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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 August 2019

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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  
London SE1 2RE UK  
+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):

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

On August 5, 2019, Verona Pharma plc (the "Company") issued a press release reporting the results of a Phase 2 study with dry powder inhaler ("DPI") formulation of ensifentrine (the "DPI Announcement"). The DPI Announcement is furnished herewith as Exhibit 1 to this Report on Form 6-K.

In the DPI Announcement the Company reported positive results from the second part of the Phase 2 study of the DPI formulation of ensifentrine in chronic obstructive pulmonary disease ("COPD"). The trial was conducted as a double blind, placebo controlled, seven day crossover study, which examined four dose strengths of ensifentrine and a placebo, dosed twice daily. The trial met all its primary and secondary lung function endpoints with ensifentrine delivered in a DPI format. The magnitude of improvement in lung function and duration of action were highly statistically significant and support twice daily dosing of ensifentrine for the treatment of COPD.

- Primary endpoint met:
  - Peak forced expiratory volume in one second ("FEV<sub>1</sub>"), corrected for placebo, showed improvements over baseline of 102 mL for the 150 µg dose, 175 mL for the 500 µg dose, 180 mL for the 1500 µg dose and 260 mL for the 3000 µg dose, (p<0.0001 for all doses), all highly statistically significant.
- Secondary endpoints met:
  - Statistically significant improvements in average FEV<sub>1</sub> over 12 hours were observed over seven days with all doses (average FEV<sub>1</sub> area under the curve 0-12 hours ("AUC<sub>(0-12hr)</sub>")) corrected for placebo: 36 mL for the 150 µg dose, 90 mL for the 500 µg dose, 80 mL for the 1500 µg dose and 147 mL for the 3000 µg dose; p<0.05 for all doses).
  - Ensifentrine in a handheld dry powder format was well tolerated at all doses with an adverse event profile similar to placebo. The safety profile was comparable to that observed in prior studies with nebulized ensifentrine.

This report on Form 6-K, excluding Exhibit 1, is hereby incorporated by reference into the Company's Registration Statement on Form F-3 (333-225107) and Registration Statement on Form S-8 (file no. 333-217521).

## EXHIBIT INDEX

Exhibit No.	Description
<a href="#">1</a>	<a href="#">DPI Announcement</a>

**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: August 8, 2019

By: /s/ Claire Poll

Name: Claire Poll

Title: Legal Counsel



# Verona Pharma

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## Verona Pharma Reports Positive Phase 2 Results with Dry Powder Inhaler Formulation of Ensifentrine in COPD

**LONDON, August 5, 2019** - Verona Pharma plc (AIM: VRP) (Nasdaq: VRNA) (“Verona Pharma”), a biopharmaceutical company focused on respiratory diseases, announces positive Phase 2 data with a dry powder inhaler (“DPI”) formulation of its lead development product, ensifentrine, for the maintenance treatment of chronic obstructive pulmonary disease (“COPD”). All of the primary and secondary lung function endpoints were met in the Phase 2 trial.

### Highlights:

- Primary endpoint met: highly statistically significant and clinically meaningful dose-dependent improvement in lung function
- Secondary lung function endpoints met, data supportive of twice daily dosing and ensifentrine well tolerated at all dose levels
- Delivery via DPI could substantially expand the clinical utility and commercial opportunity for ensifentrine in COPD
- Conference call and webcast to be held tomorrow (Tuesday, August 6) at 8 am EDT / 1 pm BST to discuss the Company’s second quarter financial results and the study data

The Phase 2 trial met all of its primary and secondary lung function endpoints with ensifentrine delivered in a DPI format. The magnitude of improvement in lung function and duration of action were highly statistically significant and support twice daily dosing of ensifentrine for the treatment of COPD.

- **Primary endpoint met:** peak FEV<sub>1</sub><sup>1</sup> corrected for placebo showed improvements over baseline of 102 mL for the 150 µg<sup>2</sup> dose, 175 mL for the 500 µg dose, 180 mL for the 1500 µg dose and 260 mL for the 3000 µg dose, (p<0.0001 for all doses), all highly statistically significant.
- **Secondary endpoints met:**
  - Statistically significant improvements in average FEV<sub>1</sub> over 12 hours were observed over 7 days with all doses (average FEV<sub>1</sub> AUC<sub>(0-12hr)</sub><sup>3</sup> corrected for placebo: 36 mL for the 150 µg dose, 90 mL for the 500 µg dose, 80 mL for the 1500 µg dose and 147 mL for the 3000 µg dose; p<0.05 for all doses).
  - Ensifentrine in a handheld dry powder format was well tolerated at all doses with an adverse event profile similar to placebo. The safety profile was comparable to that observed in prior studies with nebulized ensifentrine.

<sup>1</sup> FEV<sub>1</sub>: forced expiratory volume in one second, a standard measure of lung function

<sup>2</sup> µg: microgram, or mcg

<sup>3</sup> FEV<sub>1</sub> AUC<sub>(0-12hr)</sub>: area under the curve 0-12 hours calculated using the trapezoidal rule, divided by the observation time (12h) to report in mL, a measure of the aggregate effect over 12 hours

"Achieving a bronchodilator response of this magnitude in COPD patients is clinically meaningful and very encouraging," commented Joseph A Boscia, III, MD a Pulmonary Physician and Principle Investigator at Vitalink Research-Union, South Carolina. "This highlights the potential for ensifentrine's unique mechanism of action to provide lung function improvement and meet the urgent clinical need for new treatments for patients with this progressive and debilitating disease."

