA") place restrictions on our operating and financial flexibility, and if we fail to comply with certain covenants in the RIPSA, our results of operations and financial condition may be harmed; our vulnerability to natural disasters, global economic factors, geo-political actions and unexpected events, including health epidemics or pandemics; and the other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the period ended December 31, 2024, filed with the Securities and Exchange Commission ("SEC") on February 27, 2025, 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. 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 share and per share amounts)

	Three months ended December 31,		Years ended December 31,	
	2024	2023	2024	2023
Revenue				
Product sales, net	$ 36,637	$ —	$ 42,261	$ —
Other revenue	18	—	18	—
Total Revenue, net	36,655	—	42,279	—
Operating expenses				
Cost of sales	2,039	—	2,582	—
Research and development	7,870	4,122	44,574	17,216
Selling, general and administrative	45,085	14,972	149,750	50,353
Total operating expenses	54,994	19,094	196,906	67,569
Operating loss	(18,339)	(19,094)	(154,627)	(67,569)
Other income/(expense)				
Research & development tax credit	556	1,034	3,600	1,104
Loss on extinguishment of debt	—	—	(3,653)	—
Interest income	3,994	3,292	15,262	12,761
Interest expense	(10,317)	(623)	(23,542)	(2,057)
Foreign exchange gain/(loss)	(1,450)	1,206	(169)	1,866
Total other income/(expense), net	(7,217)	4,909	(8,502)	13,674
Loss before income taxes	(25,556)	(14,185)	(163,129)	(53,895)
Income tax benefit/(expense)	(8,271)	53	(10,289)	(474)
Net loss	$ (33,827)	$ (14,132)	$ (173,418)	$ (54,369)
Weighted average shares outstanding – basic and diluted	663,263,855	642,139,211	652,310,582	634,142,660
Loss per ordinary share - basic and diluted	$ (0.05)	$ (0.02)	$ (0.27)	$ (0.09)

	2024	2023
Cash and cash equivalents	$ 399,757	$ 271,772
Total assets	474,242	308,124
Shareholders' equity	$ 204,559	$ 249,283