

**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): April 29, 2021

Verona Pharma plc
(Exact name of registrant as specified in its charter)

United Kingdom
(State or other jurisdiction
of incorporation)

001-39067
(Commission
File Number)

Not Applicable
(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 April 29, 2021, Verona Pharma plc (the “Company”) announced its financial results for the quarter ended March 31, 2021. 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 April 29, 2021
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: April 29, 2021

By: /s/ David Zaccardelli, Pharm. D.

Name: David Zaccardelli, Pharm. D.

Title: Chief Executive Officer



Verona Pharma Reports First Quarter 2021 Financial Results and Provides Corporate Update

ENHANCE Phase 3 program enrollment continues on track to complete in 2H21

Board strengthened with NED appointment of Lisa Deschamps

Conference call today at 9:00 a.m. EDT / 2:00 p.m. BST

LONDON and RALEIGH, N.C., April 29, 2021 – 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 three months ended March 31, 2021, and provides a corporate update.

“The first quarter of 2021 set a positive tone for what we expect to be another exciting year of substantial progress for Verona Pharma,” said David Zaccardelli, Pharm. D., President and Chief Executive Officer. “Patient recruitment is ongoing in our Phase 3 ENHANCE (“Ensifentrine as a Novel inHAled Nebulized COPD thErapy”) clinical program. Based on our projections, we continue to expect to complete enrollment in both studies in the second half of 2021 and to report top-line data from ENHANCE-2 in the first half of 2022 and from ENHANCE-1 in the second half of 2022.

“We have already reported results from two clinical studies this year. In February, we reported positive Phase 2 results with the pressurized metered-dose inhaler (“pMDI”) formulation of ensifentrine in moderate to severe COPD patients, and, last week, we reported that data from a pilot study with pMDI ensifentrine showed that ensifentrine added on to standard of care was well tolerated in patients hospitalized with COVID-19. The study was not powered to identify statistically significant efficacy outcomes and no benefit with ensifentrine added on to standard of care was observed.

In addition to this clinical progress, we strengthened our board with the Non-Executive Director appointment of Lisa Deschamps, Senior Vice President, Chief Business Officer, Novartis Gene Therapies. Lisa’s strategic and commercial expertise will be valuable as we progress ensifentrine through Phase 3 trials and prepare for commercialization.”

First Quarter and Recent Highlights

Clinical

- In April 2021, Verona Pharma reported that results from the pilot study with pMDI ensifentrine showed ensifentrine added on to standard of care was well tolerated in patients hospitalized with COVID-19. The study was not powered to identify statistically significant efficacy outcomes and no clinical efficacy benefit with ensifentrine added on to standard of care was observed. The Company does not currently plan to conduct further studies of ensifentrine in the treatment of COVID-19.
 - In February 2021, Verona Pharma announced positive Phase 2 efficacy and safety data with pMDI ensifentrine in patients with moderate to severe COPD. The primary and secondary lung function endpoints were achieved and the data support further evaluation of twice-daily dosing. All three inhaled formulations have demonstrated statistically significant improvements in lung function in COPD patients, supporting the broad potential of ensifentrine delivered via nebulizers and handheld inhalers.
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Corporate

- In March 2021, Ms. Lisa Deschamps joined the board as a Non-Executive Director. Ms. Deschamps is Senior Vice President, Chief Business Officer, of Novartis Gene Therapies. She has significant global and US experience in bringing respiratory and other specialized therapeutic area products to the market.

Upcoming Key Milestones

The Company's near-term milestones include:

- Presenting three abstracts demonstrating positive safety, symptom and quality of life data from Phase 2b clinical studies with nebulized ensifentrine in COPD at the American Thoracic Society International Conference ("ATS") [here](#) in May 2021.
- Based on recruitment projections, the Company expects to complete enrollment in both Phase 3 trials, ENHANCE-1 and ENHANCE-2, with the nebulized formulation of ensifentrine for the maintenance treatment of COPD in the second half of 2021. With the pandemic and government and other measures in response impacting a number of clinical trial activities, the Company continues to monitor these timelines.
- Longer term, based on forecasted recruitment and study progress, the Company expects to announce top-line data from ENHANCE-2 in the first half of 2022 and from ENHANCE-1 in the second half of 2022.

First Quarter 2021 Financial Results

- **Cash position:** Cash and cash equivalents at March 31, 2021, were \$169.6 million (December 31, 2020: \$188.0 million). The Company believes our cash and cash equivalents at March 31, 2021, together with funding expected to become available under the \$30.0 million debt financing facility secured in November 2020 and from cash receipts from U.K. tax credits, will enable us to fund our planned operating expenses and capital expenditure requirements into 2023.
- **R&D Expenses:** Research and development ("R&D") expenses were \$13.6 million for the first quarter ended March 31, 2021 (Q1 2020: R&D expenses \$7.6 million). The increase was primarily due to costs associated with the Phase 3 ENHANCE program as well an increase in share-based compensation charges.
- **G&A Expenses:** General and administrative expenses ("G&A") were \$9.3 million for the first quarter ended March 31, 2021 (Q1 2020: G&A expenses \$6.9 million). This increase was driven by an increase in share-based compensation charges, partially offset by executive change costs in the prior period.
- **Net loss:** Net loss was \$21.3 million for the first quarter ended March 31, 2021 (Q1 2020: net loss \$12.3 million).

