# 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 January 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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**+44 203 283 4200**
**(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): ☐

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

On January 13, 2020, Verona Pharma plc (the "Company") issued a press release announcing top-line data from a Phase 2b dose-ranging study evaluating nebulized ensifentrine as an add-on treatment to tiotropium (the "Trial Announcement"). The Trial Announcement is furnished herewith as Exhibit 1 to this Report on Form 6-K.

In the Trial Announcement, the Company reported positive top-line data from its 4 week, 416 patient, Phase 2b dose-ranging study evaluating nebulized ensifentrine (0.375 mg, 0.75 mg, 1.5 mg and 3.0 mg) or placebo as an add-on treatment to tiotropium (Spiriva® Respimat®), a long acting anti-muscarinic ("LAMA") bronchodilator, in patients with moderate to severe chronic obstructive pulmonary disease ("COPD").

The study met its primary endpoint of improved lung function, with ensifentrine added on to inhaled tiotropium, a LAMA commonly used to treat COPD. Ensifentrine produced a clinically and statistically significant, and dose-dependent improvement in peak forced expiratory volume in one second ("$FEV_1$")[1] at week 4 compared to placebo added on to tiotropium. Additional highlights from the study include:

- Primary endpoint met at all doses: statistically significant and clinically meaningful improvement in lung function at week 4. Improvements ranged from 78 mL for the 0.375 mg dose (p=0.0368) to 124 mL for the 3.0 mg dose (p=0.0008). Effects were maintained over 4 weeks.
- Dose-dependent improvements in lung function were observed on both peak $FEV_1$ and $FEV_1$ AUC 0-12 hours[2].
- Statistically significant improvement in average $FEV_1$ AUC 0-12 hours of 87 mL for the 3.0 mg dose (p=0.0111) is supportive of twice daily dosing.
- Clinically meaningful improvements in health-related quality of life (mean SGRQ-C[3]) were observed on top of tiotropium, exceeding the minimal clinically important difference ("MCID") of 4 units compared to placebo at week 4, with the two highest doses also achieving statistical significance.
- Ensifentrine was well tolerated at all doses with an adverse event profile similar to placebo.
- These data support dose selection for Phase 3

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[1] $FEV_1$: Forced Expiratory Volume in one second, a standard measure of lung function
[2] $FEV_1$ $AUC_{(0\text{-}12hr)}$: Area Under the Curve over 0-12 hours post dose, calculated using the trapezoidal rule, divided by the observation time (12 hours) to report in mL, a measure of the aggregate effect over 12 hours
[3] SGRQ-C: St. George's Respiratory Questionnaire is a validated instrument that measures impact on overall health, daily life, and perceived well-being in patients with COPD (i.e. change in frequency and severity of COPD symptoms, and impact on activities, social functioning and psychological disturbances related to airways disease)

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The Trial Results are hereby incorporated by reference into the Company's Registration Statement on Form F-3 (333-225107) and Registration Statement on Form S-8 (333-217521).

## EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 1 | Trial 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: January 17, 2020

By: /s/ Claire Poll

Name: Claire Poll

Title: Legal Counsel

# Verona Pharma Reports Positive Top-line Data in 4 Week Phase 2b COPD Study with Nebulized Ensifentrine on Top of Tiotropium Therapy

*Primary endpoint met at all doses: ensifentrine produced clinically and statistically significant dose-dependent improvements in lung function*

*Clinically relevant secondary endpoints met, including progressive and statistically significant improvements in quality of life*

Conference call scheduled for 6.00 am PST / 9.00 am EST / 2.00 pm GMT
on Monday, January 13, 2020

**LONDON, January 13, 2020** - Verona Pharma plc (AIM: VRP) (Nasdaq: VRNA) ("Verona Pharma"), a biopharmaceutical company focused on respiratory diseases, announces positive top-line data from a 4 week, 416 patient, Phase 2b dose-ranging study evaluating nebulized ensifentrine (0.375 mg, 0.75 mg, 1.5 mg and 3.0 mg) or placebo as an add-on treatment to tiotropium (Spiriva® Respimat®), a long acting anti-muscarinic ("LAMA") bronchodilator, in patients with moderate to severe chronic obstructive pulmonary disease ("COPD").

The study met its primary endpoint of improved lung function, with ensifentrine added on to inhaled tiotropium, a LAMA commonly used to treat COPD. Ensifentrine produced a clinically and statistically significant, and dose-dependent improvement in peak forced expiratory volume in one second ("$FEV_1$")[1] at week 4 compared to placebo added on to tiotropium.

