
**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): April 29, 2025

Verona Pharma plc
(Exact name of registrant as specified in its charter)

United Kingdom
(State or other jurisdiction
of incorporation)

001-38067
(Commission
File Number)

98-1489389
(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 April 29, 2025, Verona Pharma plc announced its financial results for the quarter ended March 31, 2025. 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 April 29, 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: April 29, 2025

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

Verona Pharma Reports First Quarter 2025 Financial Results and Provides Corporate Update

*Total net revenue of \$76.3 million from Q1 2025 driven by Ohtuvayre[®] net sales of \$71.3 million (+95% vs Q4 2024)
~25,000 prescriptions filled in Q1 2025*

Q1 2025 revenue exceeds operating expenses excluding non-cash charges

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

LONDON and RALEIGH, N.C., April 29, 2025 – Verona Pharma plc (Nasdaq: VRNA) (“Verona” or the “Company”), a biopharmaceutical company focused on respiratory diseases, announces its financial results for the first quarter ended March 31, 2025, and provides a corporate update.

“The remarkably strong US launch of Ohtuvayre (ensifentrine) for the maintenance treatment of chronic obstructive pulmonary disease (“COPD”) continues to accelerate, with 95% net sales growth in the first quarter versus the fourth quarter of 2024, driven by significant increases in prescriptions, prescribers, new patients, and refills. The dramatic uptake of Ohtuvayre underscores the unmet need of patients with COPD. To continue to deepen the prescriber base and further accelerate the launch, we plan to add approximately 30 new sales representatives in the third quarter,” said David Zaccardelli, Pharm. D., President and Chief Executive Officer.

“We continue to enroll our Phase 2 clinical study of ensifentrine in non-cystic fibrosis bronchiectasis (“bronchiectasis”) and we plan to initiate the dose-ranging Phase 2b study of a fixed-dose combination of ensifentrine and glycopyrrolate for the maintenance treatment of COPD in the second half of 2025. We are extremely pleased to report that for the first time Verona’s quarterly revenue exceeded our operating expenses, excluding non-cash charges. We believe we are in a robust financial position to continue commercializing Ohtuvayre, advance our clinical pipeline and implement our global strategy.”

Ohtuvayre Q1 2025 Performance Metrics

- Approximately 25,000 prescriptions filled
- New patient starts were over 25% greater than those in Q4 2024
- Refills represented approximately 60% of overall dispenses
- Prescribers grew about 50% to approximately 5,300 compared to the end of Q4 2024
- Approximately 60% of prescribers are in Verona’s Tier 1 healthcare professionals (“HCPs”)
- Over 425 HCPs have prescribed Ohtuvayre to more than 20 patients

Program Updates and Key Milestones

Verona’s near-term milestones include:

- At the American Thoracic Society International Conference 2025 in May, Verona will present ten posters, including seven from the Phase 3 ENHANCE studies of Ohtuvayre in COPD, two from nonclinical studies and one from a real-world data analysis. The ENHANCE posters highlight subgroup analyses of patients when used as monotherapy, in patients with COPD and comorbid cardiac disorders and, separately, in patients with COPD and comorbid type 2 diabetes. In addition, the Company will host an exhibition booth with presentations led by clinical experts.

- In the second half of 2025, Verona plans to initiate a dose-ranging Phase 2b trial to assess the safety and efficacy of a fixed-dose nebulized combination of ensifentrine with glycopyrrolate for the treatment of COPD. The Company has successfully completed a Phase 2 dose-ranging trial with glycopyrrolate to support this program.
- Verona continues to enroll subjects in a Phase 2 trial to assess the efficacy and safety of nebulized ensifentrine for the treatment of bronchiectasis.
- Verona continues 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 2025.
- In the second quarter of 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.

First Quarter Highlights

- A newly granted patent (US Patent No. 12,251,384), expiring June 2044, was listed in the FDA's Orange Book for Ohtuvayre, in addition to the three original Orange Book listed patents.
- In March 2025, Verona amended its strategic financing agreements by repaying the revenue interest purchase and sales agreement and increasing the debt facility to \$450 million under more favorable terms with funds managed by Oaktree Capital and OMERS Life Sciences. These changes increased the Company's financial flexibility, reduced the cost of capital and simplified the balance sheet. At March 31, 2025 the Company had \$250 million outstanding under this facility and \$200 million available in potential future draws.
- In February 2025, Verona'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 for Ohtuvayre outside of the US.
- On January 1, 2025, Ohtuvayre's product specific J-code became effective.

