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): June 26, 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.)**

One Central Square
Cardiff CF10 1FS
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 Stock Market LLC (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 7.01. Regulation FD Disclosure

On June 26, 2024, Verona Pharma plc (the "Company") issued a press release announcing the U.S. Food and Drug Administration's ("FDA") approval of Ohtuvayre (ensifentrine) for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients. A copy of the press release is attached as Exhibit 99.1 and incorporated herein by reference.

The information contained under Item 7.01 of this Current Report on 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 incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as may be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On June 26, 2024, the Company announced that the FDA had approved Ohtuvayre (ensifentrine) for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

Ohtuvayre is a first-in-class selective dual inhibitor of the enzymes phosphodiesterase 3 and phosphodiesterase 4 that combines bronchodilator and non-steroidal anti-inflammatory effects in one molecule. Ohtuvayre is delivered directly to the lungs through a standard jet nebulizer without the need for high inspiratory flow rates or complex hand-breath coordination.

The Company expects Ohtuvayre to be available in the third quarter of 2024 through an exclusive network of accredited specialty pharmacies. Complete prescribing information is available at https://ohtuvayrehcp.com/files/Ohtuvayre-US-Prescribing-Information.pdf.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1*	Press Release, dated June 26, 2024.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

* Furnished herewith.

Forward-Looking Statements

This Current Report on Form 8-K (this "Form 8-K") 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 anticipated timing of commercial availability and our ability to successfully market and sell Ohtuvayre.

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 the Company's actual results, performance or achievements to be materially different from the Company's expectations expressed or implied by the forward-looking statements, including, but not limited to, the following: the Company's limited operating history; the Company's need for additional funding to complete development and commercialization of Ohtuvayre which may not be available and which may force the Company to delay, reduce or eliminate its development or commercialization efforts; the Company's reliance on the success of Ohtuvayre, its only commercial product; the Company's reliance on third-party manufacturers and suppliers; the efficacy of Ohtuvayre compared to competing drugs; the Company's ability to successfully commercialize Ohtuvayre; serious adverse, undesirable or unacceptable side effects associated with Ohtuvayre which could adversely affect the Company's 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; lawsuits related to patents covering Ohtuvayre and the potential for the Company's patents to be found invalid or unenforceable; lawsuits related to the Company's licensing of patents and know-how from third parties for the commercialization of Ohtuvayre; changes in the Company's tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments that could affect the Company's profitability, and audits by tax authorities that could result in additional tax payments for prior periods; and the Company's 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 the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024 filed with the Securities and Exchange Commission ("SEC") on May 10, 2024, and the Company's other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Form 8-K. While the Company may elect to update such forward-looking statements at some point in the future, the Company disclaims any obligation to do so, even if subsequent events cause the Company's views to change, except as required under applicable law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Form 8-K.

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: June 27, 2024

By: /s/ David Zaccardelli, Pharm. D.
Name: David Zaccardelli, Pharm. D.
Title: President and Chief Executive Officer

Exhibit 99.1

Verona Pharma Announces US FDA Approval of Ohtuvayre™ (ensifentrine)

Ohtuvayre is indicated for the maintenance treatment of COPD allowing for broad use in COPD patients

First inhaled COPD treatment providing bronchodilation and non-steroidal anti-inflammatory effects

Conference call tomorrow at 8:30 a.m. EDT / 1:30 p.m. BST

LONDON and RALEIGH, N.C., June 26, 2024 – Verona Pharma plc (Nasdaq: VRNA) ("Verona Pharma" or the "Company"), announces the US Food and Drug Administration ("FDA") approved Ohtuvayre (ensifentrine) for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients. Ohtuvayre is the first inhaled product with a novel mechanism of action available for the maintenance treatment of COPD in more than 20 years.

Ohtuvayre is a first-in-class selective dual inhibitor of the enzymes phosphodiesterase 3 and phosphodiesterase 4 ("PDE3 and PDE4") that combines bronchodilator and non-steroidal anti-inflammatory effects in one molecule. Ohtuvayre is delivered directly to the lungs through a standard jet nebulizer without the need for high inspiratory flow rates or complex hand-breath coordination.

"The approval of Ohtuvayre is a significant advance in COPD care, and we believe Ohtuvayre's novel profile can change the treatment paradigm for COPD," said David Zaccardelli, Pharm. D., President and Chief Executive Officer of Verona Pharma. "We plan to launch Ohtuvayre in the third quarter 2024, ensuring Ohtuvayre is available to help the millions of patients who still experience daily COPD symptoms."

Michael Wells, MD, Associate Professor in the Division of Pulmonary, Allergy, and Critical Care Medicine at the University of Alabama Birmingham, commented: "In my experience, despite maintenance therapy, most patients report grappling with daily symptoms, including breathlessness and persistent coughing. COPD has a significant impact on both mortality and morbidity in the US, and until today, innovation in inhaled treatment modalities has been limited to combinations of existing treatment classes for over two decades. Ohtuvayre, as a first-in-class PDE3 and PDE4 inhibitor, offers a needed, unique approach and is an important advance in the treatment of COPD."

The US approval of Ohtuvayre was based on extensive data including the Phase 3 ENHANCE trials, the results of which were published in the *American Journal of Respiratory and Critical Care Medicine*. In the ENHANCE trials, Ohtuvayre demonstrated clinical benefits both alone and when used with other maintenance therapies. Ohtuvayre was well-tolerated in a broad population of subjects with moderate to severe COPD.

The Company is fully staffed to launch and expects Ohtuvayre to be available in the third quarter 2024 through an exclusive network of accredited specialty pharmacies.

Conference Call

Verona Pharma will host an investment community conference call at 8:30 a.m. EDT / 1:30 p.m. BST on Thursday, June 27, 2024 to discuss the US approval of Ohtuvayre. 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.

About Ohtuvayre (ensifentrine)

Ohtuvayre is the first inhaled therapy for the maintenance treatment of COPD that combines bronchodilator and non-steroidal anti-inflammatory activities in one molecule. Verona has evaluated nebulized Ohtuvayre in its Phase 3 clinical program ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") for COPD maintenance treatment. Ohtuvayre met the primary endpoint in both ENHANCE-1 and ENHANCE-2, demonstrating statistically significant and clinically meaningful improvements in lung function. A fixed-dose combination of ensifentrine and glycopyrrolate, a LAMA, is currently under development for the maintenance treatment of COPD. Ensifentrine has potential applications for development in non-cystic fibrosis bronchiectasis, cystic fibrosis, asthma and other respiratory diseases.

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.

About COPD

Chronic obstructive pulmonary disease ("COPD") refers to a group of diseases that cause airflow blockage and breathing-related problems, such as emphysema and chronic bronchitis. More than 390 million people worldwide are living with COPD, and more than 8.6 million Americans are treated chronically[1-2]. Symptoms include increased shortness of breath, frequent coughing (with and without mucus), wheezing, tightness in the chest and unusual tiredness. Approximately 50% of COPD patients experience almost daily symptoms[3]. There is no cure for COPD and despite available treatment options, it is the third leading cause of death globally.

[1]Adeloye D, et al. *Lancet Respir Med.* 2022;10(5):447-458

[2]Verona IQVIA Ensifentrine Market Research

[3]Phreesia 2022 COPD Patient Survey

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, including COPD, non-cystic fibrosis bronchiectasis, cystic fibrosis, asthma and other respiratory diseases. For more information, please visit www.veronapharma.com.

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Forward-Looking Statements

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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; 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; 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 March 31, 2024 filed with the Securities and Exchange Commission (“SEC”) on May 10, 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.