**Highlights for ensifentrine as an add-on to tiotropium**

- Primary endpoint met at all doses: statistically significant and clinically meaningful improvement in lung function at week 4. Improvements ranged from 78 mL for the 0.375 mg dose (p=0.0368) to 124 mL for the 3.0 mg dose (p=0.0008). Effects were maintained over 4 weeks.
- Dose-dependent improvements in lung function were observed on both peak $FEV_1$ and $FEV_1$ AUC 0-12 hours[2].
- Statistically significant improvement in average $FEV_1$ AUC 0-12 hours of 87 mL for the 3.0 mg dose (p=0.0111) is supportive of twice daily dosing.
- Clinically meaningful improvements in health-related quality of life (mean SGRQ-C[3]) were observed on top of tiotropium, exceeding the minimal clinically important difference ("MCID") of 4 units compared to placebo at week 4, with the two highest doses also achieving statistical significance.
- Ensifentrine was well tolerated at all doses with an adverse event profile similar to placebo.
- These data support dose selection for Phase 3.

Gary Ferguson, MD, a pulmonary physician and Principal Investigator at the Pulmonary Research Institute of Southeast Michigan commented: “The strong effect on both bronchodilation and quality of life as an add-on to tiotropium is impressive and consistent with prior studies with ensifentrine. I am particularly interested to see the significant improvements in quality of life measurements over the 4 week treatment period. This is very important for patients that remain symptomatic despite using standard COPD medications.”

Jan-Anders Karlsson, PhD, CEO of Verona Pharma, said: “We are delighted with these results in symptomatic COPD patients already on steady-state maintenance treatment with a long-acting LAMA bronchodilator. These data bring clarity to planning the design, including dose selection, endpoints and background therapy, of our Phase 3 program. We look forward to discussing these new and compelling data, together with the positive results from our previous clinical studies, in an End-of-Phase 2 meeting with the FDA planned for 2Q 2020. We are committed to demonstrating ensifentrine’s potential to produce sustained bronchodilation and anti-inflammatory effects in symptomatic COPD patients in Phase 3 trials, which we expect to start in 3Q 2020.”

**Phase 2b Study Design**

This 4 week randomized, double-blind, placebo-controlled dose-ranging Phase 2b trial enrolled a total of 416 patients with moderate to severe symptomatic COPD at 46 sites in the U.S. The trial was designed to evaluate the safety and efficacy of nebulized ensifentrine as an add-on to inhaled tiotropium, a long acting anti-muscarinic (“LAMA”) commonly used to treat patients with COPD.

Patients received nebulized ensifentrine at 4 dose levels: 0.375 mg, 0.75 mg, 1.5 mg and 3.0 mg or placebo twice daily for 4 weeks. The trial’s primary endpoint was improvement in lung function with ensifentrine after 4 weeks of treatment, as measured by peak $FEV_1$, a standard measure of lung function. Key additional endpoints included other lung function measures, as well as measurements of symptoms associated with COPD and quality of life outcomes.

Full data from the Phase 2b study will be released at a subsequent scientific meeting, pending further data analysis. For further information on this clinical trial, please visit ClinicalTrials.gov, NCT03937479.

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[3] SGRQ-C: St. George’s Respiratory Questionnaire is a validated instrument that measures impact on overall health, daily life, and perceived well-being in patients with COPD (i.e. change in frequency and severity of COPD symptoms, and impact on activities, social functioning and psychological disturbances related to airways disease)

**Conference Call**
Verona Pharma will host an investment community conference call today (Monday, January 13, 2020) at 6.00 am PST / 9.00 am EST / 2.00 pm GMT to discuss the Phase 2b study data. Analysts and investors may participate in the conference call using the conference ID: 2874368 and dialing the following numbers:

- 866 940 4574 for callers in the United States
- 0800 028 8438 for callers in the United Kingdom
- 0800 181 5287 for callers in Germany

Those interested in listening to the conference call live via the internet may do so by visiting the “Events and Presentations” page on the “Investors” section of Verona Pharma’s website at www.veronapharma.com/investors/upcoming-events and clicking on the webcast link. Slides highlighting the data will also be posted to the “Events and Presentations” page.

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF REGULATION (EU) NO 596/2014.

**About COPD**
COPD is a progressive and life-threatening respiratory disease without a cure. The World Health Organization estimates that it will become the third leading cause of death worldwide by 2030. 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. In the United States alone, the total annual medical costs related to COPD are projected to rise to $49 billion in 2020. About 1.2 million US 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**
Nebulized ensifentrine (RPL554) has shown significant and clinically meaningful improvements in both lung function and COPD symptoms, including breathlessness, in Verona Pharma’s prior Phase 2 clinical studies in patients with moderate to severe COPD. In addition, nebulized ensifentrine showed further improved lung function and reduced lung volumes in 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 1250 people 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. Verona Pharma is currently in Phase 2 development with three formulations of ensifentrine for the treatment of COPD: nebulized, dry powder inhaler, and pressurized metered-dose inhaler. Ensifentrine also 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 clinical trials and data and meetings with the U.S. FDA, estimates of medical costs for COPD, 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 activities in a single molecule, the distinct benefits of ensifentrine's novel mechanism of action in treating COPD, and the potential application of ensifentrine for the treatment of 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; material differences between our "top-line" data and final data; our reliance on third parties, including 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. 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 March 19, 2019, 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.

**For further information, please contact:**


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