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): May 9, 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 May 9, 2024, Verona Pharma plc announced its financial results for the quarter ended March 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 May 9, 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: May 9, 2024

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

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

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

PDUFA Target Action Date for Ensifentrine of June 26, 2024

Finalizing commercial launch preparations

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., May 9, 2024 – Verona Pharma plc (Nasdaq: VRNA) ("Verona Pharma" or the "Company"), a biopharmaceutical company focused on respiratory diseases, announces its financial results for the first quarter ended March 31, 2024, and provides a corporate update.

"As we approach the PDUFA target action date for ensifentrine of June 26, we are finalizing our preparations for a potential US launch in the third quarter of 2024," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "If approved, ensifentrine is expected to be the first novel inhaled mechanism available for the treatment of COPD in more than 20 years, and we continue to work with the US Food and Drug Administration during their review. Our goal is to address the significant unmet need in COPD and provide a novel and effective treatment for patients that continue to experience symptoms, despite existing therapies.

"We believe ensifentrine's bronchodilator and non-steroidal anti-inflammatory activity has the potential to change the treatment paradigm for COPD and we look forward to providing updates later this year on our planned clinical programs for a fixed-dose combination of ensifentrine and glycopyrrolate in COPD and ensifentrine in non-cystic fibrosis bronchiectasis.

"With the financing announced this morning, we are pleased to have further strengthened our balance sheet and enhanced our financial flexibility as we prepare for the potential launch of ensifentrine with access to up to $650 million in addition to our existing cash of $255 million. We refinanced our $400 million debt facility to one with a lower overall cost of capital and favorable financial covenants. In addition, we have entered into a $250 million capped revenue interest sales transaction with repayment based on a percentage of future ensifentrine revenues. We expect these funds, along with existing cash, to support the Company's growth through the planned commercialization beyond 2026."

Program Updates and Key Milestones

The Company's near-term milestones include:

- The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") target action date for ensifentrine of June 26, 2024 and notified the Company that it is not currently planning to hold an advisory committee meeting to discuss the application. If approved, the Company intends to launch ensifentrine in the US market in the third quarter of 2024.
- In the second quarter of 2024, the Company continues to finalize key launch preparations including sales force deployment strategy, pricing, distribution and patient services, healthcare professional and patient engagement plans.

- In the second quarter of 2024, the Company will continue to highlight the burden of chronic obstructive pulmonary disease ("COPD") through the "Unspoken COPD" disease awareness campaign. Through the first quarter of 2024, 85% of targeted healthcare professionals (“HCPs”) were reached with the campaign and over 2,000 HCPs engaged with the website.
- In May 2024, the Company will present eight posters including two mini oral symposia, at the American Thoracic Society International Conference (“ATS”) 2024. The posters will highlight additional pooled analyses of the Phase 3 ENHANCE studies with ensifentrine for the treatment of COPD. A pooled analysis demonstrating reductions in the rate and risk of exacerbations with ensifentrine will be presented as part of the ‘Late Breaking Mini Symposium’ designed to highlight new breakthroughs. In addition, the Company will host an exhibition booth exploring the role of phosphodiesterase (“PDE”) in inflammation and lung function impairment in COPD as well as three innovation hub presentations led by clinical experts.
- In the second half of 2024, the Company intends to submit an investigational new drug application (“IND”) to the FDA and, subject to clearance, initiate a Phase 2 clinical trial assessing the safety and efficacy of a fixed-dose combination formulation of ensifentrine and glycopyrrolate, a long-acting muscarinic antagonist ("LAMA"), for the maintenance treatment of patients with COPD via delivery in a nebulizer.
- Also in the second half 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"), subject to clearance by the FDA.

Financing and Recent Highlights

- In May 2024, the Company refinanced its $400 million debt facility and entered into a $250 million capped revenue interest sales transaction with Oaktree Capital and OMERS Life Sciences (collectively “the $650 million strategic financing”).
- Also in May 2024, the Company presented posters at the International Society for Pharmacoeconomics and Outcomes Research (“ISPOR”) Annual International Conference 2024. Posters at ISPOR included claims data demonstrating exacerbations persist for patients even when they are receiving treatment regimens containing inhaled corticosteroids, resulting in a significant burden to the healthcare system.

First Quarter 2024 Financial Results

- **Cash position:** Cash and cash equivalents at March 31, 2024, were $254.9 million (December 31, 2023: $271.8 million). The Company believes cash and cash equivalents at March 31, 2024, and funding expected to become available under the $650 million strategic financing facility, will enable Verona Pharma to fund planned operating expenses and capital expenditure requirements beyond 2026 including the commercial launch of ensifentrine in the US, if approved.
- **R&D Expenses:** Research and development (“R&D”) expenses were $6.8 million for the first quarter ended March 31, 2024 (Q1 2023: $12.6 million). This decrease of $5.8 million was primarily due to expense of $7.2 million in the three months ended March 31, 2023 for finalizing all matters related to the Phase 3 ENHANCE program. As the program completed in 2023, no similar costs were incurred in 2024. This decrease was partially offset by $1.5 million of pre-approval active pharmaceutical ingredient manufacturing-related costs as well as an increase of $0.7 million in people related costs including share-based compensation.
- **SG&A Expenses:** Selling general and administrative expenses (“SG&A”) were $20.4 million for the first quarter ended March 31, 2024 (Q1 2023: $9.6 million). The increase of $10.8 million was primarily due to an increase of $4.6 million related to marketing, commercial preparation and other pre-commercial activities, $1.1 million related to professional fees, consulting costs and other administrative expenses, which support our continued growth and evolution of our business, and $0.7 million related to the continued build-out of our information technology infrastructure. Additionally, people related costs increased by $4.1 million including share-based

compensation as we increased our headcount in our commercial and support functions in preparation for the planned commercial launch.

