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): August 5, 2021

Verona Pharma plc

(Exact name of registrant as specified in its charter)

United Kingdom	**001-39067**	**98-1489389**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 August 5, 2021, Verona Pharma plc (the "Company") announced its financial results for the quarter ended June 30, 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 August 5, 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: August 5, 2021

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

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

ENHANCE Phase 3 program on track to report top-line data in 2022

Up to $219 million strategic collaboration with Nuance Pharma in Greater China

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

LONDON and RALEIGH, N.C., August 5, 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 June 30, 2021, and provides a corporate update.

"During the second quarter, we continued steady progress on patient recruitment in our Phase 3 ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") clinical program," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "Patient enrollment in both ENHANCE-1 and ENHANCE-2 continues across our international clinical trial sites. Over the past quarter, numerous COVID-19 related challenges, including new variants and increased infection and hospitalization rates across a number of countries, have put pressure on our recruitment timelines. We have implemented various mitigation strategies to address these challenges. Based on our current models, our projections for reporting top-line data are in-line with previous guidance, with ENHANCE-2 expected to report in the first half of 2022 and ENHANCE-1 in the second half of 2022. Should COVID-19 related challenges continue to increase, we predict top-line data would be expected in the third quarter of 2022 from ENHANCE-2 and the fourth quarter of 2022 from ENHANCE-1.

"In addition to our clinical progress, we are pleased to have executed on our strategy to partner ensifentrine outside the US. In June, we announced a strategic collaboration with Nuance Pharma, a Shanghai-based specialty pharmaceutical company, with a potential value of up to $219 million, to which we granted the rights to develop and commercialize ensifentrine in Greater China. The collaboration highlights ensifentrine's potential clinical value to respiratory patients globally and provides us with additional funds to support our efforts to develop and bring ensifentrine to patients in need. Nuance Pharma intends to meet with China's National Medical Products Administration to develop a plan to file an Investigational New Drug application for the treatment of COPD and we look forward to reporting on the progress."

Program Updates and Key Milestones

As of the end of July, ENHANCE-2 had 63% of patients randomized into the study. Including those patients currently entered in the run-in period, we expect ENHANCE-2 to be approximately 70% enrolled by the end of August. Additionally, at the end of July, the 48-week subset in ENHANCE-1 had 70% of patients randomized into the study. Including those patients currently entered in the run-in period, we expect the 48-week subset in ENHANCE-1 to be approximately 80% enrolled by the end of August. Completing recruitment of the 48-week subset in ENHANCE-1 is a critical driver of the timeline for reporting top-line data from the study.

The Company's near-term milestones include:

- In September, the Company will present an abstract describing the results of a study that assessed the effect of fluconazole on the pharmacokinetics of ensifentrine in healthy individuals at the European Respiratory Society International Congress ("ERS") 2021.
- In October, the Company will present an abstract at CHEST Annual Meeting 2021: a follow-up from Verona Pharma's Phase 2 trial investigating the pressurized metered-dose inhaler ("pMDI") formulation of ensifentrine in COPD, which was reported in February 2021.
- Based on our current models of forecasted recruitment and study progress, ENHANCE-2 is expected to report top-line data in the first half of 2022 and ENHANCE-1 in the second half of 2022. Should COVID-19 related challenges continue to increase, our models predict top-line data would be expected in the third quarter of 2022 from ENHANCE-2 and the fourth quarter of 2022 from ENHANCE-1. With the COVID-19 pandemic and government and other measures continuing to impact a number of clinical trial activities, the Company continues to closely monitor these timelines.

Second Quarter and Recent Highlights

Clinical

- In May 2021, three abstracts highlighting new analyses from Phase 2b clinical trials with nebulized ensifentrine for the treatment of COPD were presented at the American Thoracic Society International Conference ("ATS") 2021. The abstracts were published on the ATS website and in the peer reviewed publication, *American Journal of Respiratory and Critical Care Medicine*. The new subgroup analysis demonstrated the positive effect of ensifentrine on severe and moderate COPD subgroups from the 4-week Phase 2b study first reported by the Company in January 2020 with nebulized ensifentrine as a maintenance treatment for COPD.
- In April 2021, the Company published its Phase 2b clinical results with nebulized ensifentrine added on to maintenance bronchodilator therapy in symptomatic COPD patients in the peer reviewed journal, *International Journal of Chronic Obstructive Pulmonary Disease*. The 416-patient study, reported in January 2020, was the second of two large Phase 2b trials with nebulized ensifentrine for this indication. The study met its primary endpoint demonstrating that ensifentrine produced clinically and statistically significant dose-dependent improvements in lung function at all doses. In addition, clinically relevant secondary endpoints were met including statistically significant and clinically meaningful improvements in quality of life.
- In April 2021, the Company reported results from its pilot study in patients hospitalized with COVID-19 with a pMDI formulation of ensifentrine demonstrating ensifentrine added on to standard of care was well tolerated. 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 plan to conduct further studies of ensifentrine in the treatment of COVID-19.

