

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2021

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _____ TO _____
Commission File Number: 001-38067

Verona Pharma plc

(Exact name of Registrant as specified in its Charter)

United Kingdom

98-1489389

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

**3 More London Riverside
London SE1 2RE United Kingdom**

Not Applicable

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: +44 203 283 4200

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 Stock Market LLC (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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes No

As of April 27, 2021, the registrant had 463,745,750 ordinary shares, nominal value £0.05 per share, outstanding, which if all held in ADS form, would be represented by 57,968,219 American Depositary Shares, each representing eight (8) ordinary shares.

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PART I - FINANCIAL INFORMATION

Item 1. Financial statements

Verona Pharma plc
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except per share amounts and par value of shares)

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 169,598	\$ 187,986
Prepaid expenses	7,247	4,538
Tax and tax incentive receivables	10,272	8,260
Other current assets	1,484	1,720
Total current assets	<u>188,601</u>	<u>202,504</u>
Non-current assets:		
Furniture and equipment, net	98	107
Goodwill	545	545
Right-of-use assets	906	1,050
Total non-current assets	<u>1,549</u>	<u>1,702</u>
Total assets	<u>\$ 190,150</u>	<u>\$ 204,206</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 541	\$ 178
Accrued expenses	8,514	10,863
Operating lease liability	757	798
Warrants	2,753	2,246
Other current liabilities	133	118
Total current liabilities	<u>12,698</u>	<u>14,203</u>
Non-current liabilities:		
Term loan	4,685	4,635
Operating lease liability	353	514
Total non-current liabilities	<u>5,038</u>	<u>5,149</u>
Total liabilities	<u>17,736</u>	<u>19,352</u>
Commitments and contingencies		
Shareholders' equity:		
Ordinary £0.05 par value shares; 488,304,446 and 488,304,446 issued, and 463,745,750 and 463,304,446 outstanding, at March 31, 2021 and December 31, 2020, respectively	31,794	31,794
Additional paid-in capital	375,261	366,411
Ordinary shares held in treasury	(1,670)	(1,700)
Accumulated other comprehensive loss	(4,601)	(4,601)
Accumulated deficit	(228,370)	(207,050)
Total shareholders' equity	<u>172,414</u>	<u>184,854</u>
Total liabilities and shareholders' equity	<u>\$ 190,150</u>	<u>\$ 204,206</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Verona Pharma plc
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except per share amounts)

	Three months ended March 31,	
	2021	2020
Operating expenses		
Research and development	\$ 13,574	\$ 7,622
General and administrative	9,282	6,862
Total operating expenses	<u>22,856</u>	<u>14,484</u>
Operating loss	(22,856)	(14,484)
Other income / (expense)		
Benefit from research and development tax credit	2,070	1,685
Interest income	4	69
Interest expense	(84)	—
Fair value movement on warrants	(507)	142
Foreign exchange gain	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>
Other comprehensive (loss) / income:		
Foreign currency translation adjustments	—	(2,157)
Total comprehensive loss attributable to shareholders of the Company	<u>\$ (21,290)</u>	<u>\$ (14,503)</u>
Loss per ordinary share - basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.12)</u>
Weighted-average shares outstanding - basic and diluted	469,465,085	105,453,364

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Verona Pharma plc
Condensed Consolidated Statements of Shareholders' Equity
(unaudited)
(in thousands except share data)

	Ordinary shares		Additional paid-in capital	Ordinary shares held in treasury	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity
	Number	Amount					
Balance at January 1, 2021	488,304,446	\$ 31,794	\$366,411	\$ (1,700)	\$ (4,601)	\$ (207,050)	\$ 184,854
Net loss		—	—	—	—	(21,290)	(21,290)
Restricted share units vested	—	—	—	30	—	(30)	—
Share-based compensation	—	—	8,850	—	—	—	8,850
Balance at March 31, 2021	488,304,446	\$ 31,794	\$375,261	\$ (1,670)	\$ (4,601)	\$ (228,370)	\$ 172,414