- **Net loss:** Net loss was $25.8 million for the first quarter ended March 31, 2024 (Q1 2023: net loss $16.7 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, May 9, 2024, to discuss the first 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 first 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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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. In the third quarter of 2023, the US Food and Drug Administration accepted for review the Company's NDA for ensifentrine for the maintenance treatment of patients with COPD and assigned a PDUFA target action date of June 26, 2024. If approved, ensifentrine has the potential to become the first inhaled non-steroidal therapy for the treatment of respiratory diseases that combines bronchodilator and anti-inflammatory activities in one molecule. The Company has evaluated nebulized ensifentrine in its Phase 3 clinical program ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") for COPD maintenance treatment. Ensifentrine met the primary endpoint in both ENHANCE-1 and ENHANCE-2 trials demonstrating statistically significant and clinically meaningful improvements in lung function. In addition, ensifentrine substantially reduced the rate and risk of COPD exacerbations in pooled analysis from ENHANCE-1 and ENHANCE-2. Two additional formulations of ensifentrine have been evaluated in Phase 2 trials for the treatment of COPD: dry powder inhaler ("DPI") and pressurized metered-dose inhaler ("pMDI") and a fixed-dose combination formulation with ensifentrine and glycopyrrolate, a LAMA, is currently under development, also for the treatment of COPD. Ensifentrine also has potential applications in cystic fibrosis, non-cystic fibrosis bronchiectasis, 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 that

do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding our operational review, financial review, program updates and key milestones, the timing of the approval of the NDA for ensifentrine for the maintenance treatment of COPD, the development of ensifentrine in other formulations and for other indications and planned regulatory submissions and timing thereof, including the timing of submission of an IND for a fixed-dose combination formulation with ensifentrine and glycopyrrolate, a LAMA, for the maintenance treatment of patients with COPD and the timing of clinical studies to assess ensifentrine in patients with NCFBE, the planned US commercial launch of ensifentrine in 2024, the potential for ensifentrine to be the first therapy for the treatment of respiratory diseases to combine bronchodilator and non-steroidal anti-inflammatory benefits in one compound, the potential of ensifentrine to change the treatment paradigm for COPD patients, the potential of ensifentrine in the treatment of cystic fibrosis, NCFBE, asthma and other respiratory diseases, as well as the potential of the DPI and pMDI formulations of ensifentrine, the funding we expect to become available under our $650 million strategic financing facility, and the sufficiency of cash and cash equivalents, and the cash runway period provided by the sources of financing to fund planned operating expenses and capital expenditure requirements beyond 2026 including the commercial launch of ensifentrine in the US, if approved.

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 ability to operate our business due to restrictions from our $400 million debt financing facility and any other existing or future indebtedness; our need for additional funding to complete development and commercialization of any future product candidates or development and commercialization of other formulations or target indications of ensifentrine, which may not be available and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts; the reliance of our business on the success of ensifentrine, our only product candidate under development; economic, political, regulatory and other risks involved with international operations; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; serious adverse, undesirable or unacceptable side effects associated with ensifentrine, which could adversely affect our ability to develop or commercialize ensifentrine; we may not be successful in developing ensifentrine in other formulations or for multiple indications; our ability to obtain approval for and commercialize ensifentrine in multiple major pharmaceutical markets; misconduct or other improper activities by our employees, consultants, principal investigators, third-party service providers and licensees; our inability to realize the anticipated benefits under licenses granted by us to third parties to develop and commercialize ensifentrine, our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel; material differences between our “top-line” data and final data; our reliance on third parties, including clinical research organizations, clinical investigators, manufacturers and suppliers, and the risks related to these parties’ ability to successfully develop and commercialize ensifentrine; lawsuits related to patents covering ensifentrine and the potential for our patents to be found invalid or unenforceable; lawsuits related to our licensing of patents and know-how with third parties for the development and commercialization of ensifentrine; changes in our tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments could affect our profitability, and audits by tax authorities could result in additional tax payments for prior periods; and our vulnerability to natural disasters, global economic factors, geo-political actions and unexpected events, including health epidemics or pandemics, and conflicts such as the Russia-Ukraine conflict, which has and may continue to adversely impact our business. These and other important factors under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, as updated in our Quarterly Report on Form 10-Q for the quarter ended March 31, 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. Although management believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. 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 by 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,	
	2024	2023
Operating expenses		
Research and development	6,764	12,610
Selling, general and administrative	20,434	9,589
Total operating expenses	27,198	22,199
Operating loss	(27,198)	(22,199)
Other income/(expense)		
Research and development tax credit	585	2,313
Interest income	3,378	2,677
Interest expense	(1,586)	(293)
Foreign exchange (loss)/gain	(219)	932
Total other income, net	2,158	5,629
Loss before income taxes	(25,040)	(16,570)
Income tax expense	(754)	(173)
Net loss	$ (25,794)	$ (16,743)
Weighted average shares outstanding – basic and diluted	645,701,197	621,450,900
Loss per ordinary share - basic and diluted	$ (0.04)	$ (0.03)

	Mar-31 2024	Mar-31 2023
Cash and cash equivalents	$ 254,882	$ 291,415
Total assets	$ 289,912	$ 323,146
Shareholders' equity	$ 224,988	$ 276,749