Corporate

- In June 2021, Verona Pharma and Nuance Pharma entered into a $219.0 million strategic collaboration to develop and commercialize ensifentrine in Greater China. Under the terms of the agreement, Verona Pharma granted Nuance Pharma the exclusive rights to develop and commercialize ensifentrine in Greater China. In return, Verona Pharma received an aggregate $40.0 million upfront payment

consisting of $25.0 million in cash and an equity interest valued at $15.0 million in Nuance Biotech, the parent company of Nuance Pharma, as of June 9, 2021. Verona Pharma is eligible to receive future milestone payments of up to $179.0 million, triggered upon achievement of certain clinical, regulatory, and commercial milestones as well as tiered double-digit royalties on net sales in Greater China.

Second Quarter 2021 Financial Results

- **Cash position:** Cash and cash equivalents at June 30, 2021, were $146.0 million (March 31, 2021: $169.6 million). In July 2021, the Company received the $25.0 million upfront payment from Nuance Pharma and $8.0 million in a U.K. tax credit. The Company believes our cash and cash equivalents at June 30, 2021, together with the recently received $25.0 million Nuance payment, the recent and anticipated future receipts from the U.K. tax credit program and funding expected to become available under the $30.0 million debt financing facility secured in November 2020 will enable us to fund our planned operating expenses and capital expenditure requirements through at least 2023.
- **R&D Expenses:** Research and development (“R&D”) expenses were $20.6 million for the second quarter ended June 30, 2021 (Q2 2020: R&D expenses $7.8 million). The increase of $12.8 million was primarily due to costs associated with the Phase 3 ENHANCE program as well as an increase in share-based compensation charges.
- **G&A Expenses:** General and administrative expenses (“G&A”) were $8.0 million for the second quarter ended June 30, 2021 (Q2 2020: G&A expenses $3.2 million). This increase of $4.8 million was driven primarily by an increase in share-based compensation charges, partially offset by executive change costs in 2020.
- **Net loss:** Net loss was $22.1 million for the second quarter ended June 30, 2021 (Q2 2020: net loss $9.0 million) and the net cash used in operating activities for the quarter was $20.2 million.

Conference Call and Webcast Information

Verona Pharma will host an investment community conference call at 8:30 a.m. EDT /
1:30 p.m. BST on Thursday, August 5, 2021 to discuss the second quarter 2021 financial results and the corporate update.

Analysts and investors may participate by dialing one of the following numbers and reference conference ID 8333487:

- 1 +1-888-317-6003 for callers in the United States
- 2 +1-412-317-6061 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. An electronic copy of the second 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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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 continue to impact 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.

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 assumptions underlying the Company's models on clinical trial recruitment and progress, including the potential impact of the COVID-19 pandemic on such progress and on our business and operations and the Company's future financial results, 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 timing of Nuance Pharma filing an Investigational New Drug application with China's National Medical Products Administration and the funding we expect to receive from the strategic collaboration with Nuance Pharma, 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, third-party service providers and licensees; our inability to realize the anticipated benefits under licenses granted by us to third parties to develop and commercialize ensifentrine, 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; lawsuits related to patents covering ensifentrine and the potential for our patents to be found invalid or unenforceable; lawsuits related to our licensing of patents and know-how with third parties for the development and commercialization of ensifentrine; 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, our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, 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 June 30,	
	2021	2020
Operating expenses		
Research and development	$ 20,563	$ 7,811
General and administrative	7,985	3,172
Total operating expenses	28,548	10,983
Operating loss	(28,548)	(10,983)
Other income / (expense)		
Benefit from R&D tax credit	3,836	1,786
Interest income	3	34
Interest expense	(85)	-
Fair value movement on warrants	2,711	89
Foreign exchange gain / (loss)	40	51
Total other income, net	6,505	1,960
Loss before income taxes	(22,043)	(9,023)
Income tax expense	(25)	(15)
Net loss	$ (22,068)	$ (9,038)
Weighted average shares outstanding	470,786,767	106,360,580
Loss per ordinary share — basic and diluted	$ (0.05)	$ (0.08)

	June 30 2021	December 31 2020
Cash, cash equivalents and short term investments	$ 146,035	$ 187,986
Total assets	$ 218,502	$ 204,206
Equity	$ 154,397	$ 184,854