First Quarter 2025 Financial Results

- **Cash position:** Cash and cash equivalents at March 31, 2025, were \$401.4 million (December 31, 2024: \$399.8 million).
- **Net revenue:** Total net revenue was \$76.3 million, driven by Ohtuvayre net sales of \$71.3 million, for the first quarter ended March 31, 2025 (Q1 2024: \$0 million). Additionally, the Company recognized \$5.0 million in a clinical milestone from Nuance Pharma.
- **Cost of sales:** Cost of sales was \$3.4 million for the first quarter ended March 31, 2025 (Q1 2024: \$0 million), which included Ohtuvayre manufacturing costs, inventory overhead costs and sales-based royalties.
- **R&D Expenses:** Research and development ("R&D") expenses were \$14.1 million for the first quarter ended March 31, 2025 (Q1 2024: \$6.8 million). This increase of \$7.3 million was primarily due to an increase of \$5.5 million in share-based compensation as well as an increase of \$1.9 million for clinical trial and other development costs 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.
- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were \$69.1 million for the first quarter ended March 31, 2025 (Q1 2024: \$20.4 million). The increase of \$48.7 million was driven primarily by an increase of \$9.3 million in people-related costs and \$27.1 million in share-based compensation, each of which were impacted by the hiring of our field sales team in mid-2024 in the lead-up to the launch of Ohtuvayre. Additionally, our marketing and other commercial related activities, including travel, increased by \$7.8 million as we continue to incur costs supporting

the launch of Ohtuvayre. We also had an increase of \$2.7 million related to professional and consulting fees, information technology costs and other support costs due to the continued buildout of our commercial organization as well as an increase of \$1.0 million related to our RIPSAs repayment and the amendment and draw of Tranche C of the 2024 Term Loans.

- **Net loss and Adjusted Net Income*:** Net loss was \$16.3 million and Adjusted Net Income was \$20.5 million for the first quarter ended March 31, 2025 (Q1 2024: Net loss \$25.8 million and Adjusted Net Loss \$21.5 million).

*See “Non-GAAP Financial Measures” below for further details and a reconciliation of this non-GAAP measure to its nearest comparable GAAP measure.

Conference Call and Webcast Information

Verona Pharma will host a live webcast and a conference call at 9:00 a.m. EDT / 2:00 p.m. BST on Tuesday, April 29, 2025, to discuss the first quarter 2025 financial results and corporate update.

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

- +1-800-715-9871 for callers in the United States
- +1-646-307-1963 for international callers

The webcast will be available under Events and Presentations on the Investors page of the Company's website, www.veronapharma.com/investors, and the audio replay will be available for 90 days.

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. Enifentrine 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 and prescriber growth, the ongoing commercialization of Ohtuvayre and the growth of our sales team, 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, the amounts expected to become available and the conditions under the debt facility, our participation in the upcoming events and presentations, 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 place restrictions on our operating and financial flexibility, and if we fail to comply with certain covenants, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, and our other reports filed 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 March 31,	
	2025	2024
Revenue		
Product sales, net	\$ 71,256	\$ —
Other revenue	5,000	—
Total revenue, net	<u>76,256</u>	<u>—</u>
Operating expenses:		
Cost of sales	3,407	—
Research and development	14,054	6,764
Selling, general and administrative	69,112	20,434
Total operating expenses	<u>86,573</u>	<u>27,198</u>
Operating loss	(10,317)	(27,198)
Other income/(expense)		
Research and development tax credit	—	585
Loss on extinguishment of debt	(407)	—
Interest income	3,891	3,378
Interest expense	(10,195)	(1,586)
Foreign exchange gain/(loss)	470	(219)
Total other (expense)/income, net	<u>(6,241)</u>	<u>2,158</u>
Loss before income taxes	(16,558)	(25,040)
Income tax benefit/(expense)	239	(754)
Net loss	<u>\$ (16,319)</u>	<u>\$ (25,794)</u>
Weighted average shares outstanding – basic and diluted	<u>679,405</u>	<u>645,701</u>
Loss per ordinary share - basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.04)</u>
	<u>Mar-31</u>	<u>Dec-31</u>
	2025	2024
Cash and cash equivalents	\$ 401,415	\$ 399,757
Total assets	\$ 525,936	\$ 474,242
Shareholders' equity	\$ 226,595	\$ 204,559

Non-GAAP Financial Measures

Adjusted Net Income/(Loss)

We define Adjusted Net Income/(Loss) as net income/(loss) excluding share-based compensation expense.

Management believes that this non-GAAP financial measure provides useful information to investors by reflecting additional ways of viewing aspects of our operations that, when reconciled to the corresponding GAAP measure, help our investors understand the long-term profitability trends of our business, and facilitate comparisons of our profitability to prior and future periods and to our peers.

Adjusted Net Income/(Loss) is a supplemental measure of our operating performance and has important limitations. For example, Adjusted Net Income/(Loss) excludes the impact of certain costs required to be recorded under GAAP and could differ substantially from similarly titled measures presented by other companies in our industry or companies in other industries. Accordingly, this non-GAAP measure should not be considered in isolation or as a substitute for analysis of our results as reported under GAAP. We include a reconciliation of Adjusted Net Income/(Loss) to the most directly comparable GAAP financial measure, which is Net loss.

Verona Pharma plc

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL MEASURES

(unaudited)

(in thousands)

The following table presents a reconciliation of our Adjusted Net Income/(Loss) to our Net loss, which is the most directly comparable GAAP measure, for the periods indicated.

	Three months ended March 31,	
	2025	2024
Net loss (GAAP)	(16,319)	(25,794)
Adjustments:		
Share-based compensation	36,838	4,258
Adjusted Net Income/(Loss)	20,519	(21,536)