	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity
	Number	Amount				
Balance at January 1, 2020	105,326,638	\$ 7,265	\$179,535	\$ (2,280)	\$ (141,779)	\$ 42,741
Net loss	—	—	—	—	(12,346)	(12,346)
Retranslation of foreign operations	—	—	—	(2,157)	—	(2,157)
Share options exercised during the period	887,080	52	—	—	—	52
Share-based compensation	—	—	1,867	—	—	1,867
Balance at March 31, 2020	106,213,718	\$ 7,317	\$181,402	\$ (4,437)	\$ (154,125)	\$ 30,157

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Verona Pharma plc
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Three months ended March 31,	
	2021	2020
Operating activities:		
Net loss:	\$ (21,290)	\$ (12,346)
<i>Adjustments to reconcile net income to net cash used in operating activities:</i>		
Foreign exchange gain	(155)	(234)
Amortization of debt issue costs	19	—
Accretion of redemption premium on debt	31	—
Fair value movement on warrants	507	(142)
Impairment of right-of-use asset	—	289
Share-based compensation	8,850	1,867
Depreciation and amortization	153	160
<i>Changes in operating assets and liabilities:</i>		
Prepaid expenses	(2,709)	195
Tax and tax incentive receivables	(2,012)	(1,632)
Other current assets	236	845
Non-current assets	—	(716)
Accounts payable	363	(1,106)
Accrued expenses	(2,349)	(1,343)
Lease liabilities	(210)	575
Other liabilities	15	364
Net cash used in operating activities	<u>(18,551)</u>	<u>(13,224)</u>
Cash flows from investing activities:		
Purchases of furniture and equipment	—	(5)
Sale of short-term investments	—	9,792
Net cash provided by investing activities	<u>—</u>	<u>9,787</u>
Cash flows from financing activities:		
Net cash provided by financing activities	<u>—</u>	<u>—</u>
Effect of exchange rate changes on cash and cash equivalents	<u>163</u>	<u>(2,008)</u>
Net increase in cash and cash equivalents	<u>(18,388)</u>	<u>(5,445)</u>
Cash and cash equivalents at beginning of the period	<u>187,986</u>	<u>30,428</u>
Cash and cash equivalents at end of the period	<u>\$ 169,598</u>	<u>\$ 24,983</u>
Supplemental disclosure of cash flow information:		
Income taxes paid	\$ —	\$ —
Interest paid	\$ 55	\$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Verona Pharma plc
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 1 - Organization and description of business operations

Verona Pharma plc (the “Company”) is incorporated and domiciled in the United Kingdom. Verona Pharma plc has two wholly-owned subsidiaries, Verona Pharma, Inc., a Delaware corporation, and Rhinopharma Limited (“Rhinopharma”), a Canadian company. The address of the registered office is 1 Central Square, Cardiff, CF10 1FS, United Kingdom.

The Company is a clinical-stage biopharmaceutical group focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical needs. The Company’s American Depository Shares (“ADSs”) are listed on Nasdaq, which trade under the symbol “VRNA”.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception, and has an accumulated deficit of \$228.4 million as of March 31, 2021. The Company expects to incur additional losses and negative cash flows from operations until its products potentially gain regulatory approval and reach commercial profitability, if at all.

The Company expects that its cash and cash equivalents as of March 31, 2021, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance.

On March 19, 2021, the Company entered into an open market sale agreement with respect to an at-the-market offering program (the “ATM Program”) under which the Company may issue and sell its ADSs, with an aggregate offering price of up to \$100.0 million.

Note 2 - Basis of Presentation and Summary of Significant Accounting policies

Basis of presentation and consolidation

The unaudited condensed consolidated financial statements include the accounts of Verona Pharma plc and its wholly-owned subsidiaries Verona Pharma, Inc. and Rhinopharma. All inter-company balances and transactions have been eliminated.

The accompanying unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q and have been prepared in conformity with accounting principles generally accepted in the U.S. (“US GAAP”).

