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): August 8, 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 August 8, 2024, Verona Pharma plc announced its financial results for the quarter ended June 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 August 8, 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: August 8, 2024

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

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

Ohtuvayre™ (ensifentrine) now available; patient shipments started

Strong balance sheet supports commercialization and pipeline expansion

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

LONDON and RALEIGH, N.C., August 8, 2024 – Verona Pharma plc (Nasdaq: VRNA) ("Verona Pharma" or the "Company"), a biopharmaceutical company focused on respiratory diseases, announces its financial results for the second quarter ended June 30, 2024, and provides a corporate update.

"We are very pleased today to announce that Ohtuvayre (ensifentrine) is now available in the US for the maintenance treatment of chronic obstructive pulmonary disease ("COPD") in adults," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "Ohtuvayre is the first novel inhaled product available for the treatment of COPD in more than 20 years. Healthcare professionals ("HCPs") and patients are excited about Ohtuvayre's potential to relieve COPD symptoms and we believe its bronchodilator and non-steroidal anti-inflammatory activity will redefine the treatment paradigm for COPD.

"Our field sales force began interacting with HCPs in late July and, to date, we have conducted over 2,000 HCP visits and more than 100 unique HCPs have prescribed Ohtuvayre through our exclusive network of specialty pharmacies. We are confident in the launch of Ohtuvayre and look forward to updating you on our progress."

Program Updates and Key Milestones

The Company's near-term milestones include:

- In July 2024, the Company submitted an investigational new drug application ("IND") to the FDA to allow initiation of the clinical program for development of a fixed-dose combination of ensifentrine and glycopyrrolate, a long-acting muscarinic antagonist ("LAMA"), for the maintenance treatment of COPD via a nebulizer. Subject to clearance of the IND, the Company intends to initiate a Phase 2 dose-ranging trial in the third quarter of 2024.
- Also in the third quarter of 2024, the Company plans to initiate a Phase 2 clinical trial to assess the efficacy and safety of nebulized ensifentrine in patients with non-cystic fibrosis bronchiectasis ("NCFBE").
- In the second half of 2024, the Company plans to present further analyses from the Phase 3 ENHANCE trials at the European Respiratory Society International Congress 2024 and at CHEST Annual Meeting 2024.

Second Quarter Highlights

- On June 26, 2024, the FDA approved Ohtuvayre (ensifentrine) for the maintenance treatment of COPD and the product is now available in the US.
- In June 2024, the Company submitted the J-code application and local coverage determination documents to support the launch and expects to receive a permanent, product-specific J-code for Ohtuvayre effective January 2025.
- In May 2024, the Company refinanced its $400 million debt facility and entered into a $250 million capped revenue interest purchase and sales agreement ("RIPSA") with

Oaktree Capital and OMERS Life Sciences (collectively the “$650 million strategic financing”).

- Also in May 2024, the Company presented eight posters including two oral presentations, at the American Thoracic Society International Conference (“ATS”) 2024. The posters highlighted additional pooled analyses of the Phase 3 ENHANCE trials with ensifentrine for the treatment of COPD. The abstracts are published on the ATS website and in the *American Journal of Respiratory and Critical Care Medicine*.

Second Quarter 2024 Financial Results

- **Cash position:** Cash and cash equivalents at June 30, 2024 were $404.6 million (December 31, 2023: $271.8 million). Following the approval of Ohtuvayre, the Company drew $70 million under the debt facility and $100 million under the RIPSA leading to the $404.6 million cash balance. The Company believes cash and cash equivalents at June 30, 2024, along with the funding expected to become available under the $650 million strategic financings will enable Verona Pharma to fund planned operating expenses and capital expenditure requirements beyond 2026 including the commercial launch of Ohtuvayre in the US.
- **R&D Expenses:** Research and development (“R&D”) expenses were $19.4 million for the second quarter ended June 30, 2024 (Q2 2023: a net reversal of costs of $2.5 million). This increase of $21.9 million was primarily driven by the accrual of the $6.3 million approval milestone due to Ligand, $2.5 million increase in share-based compensation largely driven by the recognition of performance restricted stock units ("PRSU") expense and $1.7 million of expense related to pre-launch inventory production. Further, we had $2.5 million in clinical trial and other development costs in the three months ended June 30, 2024 while in the three months ended June 30, 2023, we recorded a reversal of costs of $6.3 million related to the resolution of a supplier matter, which resulted in net negative research and development expense for the three months ended June 30, 2023.
- **SG&A Expenses:** Selling general and administrative expenses (“SG&A”) were $49.0 million for the second quarter ended June 30, 2024 (Q2 2023: $12.4 million). This increase of $36.6 million was driven primarily by an accrual of the $15.0 million first sale milestone payment due to Ligand, an increase of $7.4 million for marketing and other commercial launch related activities and an increase of $2.3 million in other support costs including travel, professional and consulting fees and information technology costs. Additionally, share-based compensation increased by $8.0 million largely driven by the recognition of PRSU expense as well as an increase of $4.3 million in people-related costs as we built out our commercial organization including much of the field sales team.
- **Net loss:** Net loss was $70.8 million for the second quarter ended June 30, 2024 (Q2 2023: net loss $8.8 million).

Conference Call and Webcast Information

Verona Pharma will host an investment community webcast and conference call at 9:00 a.m. EDT / 2:00 p.m. BST on Thursday, August 8, 2024, to discuss the second quarter 2024 financial results and the corporate update.

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

- +1-833-816-1396 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 second 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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Leslie Humbel	

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. 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, efficacy and commercial strategy for Ohtuvayre, including, but not limited to, statements relating to the potential to change the treatment paradigm for adult COPD patients, the Company's ability to successfully market and sell Ohtuvayre, the timing of the Company's Phase 2 trial for the development of a fixed-dose combination of ensifentrine and glycopyrrolate for the maintenance treatment of COPD via delivery in a nebulizer and the Phase 2 clinical trial to assess the efficacy and safety of nebulized ensifentrine in patients with non-cystic fibrosis bronchiectasis, the potential applications of ensifentrine, the Company's participation in upcoming events and presentations, and the Company's cash runway.

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 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; and our vulnerability to natural disasters, global economic factors, geo-political actions and unexpected events, including health epidemics or pandemics. These and other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the period ended June 30, 2024 filed with the Securities and Exchange Commission (“SEC”) on August 8, 2024, 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, 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 June 30,	
	2024	2023
Operating expenses		
Research and development	$ 19,388	$ (2,474)
Selling, general and administrative	49,035	12,439
Total operating expenses	68,423	9,965
Operating loss	(68,423)	(9,965)
Other income/(expense)		
Research and development tax credit	847	(1,934)
Loss on extinguishment of debt	(3,653)	—
Interest income	3,140	3,402
Interest expense	(1,757)	(740)
Foreign exchange gain	25	740
Total other (expense)/income, net	(1,398)	1,468
Loss before income taxes	(69,821)	(8,497)
Income tax expense	(1,014)	(310)
Net loss	$ (70,835)	$ (8,807)
Weighted average shares outstanding – basic and diluted	648,217,411	634,469,423
Loss per ordinary share - basic and diluted	$ (0.11)	$ (0.01)

	Jun-30 2024	Mar-31 2024
Cash and cash equivalents	$ 404,599	$ 254,882
Total assets	$ 434,123	$ 289,912
Shareholders' equity	$ 168,274	$ 224,988