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): February 25, 2021

Verona Pharma plc

(Exact name of registrant as specified in its charter)

United Kingdom	**001-39067**	**Not Applicable**
(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 February 25, 2021, Verona Pharma plc announced its financial results for the quarter and year ended December 31, 2020. 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 February 25, 2021

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: February 25, 2021

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

Exhibit 99.1

Verona Pharma Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

Positive Phase 2 results with pMDI ensifentrine in COPD

Enrollment ongoing in ENHANCE Phase 3 program

Up to $30 million debt finance facility increases financial flexibility

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

LONDON and RALEIGH, N.C., February 25, 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 fourth quarter and full year ended December 31, 2020, and provides a corporate update.

"2020 was a transformative year for Verona Pharma," said David Zaccardelli, Pharm. D., President and Chief Executive Officer. "We started the year with positive data from a Phase 2b trial where nebulized ensifentrine demonstrated clinically meaningful improvements in lung function and quality of life measures when added-on to single bronchodilator therapy. In May, we received End-of-Phase 2 guidance from the U.S. Food and Drug Administration on the design of our Phase 3 ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") clinical development program and, in September, we began enrollment. This progress was made possible by strong support from the investment community through our $200 million private placement completed in July.

"2021 is already off to a great start with the recently announced positive Phase 2 clinical results with the pMDI formulation of ensifentrine in moderate to severe COPD patients. We anticipate top-line data from the pilot COVID-19 study of ensifentrine in the second quarter of 2021. In addition, patient enrollment in the ENHANCE program is ongoing and we expect to complete enrollment in both studies in the second half of 2021. Based on our recruitment projections, top-line data from ENHANCE-2 is expected in the first half of 2022 and from ENHANCE-1 in the second half of 2022."

Fourth Quarter and Recent Highlights

Clinical

- 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 twice-daily dosing.

- In January 2021, the Company completed enrollment of 45 patients in its pilot clinical study evaluating the efficacy and safety of pMDI ensifentrine in U.S. patients hospitalized with COVID-19. Top-line results are expected in the second quarter of 2021.

- In October 2020, the Company presented favorable symptom and quality of life data from a Phase 2b clinical trial with nebulized ensifentrine in COPD at CHEST Annual Meeting 2020. The posters highlighted ensifentrine's potential to provide rapid benefits to symptomatic patients.

Financial

- In November 2020, the Company entered into a debt financing facility for up to $30 million with Silicon Valley Bank. The non-dilutive capital provides further financial flexibility to support pre-commercialization activities for ensifentrine.

- In October 2020, Verona Pharma delisted from the AIM Market of the London Stock Exchange in an effort to enhance liquidity of trading by combining all transactions on the Nasdaq Global Market ("Nasdaq") and to reduce costs through removing duplicative listing and compliance fees. The Company's American Depositary Shares remain publicly traded on Nasdaq.

Upcoming Key Milestones

The Company's near-term milestones include:

- Reporting top-line data from a pilot clinical study evaluating the pMDI formulation of ensifentrine in U.S. patients hospitalized with COVID-19 in the second quarter of 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.

- Longer term, based on forecasted recruitment, the Company expects to announce top-line data from ENHANCE-2 in the first half of 2022 and ENHANCE-1 in the second half of 2022.

Fourth Quarter and Full Year 2020 Financial Results

- **Cash position:** Cash, cash equivalents and short term investments at December 31, 2020, were $188.0 million (December 31, 2019: $40.8 million). We believe our cash and cash equivalents at December 31, 2020, together with funding expected to become available under the $30.0 million debt financing facility secured in November 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 $16.4 million for the fourth quarter ended December 31, 2020 (Q4 2019: $7.2 million) and $44.5 million for the year ended December 31, 2020 (full year 2019: $42.4 million). The increase of $2.1 million was primarily attributable to an increase in share-based compensation charges and salary and related costs as we expanded the clinical development team.

- **G&A Expenses:** General and administrative expenses ("G&A") were $11.3 million for the fourth quarter ended December 31, 2020 (Q4 2019: G&A expenses $2.3 million) and $29.8 million for the year ended December 31, 2020 (full year 2019: G&A expenses $10.0 million), an increase of $19.8 million. This increase was primarily due to share-based compensation charges, severance costs, salaries, higher Director and Officers insurance premiums and costs related to the private placement.

- **Net loss:** Net loss was $24.8 million for the fourth quarter ended December 31, 2020 (Q4 2019: net loss $9.5 million) and $65.1 million for the year ended December 31, 2020 (full year 2019: net loss $40.6 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 Thursday, February 25, 2021 to discuss the fourth quarter and full year 2020 financial results and the corporate update.

Analysts and investors may participate by dialing one of the following numbers and reference conference number: 7681320:

- +1-888-317-6003 for callers in the United States
- +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 an audio replay will be available there for 30 days. An electronic copy of the fourth quarter and full year 2020 results 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.

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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 currently in Phase 2 development for the treatment of COPD: dry powder inhaler ("DPI") and pressurized metered-dose inhaler ("pMDI"). Ensifentrine is being evaluated in a pilot clinical study in patients hospitalized with COVID-19 and has potential applications in cystic fibrosis, asthma and other respiratory diseases. For more information, please visit www.veronapharma.com.

COVID-19 Impact

To help protect the health and safety of the patients, caregivers and healthcare professionals involved in its ongoing clinical trials of ensifentrine, 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 Company continues to review this guidance and the effect of the COVID-19 pandemic on its operations and clinical trials and will provide an update if it becomes aware of any meaningful disruption caused by the pandemic to its clinical trials.

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, operational review, outlook and financial review contain 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 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 effects in one compound, the potential of ensifentrine in the treatment of COPD, COVID-19, 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 Term Loan 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 novel coronavirus (COVID-19), 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 December 31,		Years ended December 31,	
	2020	2019	2020	2019
Operating expenses				
Research and development	$ 16,356	$ 7,217	$ 44,505	$ 42,417
General and administrative	11,347	2,273	29,772	9,986
Total operating expenses	27,703	9,490	74,277	52,403
Operating loss	(27,703)	(9,490)	(74,277)	(52,403)
Other income / (expense)				
Benefit from R&D tax credit	2,458	1,606	8,267	9,283
Interest income	5	120	121	964
Interest expense	(35)	-	(35)	-
Fair value movement on warrants	(389)	(629)	(1,136)	2,066
Foreign exchange gain / (loss)	872	(1,108)	2,060	(399)
Total other income, net	2,911	(11)	9,277	11,914
Loss before income taxes	(24,792)	(9,501)	(65,000)	(40,489)
Income tax expense	(36)	(27)	(146)	(72)
Net loss	$ (24,828)	$ (9,528)	$ (65,146)	$ (40,561)
Weighted average shares outstanding	462,798,050	105,326,638	262,932,653	105,326,638
Loss per ordinary share — basic and diluted	$ (0.05)	$ (0.09)	$ (0.25)	$ (0.39)

	2020	2019
Cash, cash equivalents and short term investments	$ 187,986	$ 40,808
Total assets	204,206	56,234
Equity	184,854	42,741