The unaudited condensed consolidated financial statements presented in this Quarterly Report should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company’s Annual Report on Form 10-K filed with the SEC on February 25, 2021 (the “2020 Form 10-K”). The balance sheet as of December 31, 2020 was derived from audited consolidated financial statements included in the 2020 Form 10-K but does not include all disclosures required by U.S. GAAP for complete financial statements. The Company’s significant accounting policies are described in Note 2 to those consolidated financial statements.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from these interim financial statements. The unaudited condensed consolidated financial statements reflect all adjustments which in the opinion of management are necessary for a fair statement of results of operations, comprehensive income, financial condition, cash flows and stockholders' equity for the periods presented. Except as otherwise disclosed, all such adjustments are of a normal recurring nature. Operating results for the interim periods are not necessarily indicative of the results that may be expected for the full year.

Segment reporting

The Company has one operating and reportable segment, pharmaceutical development.

Verona Pharma plc
Notes to Condensed Consolidated Financial Statements
(unaudited)

Use of estimates

The preparation of interim unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these unaudited condensed consolidated financial statements include, but are not limited to, the accrual and prepayment of research and development expenses, the fair value of share-based compensation and the fair value of warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from the Company's estimates.

Recently adopted accounting standards and recent accounting standards not yet adopted

There are no recently adopted accounting standards and recent accounting standards not yet adopted that the Company believes will have a material impact on the Company's consolidated financial statements.

Note 3 - Prepaid expenses

Prepaid expenses consisted of the following (in thousands):

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Clinical trial and other development costs	\$ 6,296	\$ 2,551
Insurance	574	1,701
Other	377	286
Total prepaid expenses and other current assets	<u>\$ 7,247</u>	<u>\$ 4,538</u>

Note 4 - Tax and tax incentive receivables

Taxes receivable consisted of the following (in thousands):

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Research and development tax credit receivable - U.K.	\$ 10,272	\$ 8,202
Tax receivable - U.S.	—	58
Total tax receivable	<u>\$ 10,272</u>	<u>\$ 8,260</u>

Note 5 - Accrued expenses

Accrued expenses consisted of the following (in thousands):

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Clinical trial and other development costs	\$ 6,536	\$ 8,607
Professional fees and general corporate costs	1,454	2,149
People related costs	524	107
Total accrued expenses	<u>\$ 8,514</u>	<u>\$ 10,863</u>

Other costs include people costs, professional fees and other accrued costs.

Verona Pharma plc
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 6 - Warrants

In the periods ended March 31, 2021, and December 31, 2020, no warrants were exercised or forfeited. The warrants had no intrinsic value as at March 31, 2021.

There have been no changes in valuation techniques or transfers between fair value measurement levels during the period ended March 31, 2021. They are measured at fair value and included at level 3 in the fair value hierarchy. The warrants are valued using the Black-Scholes model and the table below presents the assumptions used:

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Shares potentially issued under warrants	12,401,262	12,401,262
Exercise price in pounds sterling	£ 1.7238	£ 1.7238
Risk-free interest rate	0.08 %	— %
Expected term to exercise	1.09	1.33
Annualized volatility	109.1 %	105.4 %
Dividend rate	— %	— %
Calculated value of the warrants, in thousands of U.S. dollars	<u>\$ 2,753</u>	<u>\$ 2,246</u>

For the amount recognized at March 31, 2021, the effect when the following parameter deviates up or down is presented in the below table (in thousands):

10% volatility increase	\$ 3,282
Base case, reported fair value	2,753
10% volatility decrease	\$ 2,234

Note 7 - Term loan

In November 2020, the Company entered into a term loan facility of up to \$30.0 million (the “Term Loan”), consisting of advances of \$5.0 million funded at closing and \$10.0 million and \$15.0 million contingent upon achievement of certain clinical development milestones and other specified conditions. As at March 31, 2021, the Company had \$5.0 million principal outstanding under the Term Loan.

As at March 31, 2021, the carrying value of the Term Loan was approximately \$4.7 million, of which all was due in more than 12 months. The debt balance has been categorized within Level 3 of the fair value hierarchy. The carrying amount of the debt approximates its fair value based on prevailing interest rates as at the balance sheet date.

