# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

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# FORM 6-K

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**REPORT OF FOREIGN PRIVATE ISSUER**
**PURSUANT TO RULE 13a-16 OR 15d-16**
**UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**For the month of September 2020**

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**Commission File Number: 001-38067**

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# Verona Pharma plc
**(Translation of registrant's name into English)**

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**3 More London Riverside**
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**(Address of principal executive office)**

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

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**INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K**

Initiation of Phase 3 Clinical Trials with Nebulized Ensifentrine for the Maintenance Treatment of COPD

On September 23, 2020, Verona Pharma plc announced the initiation of of its ENHANCE (“Ensifentrine as a Novel inHAled Nebulized COPD thErapy”) Phase 3 trials to evaluate the efficacy and safety of nebulized ensifentrine in patients with moderate to severe chronic obstructive pulmonary disease (the "Announcement").

The Announcement is furnished herewith as Exhibit 1.1 to this Report on Form 6-K.

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 1.1 | Initiation of Phase 3 Announcement |

**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, thereunto duly authorized.

**VERONA PHARMA PLC**

Date: September 25, 2020

By: /s/ Claire Poll

Name: Claire Poll

Title: Legal Counsel

# Verona Pharma Initiates Phase 3 Clinical Trials with Nebulized Ensifentrine for the Maintenance Treatment of COPD

**LONDON and RALEIGH, N.C., September 23 2020** – Verona Pharma plc (AIM: VRP) (Nasdaq: VRNA) ("Verona Pharma"), a clinical-stage biopharmaceutical company focused on respiratory diseases, announces the initiation of its ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") Phase 3 trials to evaluate the efficacy and safety of nebulized ensifentrine in patients with moderate to severe chronic obstructive pulmonary disease ("COPD").

David Zaccardelli, Pharm. D., President and CEO of Verona Pharma, said: "We are excited to start our pivotal ENHANCE Phase 3 studies. If successful, the data will support the submission of a New Drug Application in the U.S. for nebulized ensifentrine for the maintenance treatment of COPD. This is an important milestone for Verona Pharma and we look forward to addressing the urgent need for a novel therapy for the treatment of COPD."

Ensifentrine is a first-in-class product candidate that combines bronchodilator and anti-inflammatory activities in one compound. In prior clinical studies in COPD, ensifentrine has shown significant and clinically meaningful improvements in lung function, symptoms and quality of life as a monotherapy or added onto a maintenance bronchodilator. Ensifentrine has been well tolerated in clinical trials involving more than 1,300 subjects to date.

**About the ENHANCE program**

The two randomized, double-blind, placebo-controlled studies (ENHANCE-1 and ENHANCE-2) will evaluate the efficacy and safety of nebulized ensifentrine as monotherapy and added onto a single bronchodilator, either a LAMA ("long acting muscarinic antagonist") or a LABA ("long acting beta-agonist"), compared to placebo. The two study designs will replicate measurements of efficacy and safety data over 24 weeks and ENHANCE-1 will also evaluate longer-term safety over 48 weeks.

- Patient Population: Each study will enroll approximately 800 moderate to severe, symptomatic, COPD patients at sites primarily in the U.S. and Europe.
- Dose/Duration: Patients will be randomized to receive a 3 mg nebulized dose of ensifentrine or nebulized placebo twice daily for 24 weeks in ENHANCE-2 or 48 weeks in ENHANCE-1.
- Primary Endpoint: Improvement in lung function as measured by forced expiratory volume* in one second ("$FEV_1$") over 12 hours with ensifentrine after 12 weeks of treatment.
- Key Secondary Endpoints: COPD symptoms and health-related quality of life through 24 weeks via the validated patient reported outcome tools, SGRQ and E-RS: COPD. Additional lung function endpoints including peak and morning trough $FEV_1$ will also be assessed.
- Safety: Assessed over 24 weeks in both studies and over 48 weeks in approximately 400 patients in ENHANCE-1.

Further information about this study can be found at www.clinicaltrials.gov, NCT04535986 (ENHANCE-1) and NCT04542057 (ENHANCE-2).

