

**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): January 7, 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 January 7, 2025, Verona Pharma plc (the “Company”) issued a press release in which the Company stated that, although it has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2024, the Company expects to report that it had approximately \$400 million in cash and cash equivalents as of December 31, 2024, and also expects to report that net product sales were approximately \$36 million for the fourth quarter ended December 31, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the “Form 8-K”) and is incorporated herein by reference.

These preliminary financial results are based on preliminary unaudited information and the Company’s current estimate of its results for the fourth quarter and fiscal year ended December 31, 2024, and remain subject to change based on the completion of closing and review procedures and the execution of the Company’s internal control over financial reporting. The Company’s independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, these preliminary estimates.

The information contained in this Item 2.02 of this Form 8-K (including Exhibit 99.1) 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 to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such 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 January 7, 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: January 7, 2025

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer



Verona Pharma Reports Strong Ohtuvayre™ Launch and Provides Preliminary Fourth Quarter and Full Year 2024 Financial Highlights

Approximately \$36 million and \$42 million net product sales of Ohtuvayre for the fourth quarter and full year 2024, respectively

More than 3,500 unique prescribers and over 16,000 prescriptions filled in 2024 across a broad COPD population

Approximately 45% of Tier 1 HCPs prescribed Ohtuvayre

LONDON and RALEIGH, N.C., January 7, 2025 – Verona Pharma plc (Nasdaq: VRNA) (“Verona Pharma” or the “Company”), a biopharmaceutical company focused on respiratory diseases, announces preliminary unaudited net product sales for the fourth quarter and full year ended December 31, 2024, and provides a corporate update.

“2024 was another transformational year for Verona with the approval and US launch of Ohtuvayre (ensifentrine) for the maintenance treatment of chronic obstructive pulmonary disease (“COPD”),” said David Zaccardelli, Pharm. D., President and Chief Executive Officer. “We are very pleased to report the exceptionally strong start to the launch of Ohtuvayre continues with more than 3,500 unique healthcare professionals (“HCPs”) prescribing Ohtuvayre and over 16,000 prescriptions filled of which approximately one-third were patient refills in 2024. During these initial 20 weeks, key metrics showed month over month growth including number of unique prescribers, new patient prescriptions, refill prescriptions, and net sales while maintaining approximately two weeks of inventory at the specialty pharmacies. Specifically, filled prescriptions increased by over 35% each month in the fourth quarter and physicians continued to prescribe Ohtuvayre across a broad COPD population including those receiving background single, dual and triple therapy.

“We recorded net product sales of approximately \$36 million in the fourth quarter and \$42 million for full year 2024. While it is still early in the launch, feedback from HCPs and patients is consistently positive including robust refill rates, and increasing prescriber depth with over 150 HCPs prescribing Ohtuvayre to more than 20 patients in their practice. These trends reinforce our belief that Ohtuvayre’s bronchodilator and non-steroidal anti-inflammatory activity can re-define the COPD treatment paradigm. We are excited by the initial impact of Ohtuvayre and look forward to building on this momentum in 2025.”

Program Updates and Key Milestones

- Ohtuvayre’s product specific J-code, J7601, became effective on January 1, 2025.
 - In November 2024, the Company completed enrollment in a Phase 2 dose-ranging trial with glycopyrrolate, a long-acting muscarinic antagonist (“LAMA”), supporting a fixed-dose combination program for the maintenance treatment of COPD via a nebulizer. Results will support initiation of a Phase 2b trial with a fixed dose combination of ensifentrine with glycopyrrolate in the third quarter of 2025.
 - The Company continues to enroll subjects in a Phase 2 trial to assess the efficacy and safety of nebulized ensifentrine in patients with non-cystic fibrosis bronchiectasis (“NCFBE”).
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Preliminary Fourth Quarter 2024 Financial Results

- **Cash position:** Although the Company has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2024, the Company expects to report that its cash and cash equivalents at December 31, 2024, were approximately \$400 million (December 31, 2023: \$271.8 million). The Company sold \$100 million of its ordinary shares, in the form of ADSs, under its “at the market” equity offering program with Jefferies at an average price of \$39.35 per ADS (equivalent to \$4.92 per ordinary share) in the fourth quarter of 2024.
- **Product sales:** The Company expects to report that net product sales were approximately \$36 million for the fourth quarter ended December 31, 2024 (Q4 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.

Set forth in this release are certain estimated preliminary financial results for the fourth quarter and fiscal year ended December 31, 2024. These estimates are based on the information available to the Company at this time. The Company’s financial closing procedures for the fourth quarter and full year 2024 are not yet complete and, as a result, actual results may vary from the estimated preliminary results presented here due to the completion of the Company’s financial closing and review procedures, the execution of the Company’s internal control over financial reporting, final adjustments and other developments that may arise between now and the time the financial results for the fourth quarter and fiscal year ended December 31, 2024, are finalized. The estimated preliminary financial results have not been audited or reviewed by the Company’s independent registered public accounting firm. These estimates should not be viewed as a substitute for the Company’s full interim or annual financial statements. Accordingly, you should not place undue reliance on this preliminary data.

For further information please contact:

Verona Pharma plc	Tel: +1-844-341-9901
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: +1-781-316-4424 tbcverona@tenbridgecommunications.com
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. OhtuvayreTM (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, our anticipated financial results for the fourth quarter and full year ended December 31, 2024, the commercial growth 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 following: risks related to the completion of closing and review procedures and the execution of our internal control of financial reporting; 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 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. 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.