Verona Pharma plc
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 8 - Share-based compensation

The following table shows the allocation of share-based compensation between research and development and general and administrative costs (in thousands):

	Three months ended March 31,	
	2021	2020
Research and development	\$ 3,432	\$ 493
General and administrative	5,418	1,374
Total	\$ 8,850	\$ 1,867

Share options

The following table shows share option activity in the period:

	2021	
	Number of share options outstanding	Weighted average exercise price
Outstanding at January 1	13,125,672	\$ 1.41
Forfeited	(996,720)	1.17
Outstanding at March 31	12,128,952	\$ 1.43

Restricted stock units activity

The following table shows restricted stock unit (“RSU”) activity in the period:

	2021	
	Number of RSUs outstanding	Weighted average remaining contractual term (years)
Outstanding at January 1	61,992,360	1.5
Granted	750,928	
Vested	(441,304)	
Outstanding at March 31	62,301,984	1.3

Verona Pharma plc
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 9 - Net loss per share

Net loss per share is calculated on an ordinary share basis. The Company's ADSs that are listed on the Nasdaq Global Market each represent eight ordinary shares. The following table shows the computation of basic and diluted earnings per share for the periods ended March 31, 2021 and 2020 (net loss in thousands, loss per share in dollars):

	Three months ended March 31,	
	2021	2020
Numerator:		
Net loss	\$ 21,290	\$ 12,346
Net loss available to ordinary shareholders - basic and diluted	\$ 21,290	\$ 12,346
Denominator:		
Weighted-average shares outstanding - basic and diluted	<u>469,465,085</u>	<u>105,453,364</u>
Net loss per share - basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.12)</u>

During the periods ended March 31, 2021 and 2020, outstanding share options, RSUs and warrants of 77,584,846 and 35,669,750, respectively, were not included in the computation of diluted earnings per ordinary share, because to do so would be antidilutive.

Item 2. Management’s discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and related notes as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on February 25, 2021 (the “2020 Form 10-K”).

In addition to historical information, this Quarterly Report on Form 10-Q contains statements that constitute forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including without limitation statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, the development of ensifentrine or any other product candidates, including statements regarding the expected initiation, timing, progress and availability of data from our clinical trials and potential regulatory approvals, research and development costs, timing and likelihood of success, potential collaborations, the duration of our patent portfolio, our estimates regarding expenses, future revenues, capital requirements, debt service obligations and our need for additional financing, the funding we expect to become available from cash receipts from U.K. tax credits, and the sufficiency of our cash and cash equivalents to fund operations, are forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties, assumptions, and other important factors including, but not limited to, those set forth under Part I, Item 1A of the 2020 Form 10-K under the heading “Risk Factors”. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events.

Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. We intend the forward-looking statements contained in this Quarterly Report on Form 10-Q to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical need. Our product candidate, ensifentrine, is an investigational, potential first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4, or PDE3 and PDE4, that is designed to act as both a bronchodilator and an anti-inflammatory agent. In the third quarter of 2020, we commenced our Phase 3 ENHANCE (“Ensifentrine as a Novel inHAled Nebulized COPD thERapy”) trials and, if approved, we intend to commercialize ensifentrine for the maintenance treatment of chronic obstructive pulmonary disease (“COPD”) for the nebulized formulation in the United States.

We have incurred recurring losses and negative cash flows from operations since inception, and have an accumulated deficit of \$228.4 million as of March 31, 2021. We expect to incur additional losses and negative cash flows from operations until our product candidates potentially gain regulatory approval and reach commercial profitability, if at all.

We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue to invest in the clinical development of ensifentrine for the treatment of COPD;
- manufacture ensifentrine and engage in other Chemistry, Manufacturing and Control activities;
- maintain, expand and protect our intellectual property portfolio; and
- enhance our commercial insights and capabilities.

We believe that our cash and cash equivalents as of 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.

Clinical development update

In February 2021, we announced positive Phase 2 efficacy and safety data with a pressurized metered-dose inhaler (“pMDI”) formulation of ensifentrine in patients with moderate to severe COPD. The primary and secondary lung function endpoints were achieved and the data support twice-daily dosing. The ensifentrine pMDI formulation was well tolerated at each dose with an adverse event profile similar to placebo.

On April 23, 2021, we announced that data from a pilot study of the ensifentrine pMDI formulation showed that ensifentrine was well tolerated in patients infected with SARS-CoV-2, the virus that causes COVID-19. The trial was not powered to identify statistically significant efficacy outcomes and no clinical efficacy benefit with ensifentrine treatment added on to standard of care was observed in the trial. One patient death was reported in the ensifentrine treatment group. We do not currently plan to conduct further studies of ensifentrine in the treatment of COVID-19.

