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 29, 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 February 29, 2024, Verona Pharma plc announced its financial results for the year ended December 31, 2023. 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 29, 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: February 29, 2024

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 2023 Financial Results and Provides Corporate Update

PDUFA Target Action Date for ensifentrine of June 26, 2024

Commercialization preparations advance

Strong balance sheet supports commercialization and Company's growth

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

LONDON and RALEIGH, N.C., February 29, 2024 – Verona Pharma plc (Nasdaq: VRNA) ("Verona Pharma" or the "Company"), a clinical-stage biopharmaceutical company focused on respiratory diseases, announces its financial results for the fourth quarter and full year ended December 31, 2023, and provides a corporate update.

"2023 was a pivotal year for Verona Pharma with the acceptance of our New Drug Application ("NDA") for review by the US Food and Drug Administration ("FDA") and continued advancement of our commercialization strategy in preparation for the US launch of ensifentrine, if approved," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "In August, the FDA accepted for review our NDA seeking approval of ensifentrine for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD") and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of June 26, 2024.

"The NDA acceptance brings us closer to our goal of delivering ensifentrine to the millions of patients suffering from COPD. If approved, ensifentrine is expected to be the first novel inhaled mechanism available for the treatment of COPD in more than 20 years. Supported by the results from our ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") trials, we believe ensifentrine's bronchodilator and non-steroidal anti-inflammatory activity has the potential to change the treatment paradigm for COPD.

"While we remain focused on the US commercialization efforts for ensifentrine, we progressed development of two new programs: a fixed-dose combination formulation with ensifentrine and glycopyrrolate, a long-acting muscarinic antagonist ("LAMA"), for the maintenance treatment of patients with COPD via a nebulizer and a potential second indication for nebulized ensifentrine for the treatment of non-cystic fibrosis bronchiectasis ("NCFBE").

"To support our commercialization activities and continued pipeline expansion, we enhanced our financial flexibility through a $400 million debt financing facility in December. We expect this facility, along with our existing cash, to support Verona Pharma's growth including the commercialization of ensifentrine, if approved, through at least 2026.

"Alongside our progress in 2023, our development partner Nuance Pharma continued to enroll patients into a pivotal Phase 3 trial evaluating ensifentrine for the maintenance treatment of COPD in China. Nuance Pharma are developing and, if approved, will commercialize ensifentrine in Greater China and we look forward to providing future updates.

"We expect 2024 to be a transformational year for Verona Pharma. We are finalizing our US launch preparations and look forward to commercializing ensifentrine in the second half of 2024, if approved. We also look forward to continued progress on our development programs as we work to build-out our pipeline."

Program Updates and Key Milestones

The Company's near-term milestones include:

- The FDA has assigned a PDUFA target action date 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 second half of 2024.
- In the first half of 2024, the Company will work to finalize key launch activities including pricing, distribution and patient services, healthcare professional and patient engagement plans. Additionally, Verona's disease awareness campaign, titled "Unspoken COPD," will continue to highlight to key healthcare providers the burden of COPD for patients.
- The Company is developing a fixed-dose combination formulation with ensifentrine and glycopyrrolate, a LAMA, for the maintenance treatment of patients with COPD via delivery in a nebulizer. Following development activities to confirm a feasible formulation, in the second half of 2024, the Company plans 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 the fixed-dose combination formulation in COPD patients.
- In the second half of 2024, the Company plans to commence a Phase 2 clinical trial to assess the efficacy and safety of nebulized ensifentrine in patients with NCFBE, subject to clearance by the FDA.

Fourth Quarter and Recent Highlights

- In October 2023, the Company gave four presentations on pooled and subgroup post hoc analyses from the ENHANCE trials evaluating ensifentrine in COPD covering data related to exacerbations, lung function, symptoms and quality of life endpoints, and use of daily rescue medication, at CHEST Annual Meeting 2023. Also at CHEST, the Company launched the "Unspoken COPD" disease awareness campaign, highlighting how many COPD patients struggle to talk about their condition.
- Also in October 2023, the Company presented an update on key launch preparations including the overall market opportunity for ensifentrine, if approved, the finalization of sales force deployment strategy, Hub services and distribution pathway, as well as internal infrastructure needed to support the commercialization of ensifentrine.
- In December 2023, the Company completed a debt facility providing access to up to $400 million from funds managed by Oxford Finance and Hercules Capital. The debt facility provides non-dilutive capital and further financial flexibility to support Verona Pharma's continued growth, including the commercialization of ensifentrine. The Company drew $50 million at closing, a portion of which was used to repay amounts outstanding under the previous $150 million debt facility with Oxford, and the remainder is available upon achievement of certain regulatory and commercial milestones and other conditions.
- In February 2024, Michael Austwick joined the board as a Non-Executive Director and Rishi Gupta stepped down from the board after 7 years of service. Mr. Austwick brings a wealth of strategic and operational experience in the biopharmaceutical industry including more than 15 years of respiratory expertise in leadership roles across the US, China, Europe and Japan. Most recently, he served as CEO at Vectura, and previously as Nordic General Manager and Head of the Global Respiratory Franchise at Novartis and as Head of US Respiratory and Vice President Global Inhaled Respiratory at AstraZeneca. Mr. Austwick has led the development and commercialization of more than 10 brands.