Jan-Anders Karlsson, PhD, CEO of Verona Pharma, said: "These very promising data with the DPI formulation support our view that ensifentrine is an effective bronchodilator in COPD patients, whether administered as a dry powder via a handheld inhaler or as a suspension via a nebuliser. Our proof-of-concept dry powder formulation can be adapted to different DPI devices used in the market. Millions of patients prefer to use a handheld device, and these data significantly expand ensifentrine's commercial potential. We plan to complete further development and commercialization of the DPI formulation with a partner and these clinical data strongly support this opportunity."

In addition to the DPI formulation of ensifentrine, Verona Pharma is developing a pressurized metered-dose inhaler ("pMDI") formulation of ensifentrine and expects to report initial single dose data using this widely used handheld inhaler format in the second half of 2019, with final multiple dose data from a one week study expected in the first quarter of 2020. Progression of the nebulized suspension formulation of ensifentrine continues, with data from the ongoing Phase 2b clinical trial expected around year end. Verona Pharma anticipates progressing the ensifentrine nebulizer formulation into Phase 3 clinical trials in 2020.

### **Study Design**

The randomized, double-blind, placebo-controlled, two-part Phase 2 trial (ClinicalTrial.gov NCT04027439) enrolled 35 patients with moderate-to-severe COPD at one US site to investigate the efficacy and safety of a DPI formulation of ensifentrine compared to placebo. In Part A of the trial, patients received a single dose of one (out of five) dosage strengths of ensifentrine (150 µg, 500 µg, 1500 µg, 3000 µg, or 6000 µg) or placebo. In March 2019, Verona Pharma reported positive interim efficacy and safety data from the first part of the trial, triggering initiation of the second part of the trial.

In Part B of the trial, patients were randomized to receive one of four dose levels (150 µg, 500 µg, 1500 µg, or 3000 µg) of ensifentrine DPI formulation or placebo, administered twice daily over one week. All patients received each dose level and placebo over five seven-day treatment periods. The primary endpoint was improvement in peak bronchodilator effect of repeat doses of ensifentrine delivered via DPI compared to placebo, as measured by FEV<sub>1</sub>. Secondary objectives included evaluating the safety, tolerability and bronchodilator profile of repeat doses of ensifentrine administered by DPI, as well as the pharmacokinetic profile, onset of action, and the amount of rescue medication use during treatment periods.

Data on the primary and secondary lung function and pharmacokinetic profile endpoints have been received and all endpoints were met. Data on the amount of rescue medication use during treatment periods are expected later this month.

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## Conference Call

Verona Pharma will host an investment community conference call tomorrow (*Tuesday, August 6*) at 8 am EDT / 1 pm BST to discuss the second quarter financial results and the study data.

Analysts and investors may participate in the conference call using the conference ID: 7433729 and dialing the following numbers:

- 866-940-4574 or 409-216-0615 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 <http://investors.veronapharma.com/events-and-presentations/events> and clicking on the webcast link. Slides highlighting the top-line 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 2010 total annual medical costs related to COPD were estimated to be \$32 billion and are projected to rise to \$49 billion in 2020. In the US, DPI and pMDI handheld inhalers are the most widely used option for medication in COPD, where an estimated 5.5 million people use inhalers for COPD maintenance therapy. This market was valued at approximately \$6 billion in 2017. About 800,000 US COPD patients on dual/triple inhaled therapy (LAMA/LABA +/- ICS) remain uncontrolled, experiencing symptoms that impair quality of life. These patients urgently need better treatments.

### About Verona Pharma plc

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. Verona Pharma’s product candidate, ensifentrine (RPL554), is a first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4 that has been shown to act as both a bronchodilator and an anti-inflammatory agent in a single compound. Three formulations of ensifentrine are under development for the treatment of COPD: nebulized ensifentrine is currently in Phase 2b clinical development for the maintenance treatment of COPD and is planned to enter Phase 3 trials for this indication in 2020; a dry powder inhaler (“DPI”) formulation reported positive Phase 2 data in August 2019; a pressurized metered-dose inhaler (“pMDI”) formulation expects to report Phase 2 single dose data in the second half of 2019, with final data expected in the first quarter of 2020. Verona Pharma may also develop ensifentrine for the treatment of cystic fibrosis and asthma.

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Nebulized ensifentrine has shown significant and clinically meaningful improvements in both lung function and COPD symptoms, including breathlessness, in prior Phase 2 clinical studies in patients with moderate-to-severe COPD. In addition, nebulized ensifentrine has 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 800 people to date.

### **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, statements that ensifentrine is a first-in-class inhibitor, that inhaler formulations of ensifentrine could expand the clinical utility and commercial opportunity for ensifentrine, the plan to complete late stage development and commercialization of the DPI formulation with a partner and that the data supports this opportunity, the timing of Phase 3 trials of nebulized ensifentrine, the timing of receipt of data from clinical trials, the need for better treatment options for COPD, and projections regarding the mortality rate of, and medical costs related to, COPD.

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 Phase 2b trial; 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

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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:**

**Verona Pharma plc**

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