We have continued to enroll patients in the two Phase 3 trials underway in our ENHANCE program, and 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. With the pandemic and government and other measures in response impacting a number of clinical trial activities, we are continuing to monitor these timelines.

Intellectual property update

We hold rights in the major markets relating to certain respirable formulations comprising ensifentrine for treating respiratory disorders, as well as a crystalline form of ensifentrine, combinations of ensifentrine with certain respiratory drugs, certain salts of ensifentrine, ensifentrine for use in the treatment of cystic fibrosis, and a method of making ensifentrine.

As of March 31, 2021, our patent portfolio consisted of nine issued U.S. patents, three pending U.S. patent applications, forty-eight issued foreign patents and fifty-three pending foreign applications including three patent applications made under the Patent Cooperation Treaty. These patents and patent applications include claims directed to certain respirable formulations comprising ensifentrine, a crystalline form of ensifentrine, combinations of ensifentrine with certain respiratory drugs, certain salts of ensifentrine, ensifentrine for use in the treatment of cystic fibrosis, and a method of making ensifentrine, with expected expiry dates up to 2041.

COVID-19 impact

We are closely monitoring the potential impact of the COVID-19 pandemic on our operations and clinical trials, in particular the timelines and costs of our Phase 3 clinical program. The pandemic and government and other measures in response are impacting a number of clinical trial activities and we will provide an update if we become aware of any meaningful disruption caused by the pandemic to our clinical trials.

To help protect the health and safety of the patients, caregivers and healthcare professionals involved in our clinical trials, as well as our employees and independent contractors, we continue 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.

We are closely monitoring activities at our contract manufacturers associated with clinical supply for our clinical trials, and are 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. We continue to monitor this situation and will provide an update if we become aware of any meaningful disruption caused by the pandemic to the clinical supply of ensifentrine for our clinical trials.

We have also implemented measures to help keep our employees, families, and local communities healthy and safe. All employees are working remotely and all business travel has been restricted.

Significant contracts

Ligand agreement

In 2006 we acquired Rhinopharma and assumed contingent liabilities owed to Ligand UK Development Limited (“Ligand”) (formerly Vernalis Development Limited). We refer to the assignment and license agreement as the Ligand Agreement.

Ligand assigned to us all of its rights to certain patents and patent applications relating to ensifentrine and related compounds (the “Ligand Patents”) and an exclusive, worldwide, royalty-bearing license under certain Ligand know-how to develop, manufacture and commercialize products (the “Licensed Products”) developed using Ligand Patents, Ligand know-how and the physical stock of certain compounds.

The contingent liability comprises a milestone payment on obtaining the first approval of any regulatory authority for the commercialization of a Licensed Product, low single digit royalties based on the future sales performance of all Licensed Products and a portion equal to a mid-twenty percent of any consideration received from any sublicensees for the Ligand Patents and for Ligand know-how.

At time of the acquisition the contingent liability was not recognized as part of the acquisition accounting as it was immaterial. We will therefore record as a research and development expense the milestone payment or royalties when they are payable.

Warrants

On July 29, 2016, as part of a private placement we issued warrants to investors. The warrant holders can subscribe for an ordinary share at a per share exercise price of £1.7238. They can also opt for a cashless exercise of their warrants whereby they can choose to exchange the warrants held for a reduced number of warrants exercisable at nil consideration.

If, after a transaction, should the warrants be exercisable for unlisted securities, the warrant holders may demand a cash payment instead of the delivery of the underlying securities. Accordingly, they are accounted for as a liability under ASC 480 “Distinguishing Liabilities from Equity” and recorded at fair value using the Black-Scholes valuation methodology, on recognition and at each reporting date. The warrants are currently exercisable and may be exercised by the holders until April 2022 when the warrant instruments may either be exercised, cashlessly exercised, or expire.

Loan and security agreement

In November 2020 we entered into the Term Loan. See “Indebtedness” for additional information.