Fourth Quarter 2023 Financial Results

- **Cash position:** Cash and cash equivalents at December 31, 2023, were $271.8 million (December 31, 2022: $227.8 million). The Company believes cash and cash equivalents at December 31, 2023, and funding expected to become available under the $400 million debt facility, will enable Verona Pharma to fund planned operating expenses and capital expenditure requirements through at least the end of 2026 including the commercial launch of ensifentrine in the US, if approved.
- **R&D Expenses:** Research and development ("R&D") expenses were $4.1 million for the fourth quarter ended December 31, 2023 (Q4 2022: $6.8 million). This decrease

of $2.7 million was primarily due to a $2.1 million decrease in clinical trial and other development costs as, in the prior year, the Company was incurring costs with the then ongoing Phase 3 ENHANCE program.

- **SG&A Expenses:** Selling general and administrative expenses ("SG&A") were $15.0 million for the fourth quarter ended December 31, 2023 (Q4 2022: $8.3 million). The increase of $6.7 million was primarily due to a $3.2 million increase in people related costs, inclusive of share-based compensation, and an increase of $3.5 million related to the build-out of the commercial and information technology infrastructures in preparation for a potential commercial launch, marketing and market development expenses, travel and other corporate costs.
- **Net loss:** Net loss was $14.1 million for the fourth quarter ended December 31, 2023 (Q4 2022: net loss $10.5 million).

Full Year 2023 Financial Results

- **R&D Expenses:** R&D expenses were $17.2 million for the year ended December 31, 2023 (full year 2022: $49.3 million), a decrease of $32.1 million. This decrease was primarily due to a $32.7 million decrease in clinical trial and other development costs as we incurred less costs under the Phase 3 ENHANCE program which completed study conduct and analysis in 2023 whereas in 2022 significant costs were incurred associated with the then ongoing study conduct.
- **SG&A Expenses**: SG&A expenses were $50.4 million for the year ended December 31, 2023 (full year 2022: $26.6 million), an increase of $23.8 million. This increase was driven primarily by a $15.6 million increase in people related costs, inclusive of share-based compensation, an increase of $9.7 million related to the build-out of the commercial and information technology infrastructures in preparation for a potential commercial launch, marketing and market development expenses, travel and other corporate costs.
- **Net loss:** Net loss was $54.4 million for the year ended December 31, 2023 (full year 2022: $68.7 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 29, 2024, to discuss the fourth quarter and full year 2023 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 fourth quarter and full year 2023 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 clinical-stage 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"). 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 $400 million debt financing facility and from cash receipts from UK tax credits, and the sufficiency of cash and cash equivalents, and the cash runway period provided by the sources of financing through to at least the end of 2026 and expected to fully fund the planned commercialization of ensifentrine.

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 like the COVID-19 pandemic, 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, 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 December 31,		Years ended December 31,	
	2023	2022	2023	2022
Revenue	$ —	$ 458	$ —	$ 458
Cost of sales	—	(346)	—	(346)
Gross profit	—	112	—	112
Operating expenses				
Research and development	4,122	6,838	17,216	49,283
Selling, general and administrative	14,972	8,323	50,353	26,579
Total operating expenses	19,094	15,161	67,569	75,862
Operating loss	(19,094)	(15,049)	(67,569)	(75,750)
Other income / (expense)				
Research & development tax credit	1,034	796	1,104	9,634
Loss on extinguishment of debt	—	(815)	—	(815)
Interest income	3,292	1,862	12,761	2,821
Interest expense	(623)	(230)	(2,057)	(521)
Foreign exchange gain/(loss)	1,206	3,013	1,866	(3,817)
Total other income, net	4,909	4,626	13,674	7,302
Loss before income taxes	(14,185)	(10,423)	(53,895)	(68,448)
Income tax benefit/(expense)	53	(28)	(474)	(253)
Net loss	$ (14,132)	$ (10,451)	$ (54,369)	$ (68,701)
Weighted average shares outstanding – basic and diluted	642,139,211	604,204,929	634,142,660	529,071,526
Loss per ordinary share - basic and diluted	$ (0.02)	$ (0.02)	$ (0.09)	$ (0.13)

	2023	2022
Cash and cash equivalents	$ 271,772	$ 227,827
Total assets	308,124	259,468
Shareholders' equity	$ 249,283	$ 230,466