Conference Call and Webcast Information

Verona Pharma will host an investment community conference call at 9:00 a.m. EDT / 2:00 p.m. BST on Thursday, April 29, 2021 to discuss the first quarter 2021 financial results and the corporate update.

Analysts and investors may participate by dialing one of the following numbers and reference conference ID 7429971:

- +1-888-317-6003 for callers in the United States
 - +1-412-317-6061 for international callers
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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 an audio replay will be available there for 30 days. An electronic copy of the first quarter 2021 results press release will also be made available today on the Company's website. This press release does not constitute an offer to sell or the solicitation of an offer to buy any of the Company's securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

For further information please contact:

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Mary Clark / Eva Haas / Shabnam Bashir

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. Two additional formulations of ensifentrine are in Phase 2 development for the treatment of COPD: dry powder inhaler ("DPI") and pressurized metered-dose inhaler ("pMDI"). Ensifentrine has potential applications in cystic fibrosis, asthma and other respiratory diseases. For more information, please visit www.veronapharma.com.

COVID-19 Impact

Verona Pharma is closely monitoring the potential impact of the COVID-19 pandemic on its operations and clinical trials, in particular the timelines and costs of its Phase 3 ENHANCE clinical program. The pandemic and government and other measures in response are impacting a number of clinical trial activities and the Company will provide an update if it becomes aware of any meaningful disruption caused by the pandemic to its clinical trials.

To help protect the health and safety of the patients, caregivers and healthcare professionals involved in its clinical trials, as well as its employees and independent contractors, the Company continues to follow guidance from the FDA and other health regulatory authorities regarding the conduct of clinical trials during the COVID-19 pandemic to ensure the safety of study participants, minimize risks to study integrity, and maintain compliance with good clinical practice (GCP).

Verona Pharma is closely monitoring activities at the Company's contract manufacturers associated with clinical supply for the ongoing clinical trials, and is satisfied that appropriate plans and procedures are in place to ensure uninterrupted future supply of ensifentrine to the clinical trial sites, subject to potential limitations on their operations and on the supply chain due to the COVID-19 pandemic. The Company is continuing to monitor this situation and will provide an update if it becomes aware of any meaningful disruption caused by the pandemic to the clinical supply of ensifentrine for its clinical trials.

Verona Pharma has also implemented measures to help keep the Company's employees, families, and local communities healthy and safe. All employees are working remotely and all business travel has been restricted.

Forward-Looking Statements

This press release contains forward-looking statements. All statements contained in this press release with respect to our operational review, outlook and financial review that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the development of ensifentrine and the progress and timing of clinical trials and data, the goals and design of clinical trials, the potential for ensifentrine 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 in the treatment of COPD, cystic fibrosis, asthma and other respiratory diseases, as well as the potential of the DPI and pMDI formulations of ensifentrine, the impact of the COVID-19 pandemic on our business and operations and the Company's future financial results, the funding we expect to become available under the \$30.0 million debt financing facility and from cash receipts from U.K. tax credits, and the sufficiency of cash and cash equivalents.

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; 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 and other unexpected events, including health epidemics or pandemics like the COVID-19 pandemic, 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, 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.

Verona Pharma, plc
Consolidated Financial Summary

	Three months ended March 31,	
	2021	2020
Operating expenses		
Research and development	\$ 13,574	\$ 7,634
General and administrative	9,282	6,850
Total operating expenses	<u>22,856</u>	<u>14,484</u>
Operating loss	(22,856)	(14,484)
Other income / (expense)		
Benefit from R&D tax credit	2,070	1,685
Interest income	4	69
Interest expense	(84)	-
Fair value movement on warrants	(507)	142
Foreign exchange gain / (loss)	163	293
Total other income, net	<u>1,646</u>	<u>2,189</u>
Loss before income taxes	(21,210)	(12,295)
Income tax expense	(80)	(51)
Net loss	<u>\$ (21,290)</u>	<u>\$ (12,346)</u>
Weighted average shares outstanding	463,505,681	105,453,364
Loss per ordinary share — basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.12)</u>
	March 31	December 31
	2021	2020
Cash, cash equivalents and short term investments	\$ 169,598	\$ 187,986
Total assets	\$ 190,128	\$ 204,206
Equity	\$ 172,414	\$ 184,854