Critical accounting policies and significant judgments and estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual and prepayment of research and development expenses, the fair value of share-based compensation and the fair value of warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from our estimates. The accounting policies considered to be critical to the judgments and estimates used in the preparation of our financial statements are disclosed in the Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our 2020 Form 10-K. There have been no material changes to that information disclosed in our 2020 Form 10-K during the three months ended March 31, 2021.

Components of results of operations

We anticipate that our expenses will increase substantially if and as we:

- conduct our ongoing Phase 3 clinical trials for ensifentrine for the maintenance treatment of COPD;
- continue the clinical development of our DPI and pMDI formulations of ensifentrine and research and develop other formulations of ensifentrine;

- initiate and conduct further clinical trials for ensifentrine for the treatment of acute COPD, CF or any other indication;
- initiate and progress pre-clinical studies relating to other potential indications of ensifentrine;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our continuing operations as a U.S. public company; or
- experience any delays or encounter any issues from any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Operating expenses

Research and development costs

Research and development costs consist of salary and personnel related costs and third party costs for our research and development activities for ensifentrine. Personnel related costs include a share-based compensation charge relating to our stock option plan. The largest component of third party costs is for clinical trials, as well as manufacturing for clinical supplies and associated development, and pre-clinical studies. Research and development costs are expensed as incurred.

We expect our research and development costs to significantly increase in the near future as we progress our ENHANCE program. Due to the nature of research and development, the expected costs are inherently uncertain and may vary significantly from our current expectations.

General and administrative costs

General and administrative costs consist of salary and personnel related costs, including share-based compensation, expenses relating to operating as a public company, including professional fees, insurance and commercial related costs, as well as other operating expenses.

We expect commercial costs to increase as we continue to develop our potential commercial operations and, in the event of successful regulatory approval, we expect to incur sales force, marketing and other launch related costs. As we develop our knowledge of the market and refine our commercialization plans, expected costs may vary significantly from our current expectations.

Other income / (expense)

Other income / (expense) are driven by interest income and expense, the fair value movement of the warrant liability, foreign exchange movements on cash and cash equivalents, and the U.K. research and development tax credits.

We are entitled to participate in the U.K. Small and Medium Enterprises research and development tax relief program. The tax credits are calculated as a percentage of qualifying research and development expenditure and are payable in cash by the U.K. government to the Company. Credits recorded in the 2021 financial year are expected to be received in the 2022 financial year.

The U.K. tax authorities have reviewed legislation and have proposed to cap the amount payable in the program to a multiple of employment taxes a company pays in the year in question, from January 1, 2022. We are currently reviewing recent clarifications to these proposed changes to review the effect on our financing strategy. It is possible that our tax credit for the 2022 financial year, payable in 2023, will be impacted by the cap. If the legislation is enacted as currently drafted, we estimate the potential cash received under this program could be approximately \$6 million lower than before the changes.

Taxation

We are subject to corporate taxation in the United States and the United Kingdom. We have generated losses since inception and have therefore not paid United Kingdom corporation tax. The income taxes presented in our consolidated statements of operations and comprehensive loss represents the tax impact from our operating activities in the United States, which generates taxable income based on intercompany service arrangements.

United Kingdom losses may be carried forward indefinitely to be offset against future taxable profits, subject to various utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of U.K. taxable profits.

Results of operations for the three months ended March 31, 2021 and 2020

In prior periods, we prepared our financial information in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (“IFRS”), in pounds sterling. As a consequence of becoming a U.S. domestic issuer as of January 1, 2021, we are required to present our financial information in accordance with accounting principles generally accepted in the U.S. (“US GAAP”) and expressed in U.S. dollars from that date. The below financial information has been prepared in accordance with US GAAP. The financial information should not be expected to correspond to figures we have previously presented under IFRS, in pounds sterling.

