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): November 9, 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 November 9, 2021, Verona Pharma plc (the "Company") announced its financial results for the quarter ended September 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 November 9, 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: November 9, 2021

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

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

Enrollment in ENHANCE-1 48-week subset and ENHANCE-2 expected to complete around year-end 2021

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

Conference call today at 9:00 a.m. EST / 2:00 p.m. GMT

LONDON and RALEIGH, N.C., November 9, 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 September 30, 2021, and provides a corporate update.

"During the third quarter, we continued to make substantial 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. "We are excited to report patient enrollment is nearing completion and expect that by the end of November both the 800 patient ENHANCE-2 trial and the 400 patient 48-week subset of the ENHANCE-1 trial will be approximately 95% enrolled.

"We are pleased with our ability to advance recruitment in these international, multi-site clinical trials during a global pandemic. Although the pace of enrollment is expected to slow due to the approaching holiday season and the continued effects of the COVID-19 pandemic, we still expect to complete enrollment in ENHANCE-2 and the 48-week subset of ENHANCE-1 around year-end 2021. We expect to report top-line data from ENHANCE-2 mid-year 2022 and from ENHANCE-1 around the end of 2022."

Program Updates and Key Milestones

As of November 8, 2021, ENHANCE-2 had approximately 90% of patients randomized into the study. Including those patients currently entered in the run-in period, we expect ENHANCE-2 to be approximately 95% enrolled by the end of November 2021.

The 48-week subset of ENHANCE-1 is a critical driver of delivering top-line data. As of November 8, 2021, this subset had approximately 95% of patients randomized into the study.

The Company's near-term milestones include:

- In mid-November, Ms. Caroline Diaz will join Verona Pharma as Senior Vice President of Regulatory Affairs, bringing more than 18 years of experience in both large and small pharmaceutical companies across key regions. Ms. Diaz has served at ReViral as Vice President, Regulatory Affairs, and, previously, as Vice President, Regulatory and Quality at Dova Pharmaceuticals where she built the regulatory function from the ground up and led regulatory strategy development and implementation efforts resulting in the first marketing approvals for the company.
- In December 2021, the Company expects to report results from a 32-patient thorough QT study to evaluate the effect of ensifentrine on measures of cardiac conduction, which the Company is carrying out in support of a potential NDA submission.

- Based on our current models of forecasted recruitment and study progress the Company expects:
  - Enrollment of ENHANCE-2 and the 48-week subset of ENHANCE-1 to complete around year-end 2021. Enrollment in the full ENHANCE-1 trial is expected to complete in the second quarter of 2022.
  - Top-line data for ENHANCE-2 mid-year 2022 and for ENHANCE-1 around the end of 2022.
  - Should COVID-19 related challenges increase further, our models predict top-line data for ENHANCE-2 would be expected in the third quarter of 2022 and for ENHANCE-1 in the first quarter of 2023. With the COVID-19 pandemic and government and other measures continuing to impact a number of clinical trial activities, including contractor staffing issues and disruptions to supply chains globally, the Company continues to closely monitor these timelines.

Third Quarter and Recent Highlights

Clinical

- In October 2021, the Company presented Phase 2 data demonstrating the positive effect of a pressurized metered-dose inhaler ("pMDI") formulation of ensifentrine in COPD at the CHEST Annual Meeting 2021. Data from Part B of the two-part study, first reported in February 2021, showed ensifentrine delivered by pMDI over one week provided statistically significant, clinically meaningful and dose-dependent improvements in lung function and was well tolerated. The data with delivery via pMDI are consistent with results for dry powder inhaler ("DPI") and nebulizer formulations of ensifentrine and underline the suitability of ensifentrine for delivery to the lung via all three primary inhalation delivery platforms.
- In September 2021, the Company presented an abstract describing the results of a Phase 1 study assessing the effect of CYP2C9 inhibitor, fluconazole, on the pharmacokinetics of ensifentrine in healthy individuals at the European Respiratory Society International Congress ("ERS") 2021. Ensifentrine is primarily metabolized via the hepatic route by the cytochrome P450 enzyme, CYP2C9. Results from the study demonstrated co-administration of fluconazole had a less than 2-fold, not clinically relevant, effect on pharmacokinetic measures of the maximum concentration and area under the curve for ensifentrine.

Third Quarter 2021 Financial Results

- **Cash position:** Cash and cash equivalents at September 30, 2021, were $166.5 million (June 30, 2021: $146.0 million). We believe our cash and cash equivalents at September 30, 2021, expected cash 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 the end of 2023.
- **Revenue:** Revenue for the third quarter ended September 30, 2021, was $40.0 million (Q3 2020: $nil). This revenue was recognized from our agreement with Nuance Pharma for the development and commercialization of ensifentrine in Greater China (the "Nuance Agreement").
- **R&D Expenses:** Research and development ("R&D") expenses were $22.6 million for the third quarter ended September 30, 2021 (Q3 2020: R&D expenses $12.8 million). The increase of $9.8 million was primarily due to costs associated with the Phase 3 ENHANCE program partially offset by a reduction in share-based compensation charges.

- **S,G&A Expenses:** Selling, general and administrative expenses (“S,G&A”) were $10.9 million for the third quarter ended September 30, 2021 (Q3 2020: S,G&A expenses $8.3 million). This increase of $2.6 million was driven primarily by costs relating to the Nuance Agreement, partially offset by a reduction in costs relating to the July 2020 PIPE financing.
- **Net profit/(loss):** Net profit was $11.1 million for the third quarter ended September 30, 2021 (Q3 2020: net loss $18.9 million) and the net cash generated by operating activities for the quarter was $22.8 million.

Conference Call and Webcast Information

Verona Pharma will host an investment community conference call at 9:00 a.m. EST /
2:00 p.m. GMT on Tuesday, November 9, 2021 to discuss the third quarter 2021 financial results and the corporate update.

Analysts and investors may participate by dialing one of the following numbers and reference conference ID 7220560:

- 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 third 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 / Stella Lempidaki / Zoe Bolt	

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).

The COVID-19 pandemic is disrupting supply chains, and employee retention and recruitment, globally and the Company is closely monitoring this situation and will provide an update if it becomes aware of any meaningful disruption caused by the pandemic to the supply of ensifentrine and drug-related products, equipment and services 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, anticipated management changes, 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 September 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 September 30,	
	2021	2020
Revenue	$ 40,000	$ -
Operating expenses		
Research and development	22,560	12,820
Selling, general and administrative	10,883	8,284
Total operating expenses	33,443	21,104
Operating profit/(loss)	6,557	(21,104)
Other income/(expense)		
Benefit from R&D tax credit	4,749	2,338
Interest income	4	13
Interest expense	(86)	-
Fair value movement on warrants	40	(978)
Foreign exchange gain / (loss)	(86)	844
Total other income, net	4,621	2,217
Profit/(loss) before income taxes	11,178	(18,887)
Income tax expense	(127)	(44)
Net profit/(loss)	$ 11,051	$ (18,931)
Weighted-average shares outstanding - basic	475,334,354	344,809,792
Weighted-average shares outstanding -diluted	515,819,439	344,809,792
Profit / (loss) per ordinary share - basic	$ 0.02	$ (0.05)
Profit / (loss) per ordinary share - diluted	$ 0.02	$ (0.05)

	Sep-30 2021	Dec-31 2020
Cash and cash equivalents	$ 166,547	$ 187,986
Total assets	$ 201,560	$ 204,206
Equity	$ 168,202	$ 184,854