* $FEV_1$: Forced Expiratory Volume in one second, a standard measure of lung function

For further information, please contact:

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**About COPD**

COPD is a progressive and life-threatening respiratory disease without a cure. It is the third leading cause of death globally, according to the World Health Organization. The condition damages the airways and the lungs, leading to debilitating breathlessness that has a devastating impact on performing basic daily activities such as getting out of bed, showering, eating and walking. U.S. sales of medicines used for chronic maintenance therapy of COPD were $9.6 billion in 2019. About 1.2 million U.S. COPD patients on dual/triple inhaled therapy, long-acting beta-agonist ("LABA")/long-acting muscarinic antagonist ("LAMA") +/- inhaled corticosteroid ("ICS") remain uncontrolled, experiencing symptoms that impair quality of life. These patients urgently need better treatments.

**About Ensifentrine**

Ensifentrine (RPL554) is an investigational, first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4 ("PDE3" and "PDE4"). This dual inhibition enables it to combine both bronchodilator and anti-inflammatory effects in one compound. Ensifentrine also activates the Cystic Fibrosis Transmembrane Conductance Regulator ("CFTR"), which is beneficial in reducing mucous viscosity and improving mucociliary clearance. Ensifentrine's mechanism of action has the potential to alleviate respiratory symptoms such as breathlessness and cough and work against inflammation associated with COPD or inflammation triggered by viruses.

Ensifentrine has demonstrated significant and clinically meaningful improvements in both lung function and symptoms, including breathlessness, in Verona Pharma's Phase 2 clinical studies in patients with moderate to severe Chronic Obstructive Pulmonary Disease ("COPD"). In addition, nebulized ensifentrine showed further improved lung function and reduced lung volumes in COPD patients taking standard short- and long-acting

bronchodilator therapy, including maximum bronchodilator treatment with dual/triple therapy. Ensifentrine has been well tolerated in clinical trials involving more than 1,300 subjects to date.

**About Verona Pharma**

Verona Pharma is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of respiratory diseases with significant unmet medical needs. If successfully developed and approved, Verona Pharma's product candidate, ensifentrine, has the potential to be the first therapy for the treatment of respiratory diseases that combines bronchodilator and anti-inflammatory activities in one compound. The Company is evaluating nebulized ensifentrine in its Phase 3 clinical program ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") for COPD maintenance treatment. The Company raised gross proceeds of $200 million through a private placement in July 2020 and expects the funds to support its operations and Phase 3 clinical program into 2023. Two additional formulations of ensifentrine are currently in Phase 2 development for the treatment of COPD: dry powder inhaler ("DPI") and pressurized metered-dose inhaler ("pMDI"). Ensifentrine is in a pilot clinical study in patients hospitalized with COVID-19 and has potential applications in 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. 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, the development of ensifentrine, the progress and timing of initiation of clinical trials, the goals and design of clinical trials, patient enrolment and study completion, the potential for ensifentrine to be a first-in-class phosphodiesterase 3 and 4 inhibitor and to be the first therapy for the treatment of respiratory diseases to combine bronchodilator and anti-inflammatory effects in one compound, the potential of ensifentrine to alleviate respiratory symptoms such as breathlessness and cough and work against inflammation triggered by viruses, the Phase 3 clinical data supporting the submission of a New Drug Application in the U.S. for nebulized ensifentrine for the maintenance treatment of COPD, the sufficiency of funds to supports its operations and Phase 3 clinical program into 2023, and the potential of ensifentrine in the treatment of COVID-19, COPD, cystic fibrosis, asthma and other respiratory diseases.

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 ensifentrine, which may not be available and which may force us to delay, reduce or eliminate our development 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; potential delays in enrolling patients, which could adversely affect our research and development efforts and the completion of our clinical trials; we may not be successful in developing ensifentrine 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, and third-party service providers; 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; and lawsuits related to patents covering ensifentrine and the potential for our patents to be found invalid or unenforceable; and our vulnerability to natural disasters, global economic factors and other unexpected events, including health epidemics or pandemics like the novel coronavirus (COVID-19). These and other important factors under the caption “Risk Factors” in our Annual Report on Form 20-F filed with the Securities and Exchange Commission (“SEC”) on February 27, 2020, under the caption “Supplemental Risk Factor Disclosures” in our Report on Form 6-K filed with the SEC on April 30, 2020, under the caption “Risk Factors” in our Registration Statement on Form F-1 filed with the SEC on August 17, 2020, 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. 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.