The following table shows our statements of operations for the three months ended March 31, 2021 and 2020, (in thousands):

	Three months ended March 31,		Variance
	2021	2020	
Operating expenses			
Research and development	\$ 13,574	\$ 7,622	\$ 5,952
General and administrative	9,282	6,862	2,420
Total operating expenses	22,856	14,484	8,372
Operating loss	(22,856)	(14,484)	(8,372)
Other income / (expense)			
Benefit from research and development tax credit	2,070	1,685	385
Interest income	4	69	(65)
Interest expense	(84)	—	(84)
Fair value movement on warrants	(507)	142	(649)
Foreign exchange gain	163	293	(130)
Total other income, net	1,646	2,189	(543)
Loss before income taxes	(21,210)	(12,295)	(8,915)
Income tax expense	(80)	(51)	(29)
Net loss	\$ (21,290)	\$ (12,346)	\$ (8,944)

Research and development costs

Research and development costs were \$13.6 million for the three months ended March 31, 2021, compared to \$7.6 million for the three months ended March 31, 2020, an increase of \$6.0 million. This increase was primarily due to a \$3.4 million increase in clinical trial and other development costs, as we progress our Phase 3 ENHANCE program, as well as a \$2.9 million increase in share-based compensation charges.

Development costs were higher during the three months ended March 31, 2021 due to costs associated with having randomized patients in our ongoing Phase 3 clinical trials. In the comparative period we had only one, smaller, trial in progress as well as startup costs for Phase 3 trials and close down costs for certain Phase 2 trials. Share-based compensation costs were higher during the three months ended March 31, 2021.

General and administrative costs

General and administrative costs were \$9.3 million for the three months ended March 31, 2021 compared to \$6.9 million for the three months ended March 31, 2020, an increase of \$2.4 million.

This increase was driven primarily by an \$4.0 million increase in share-based compensation charges, as well as increased costs for Directors’ and Officers’ insurance, partially offset by severance and other executive change costs incurred in the three months ended March 31, 2020.

Other income / (expense)

The research and development tax credit for the three months ended March 31, 2021 was \$2.1 million compared to a credit of \$1.7 million for the three months ended March 31, 2020, an increase of \$0.4 million. This increase is attributable to our higher qualifying expenditure on research and development in the three months ended March 31, 2021, compared to the comparative 2020 period, as we are randomizing patients in our Phase 3 trials.

We recorded an expense of \$0.5 million in the three months ended March 31, 2021, compared to a gain of \$0.1 million in the comparative period relating to the fair value movements of the warrants, driven by the rise and fall of our share price in each period respectively, as an increase in the share price increases the fair value of the warrants.

Net loss

Net loss was \$21.3 million for the three months ended March 31, 2021, compared to \$12.3 million for the three months ended March 31, 2020. The increase in net loss was primarily the result of the increase in operating costs and the fall in other income, net, discussed above.

Cash flows

The following table summarizes our cash flows for the three months ended March 31, 2021 and 2020 (in thousands):

	<u>Three months ended March 31,</u>		
	<u>2021</u>	<u>2020</u>	<u>Variance</u>
Cash and cash equivalents at beginning of the period	\$ 187,986	\$ 30,428	\$ 157,558
Net cash used in operating activities	(18,551)	(13,224)	(5,327)
Net cash provided by investing activities	—	9,787	(9,787)
Net cash provided by financing activities	—	—	—
Effect of exchange rate changes on cash and cash equivalents	163	(2,008)	2,171
Cash and cash equivalents at end of the period	<u>\$ 169,598</u>	<u>\$ 24,983</u>	<u>\$ 144,615</u>

Operating activities

Net cash used in operating activities increased to \$18.6 million in the three months ended March 31, 2021, from \$13.2 million during the same period in 2020 an increase of \$5.4 million. Operating expenses increased by \$8.4 million, of which \$7.0 million was related to non-cash share-based compensation expenses. The remaining variance was due to the timing of supplier payments.

Investing activities

Net cash provided by investing activities decreased to nil in the three months ended March 31, 2021 from \$9.8 million in the three months ended March 31, 2020, as in the prior period all funds were moved from short-term investments to cash.

Financing activities

There was no cash used in or provided by financing activities in either period.

Liquidity and capital resources

We do not currently have any approved products and have never generated any revenue from product sales or otherwise. To date, we have financed our operations primarily through the issuances of our equity securities, including warrants, and in 2020 from borrowings under the Term Loan. See “Indebtedness” for additional information.

We have incurred recurring losses since inception, including net losses of \$21.3 million for the three months ended March 31, 2021, and \$65.1 million for the year ended December 31, 2020. As of March 31, 2021, we had an accumulated deficit of \$228.4 million. We expect to continue to generate operating losses for the foreseeable future.

We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than leases and the Term Loan with Silicon Valley Bank.

Open market sale agreement

On March 19, 2021, we entered into an open market sale agreement with Jefferies LLC (“Jefferies”) to sell shares of our ordinary shares, in the form of ADSs, with aggregate gross sales proceeds of up to \$100.0 million, from time to time, through an “at the market” equity offering program under which Jefferies will act as sales agent (the “ATM Program”). As of March 31, 2021, we had not sold any shares under the ATM Program.

Indebtedness

In November, 2020, we and Verona Pharma, Inc. entered into a term loan facility of up to \$30.0 million with Silicon Valley Bank (the “Term Loan”), consisting of term loan advances in an aggregate amount of \$5.0 million funded at closing, a term loan advance of an aggregate amount of \$10.0 million available subject to certain terms and conditions and the achievement of a specific clinical milestone, and a term loan advance of an aggregate amount of \$15 million contingent upon achievement of a specific clinical development milestone and other specified conditions. As at March 31, 2021, the Company had \$5.0 million principal outstanding under the Term Loan. Additional detail surrounding the Term Loan is included under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2020 Form 10-K. There have been no material changes to that information disclosed in our 2020 Form 10-K during the three months ended March 31, 2021.

Funding requirements

We believe that our cash and cash equivalents as of March 31, 2021, and together with funding expected to become available under both the Term Loan and from cash receipts from U.K. tax credits will enable us to fund our planned operating expenses and capital expenditure requirements into 2023. The Term Loan advances are contingent upon achievement of certain clinical development milestones and other specified conditions.

We will require significant additional capital to further advance clinical and regulatory activities, to fund prelaunch and launch related costs and to create an effective sales and marketing organization to commercialize ensifentrine. We will need to seek additional funding through public or private financings, debt financing, collaboration or licensing agreements and other arrangements. However, there is no guarantee that we will be successful in securing additional finance on acceptable terms, or at all.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders and ADS holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect such holders’ rights as a shareholder or ADS holder. Any future debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute our security holders’ ownership interests.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our future capital requirements for ensifentrine or any future product candidates will depend on many factors, including:

- the progress, timing and completion of pre-clinical testing and clinical trials for ensifentrine or any future product candidates and the potential that we may be required to conduct additional clinical trials for ensifentrine;
- the number of potential new product candidates we decide to in-license and develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of ensifentrine or any future product candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;

- the time and costs involved in obtaining regulatory approvals for ensifentrine or any future product candidate we develop and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to ensifentrine or any future product candidates;
- any licensing or milestone fees we might have to pay during future development of ensifentrine or any future product candidates;
- selling and marketing activities undertaken in connection with the anticipated commercialization of ensifentrine or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of ensifentrine or any future product candidates, if approved.

Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objective.

Off-balance sheet arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Recent accounting pronouncements

For a discussion of pending and recently adopted accounting pronouncements, see Note 2 to our consolidated financial statements included in the 2020 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 3.

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors have not changed materially from those described in Part I, Item 1A of the 2020 Form 10-K under the heading “Risk Factors”.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Incorporated by Reference to Filings Indicated

Exhibit Number	Exhibit Description	Form	File No.	Exhibit No.	Filing date	Filed / Furnished Herewith
3.1	<u>Articles of Association, as amended and as currently in effect</u>	6-K	001-38067	1	12/30/2020	
<u>31.1</u>	<u>Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer</u>					*
<u>31.2</u>	<u>Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer</u>					*
<u>32.1</u>	<u>Section 1350 Certification of Chief Executive Officer</u>					**
<u>32.2</u>	<u>Section 1350 Certification of Chief Financial Officer</u>					**
101.INS	Inline XBRL Instance Document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					

* Filed herewith.

** Furnished herewith.

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: April 29, 2021

By:

/s/ David Zaccardelli

David Zaccardelli, Pharm. D.

President and Chief
Executive Officer

Date: April 29, 2021

By:

/s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer