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, 2023

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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

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 May 2, 2023, the registrant had 635,667,302 ordinary shares, nominal value £0.05 per share, outstanding, which if all held in ADS form, would be represented by 79,458,413 American Depositary Shares, each representing eight (8) ordinary shares.

PART I - FINANCIAL INFORMATION

Item 1. Financial statements

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 291,415	$ 227,827
Prepaid expenses	1,561	2,499
Tax incentive receivable	11,842	9,282
Other current assets	2,073	3,388
Total current assets	306,891	242,996
Non-current assets:		
Furniture and equipment, net	12	73
Goodwill	545	545
Equity interest	15,000	15,000
Right-of-use assets	698	854
Total non-current assets	16,255	16,472
Total assets	$ 323,146	$ 259,468
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,237	$ 2,910
Accrued expenses	17,703	13,752
Current operating lease liabilities	650	675
Taxes payable	424	283
Other current liabilities	509	1,409
Total current liabilities	26,523	19,029
Non-current liabilities:		
Term loan	19,809	9,768
Non-current operating lease liabilities	65	205
Total non-current liabilities	19,874	9,973
Total liabilities	46,397	29,002
Commitments and contingencies		
Shareholders' equity:		
Ordinary £0.05 par value shares; 651,659,630 and 631,338,246 issued, and 631,987,078 and 606,301,054 outstanding, at March 31, 2023 and December 31, 2022, respectively	41,753	40,526
Additional paid-in capital	590,915	529,187
Ordinary shares held in treasury	(1,208)	(1,549)
Accumulated other comprehensive loss	(4,601)	(4,601)
Accumulated deficit	(350,110)	(333,097)
Total shareholders' equity	276,749	230,466
Total liabilities and shareholders' equity	$ 323,146	$ 259,468

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,	
	2023	**2022**
Operating expenses:		
Research and development	$ 12,610	$ 17,625
Selling, general and administrative	9,589	7,440
Total operating expenses	22,199	25,065
Operating loss	(22,199)	(25,065)
Other income/(expense):		
Research and development tax credit	2,313	1,302
Interest income	2,677	15
Interest expense	(293)	(84)
Foreign exchange gain/(loss)	932	(923)
Total other income, net	5,629	310
Loss before income taxes	(16,570)	(24,755)
Income tax expense	(173)	(82)
Net loss	$ (16,743)	$ (24,837)
Loss per ordinary share - basic and diluted	$ (0.03)	$ (0.05)
Weighted-average shares outstanding - basic and diluted	621,451	481,942

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 December 31, 2022	631,338,246	$ 40,526	$ 529,187	$ (1,549)	$ (4,601)	$ (333,097)	$ 230,466
Net loss	—	—	—	—	—	(16,743)	(16,743)
Issuance of ordinary shares	20,321,384	1,227	55,682	—	—	—	56,909
Restricted share units vested	—	—	—	270	—	(270)	—
Share options exercised	—	—	1,756	71	—	—	1,827
Share-based compensation	—	—	4,290	—	—	—	4,290
Balance at March 31, 2023	651,659,630	$ 41,753	$ 590,915	$ (1,208)	$ (4,601)	$ (350,110)	$ 276,749

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 December 31, 2021	489,177,550	$ 31,855	$ 385,070	$ (603)	$ (4,601)	$ (263,716)	$ 148,005
Net loss	—	—	—	—	—	(24,837)	(24,837)
Issuance of common shares under at-the-market sales agreement	80,696	5	62	—	—	—	67
Restricted share units vested	—	—	—	186	—	(186)	—
Issuance of ordinary shares to treasury	4,800,000	322	—	(322)	—	—	—
Common shares withheld for taxes on vested stock awards	—	—	(793)	—	—	—	(793)
Equity settled share-based compensation reclassified as cash-settled	—	—	118	—	—	—	118
Share-based compensation	—	—	3,747	—	—	—	3,747
Balance at March 31, 2022	494,058,246	$ 32,182	$ 388,204	$ (739)	$ (4,601)	$ (288,739)	$ 126,307

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,	
	2023	**2022**
Cash flows from operating activities:		
Net loss:	$ (16,743)	$ (24,837)
Adjustments to reconcile net income to net cash used in operating activities:		
Foreign exchange (gain)/loss	(932)	1,119
Other non-cash items	73	23
Accretion of redemption premium on debt	18	31
Share-based compensation	4,290	3,748
Depreciation	157	163
Changes in operating assets and liabilities:		
Prepaid expenses	938	2,791
Tax incentive receivable	(2,313)	(1,578)
Other current assets	1,362	(462)
Accounts payable	4,327	(1,980)
Accrued expenses	3,951	6,621
Lease liabilities	(165)	(174)
Taxes payable	141	88
Other current liabilities	(886)	(65)
Net cash used in operating activities	(5,782)	(14,512)
Cash flows from investing activities:		
Purchases of furniture and equipment	—	—
Net cash provided by investing activities	—	—
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares	56,862	67
Proceeds from draw under the Oxford Term Loan	9,996	—
Payments of withholding taxes from share-based awards	—	(793)
Proceeds from exercise of share options	1,827	—
Net cash provided by/(used in) financing activities	68,685	(726)
Effect of exchange rate changes on cash and cash equivalents	685	(378)
Net change in cash and cash equivalents	63,588	(15,616)
Cash and cash equivalents at beginning of the period	227,827	148,380
Cash and cash equivalents at end of the period	$ 291,415	$ 132,764
Supplemental disclosure of cash flow information:		
Income taxes paid	$ —	$ 1
Interest paid	$ 244	$ 53

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

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 one wholly-owned subsidiary, Verona Pharma, Inc., a Delaware corporation. 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 Depositary Shares ("ADSs") are listed on the Nasdaq Global Market ("Nasdaq") and 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 $350.1 million as of March 31, 2023. 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, 2023, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance.

During the three months ended March 31, 2023, the Company sold 20,321,384 ordinary shares (equivalent to 2,540,173 ADSs) under the at-the-market offering program entered into in March 2021 (the "2021 ATM Program"). The shares sold were at an average price of approximately $2.88 per share (equivalent to $23.08 per ADS), raising aggregate net proceeds of approximately $56.9 million after deducting issuance costs.

In March 2023 through a registration statement on Form S-3, the Company replaced the 2021 ATM Program, with an open market sale agreement with Jefferies LLC ("Jefferies") to sell its ordinary shares, in the form of ADSs, with aggregate gross proceeds of up to $200.0 million, from time-to-time, through an "at the market" equity offering program under which Jefferies will act as sales agent (the "2023 ATM Program"). Jefferies is entitled to a commission at a rate of up to 3.0% of the gross proceeds.

The Company's commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available within the year, if ever. Additionally, the Company may enter into out-licensing transactions from time to time but there can be no assurance that the Company can secure such transactions in the future. Accordingly, the Company may need to obtain substantial additional funds to achieve its business objectives including 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, if approved. Any such funding will need to be obtained through public or private financings, debt financing, collaboration or licensing arrangements or other arrangements. However, there is no guarantee the Company will be successful in securing additional capital on acceptable terms, or at all.

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 subsidiary Verona Pharma, Inc. 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 have been prepared in conformity with accounting principles generally accepted in the U.S. ("U.S. GAAP") and 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 on March 7, 2023 (the "2022 Form 10-K"). The Consolidated Balance Sheet as of December 31, 2022, was derived from audited consolidated financial statements included in the 2022 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 shareholders' 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

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company has one operating and reportable segment, pharmaceutical development.

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 and the fair value of share-based compensation. 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, and actual results could differ from the Company's estimates.

Recently adopted accounting standards and recent accounting standards not yet adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)-Measurement of Credit Losses on Financial Instruments. This guidance replaces the current incurred loss impairment methodology.

Under this model, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects its current estimate of credit losses expected to be incurred over the life of the financial instrument based on historical experience, current conditions and reasonable and supportable forecasts. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. This update became effective for the Company on January 1, 2023 and the adoption of this update did not have a material impact on the Company's financial statements and related disclosures.

Note 3 - Equity interest

The Company entered into a collaboration and license agreement (the "Nuance Agreement") with Nuance Pharma Limited ("Nuance Pharma") effective June 9, 2021 (the "Effective Date"), under which the Company granted Nuance Pharma the exclusive rights to develop and commercialize ensifentrine in Greater China (China, Taiwan, Hong Kong and Macau). In return, the Company received an unconditional right to consideration aggregating $40.0 million consisting of $25.0 million in cash and an equity interest, valued at $15.0 million as of the Effective Date, in Nuance Biotech, the parent company of Nuance Pharma.

The equity interest is recorded at cost as the Company has elected to use the measurement alternative for equity investments without readily determinable fair values. The Company evaluates this investment for indicators of impairment quarterly. The Company did not identify events or changes in circumstances that may have a significant effect on the fair value of the investment during the three months ended March 31, 2023.

Note 4 - Accrued expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Clinical trial and other development costs	$ 15,127	$ 12,314
Professional fees and general corporate costs	1,775	1,364
People related costs	801	74
Total accrued expenses	$ 17,703	$ 13,752

Note 5 - Term loan

On October 14, 2022 (the "Effective Date"), the Company entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance Luxembourg S.À R.L. ("Oxford") for an aggregate amount of up to $150.0 million (the "Oxford Term Loan"). The Oxford Term Loan provides for an initial term loan advance in an aggregate amount of $10.0 million, which was funded on the Effective Date (the "Oxford Term A Loan"), and up to four additional term loan advances in an aggregate amount of $140.0 million. The Oxford Term Loan has a maturity date of October 1, 2027.

On March 24, 2023, the Company received $10.0 million under the second term loan advance ("Oxford Term B Loan"), which was available at the option of the Company from the Effective Date up to and including March 31, 2023. The proceeds of the Oxford Term B Loan will be used for general corporate and working capital purposes as well as to build out commercial infrastructure to prepare for potential commercial launch.

The Oxford Term A Loan and Oxford Term B Loan (together, the "Oxford Term Loan Advances") bear interest at a variable rate equal to (a) the greater of (i) the 1-Month CME Term SOFR reference rate on the last day of the month that immediately precedes the month in which the interest will accrue and (ii) 2.38%, plus (b) 5.50% (the "Basic Rate") and shall not increase by more than 2.00% above the Basic Rate as of the funding date of each such term loan. For the three months ended March 31, 2023, the effective interest rate was approximately 10% per annum. There was no material difference between the carrying value and the estimated fair value of the Oxford Term Loan Advances outstanding.

Note 6 - Share-based compensation

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

	Three months ended March 31,	
	2023	**2022**
Research and development	$ 1,103	$ 1,539
Selling, general and administrative	3,187	2,209
Total	$ 4,290	$ 3,748

Share options

The following table shows share option activity, in ordinary shares, in the period:

	Number of share options outstanding
Balance as of December 31, 2022	19,276,496
Granted	1,320,000
Forfeited	(240,000)
Exercised	(1,050,192)
Balance as of March 31, 2023	19,306,304

Restricted stock units activity

The following table shows restricted stock unit ("RSU") activity, in ordinary shares, in the period:

	Number of RSUs outstanding
Balance as of December 31, 2022	34,542,344
Vested	(4,305,120)
Balance as of March 31, 2023	30,237,224

Note 7 - Net loss per share

Net loss per share is calculated on an ordinary share basis. The Company's ADSs that are listed on Nasdaq each represent eight ordinary shares. The following table shows the computation of basic and diluted net loss per share for the three months ended March 31, 2023 and 2022 (in thousands except per share amounts):

	Three months ended March 31,	
	2023	2022
Numerator:		
Net loss	$ (16,743)	$ (24,837)
Denominator:		
Weighted-average shares outstanding - basic and diluted	621,451	481,942
Net loss per share - basic and diluted	$ (0.03)	$ (0.05)

During the three months ended March 31, 2023 and 2022, outstanding share options, RSUs and warrants over 49.5 million and 60.6 million ordinary shares, respectively, were not included in the computation of diluted earnings per ordinary share, because to do so would be antidilutive.

Note 8 - Commitments and contingencies

Management is currently negotiating a matter with a supplier and has accrued up to the maximum exposure of $6.9 million which is included within Accrued expenses in the Condensed Consolidated Balance Sheets. Management expects that the matter will be resolved within the next 12 months.

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, 2022 filed with the Securities and Exchange Commission on March 7, 2023 (the "2022 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 and commercialization, research and development costs, timing and likelihood of success, potential collaborations, 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 under the $150.0 million debt facility secured in October 2022, 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 II, Item 1A of this Quarterly Report on Form 10-Q under the heading "Risk Factors" and Part I, Item 1A of the 2022 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, first-in-class, inhaled, selective, dual inhibitor of the enzymes phosphodiesterase 3 and 4 ("PDE3" and "PDE4"), combining bronchodilator and non-steroidal anti-inflammatory activities in one compound.

Initially, we are developing inhaled ensifentrine for the treatment of chronic obstructive pulmonary disease ("COPD"), a common, chronic, progressive, and life-threatening respiratory disease without a cure. If successfully developed and approved, ensifentrine would be the first therapeutic with a novel mode of action for COPD in over a decade.

During 2022, we reported positive top-line results from both of our Phase 3 ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") trials evaluating nebulized ensifentrine for the maintenance treatment of COPD. Ensifentrine met the primary endpoint in both the ENHANCE-1 and ENHANCE-2 trials demonstrating statistically significant and clinically meaningful improvements in measures of lung function. In addition, ensifentrine substantially reduced the rate and risk of COPD exacerbations in ENHANCE-1 and ENHANCE-2. Ensifentrine was well tolerated in both trials.

Based on the results from our ENHANCE program, we believe ensifentrine, if approved, has the potential to change the treatment paradigm for COPD. The totality of data from clinical trials, in particular top-line results from the ENHANCE program, support our belief. We plan to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") in the second quarter of 2023 for inhaled ensifentrine for the maintenance treatment of COPD.

If approved, we intend to commercialize inhaled ensifentrine for the maintenance treatment of COPD in the United States ("U.S."). Although we believe ensifentrine will not be regulated as a drug device combination, patients use a readily available standard jet nebulizer to take ensifentrine. Outside the U.S., we intend to license ensifentrine to companies with expertise and experience in developing and commercializing products in those regions. To that end, we have entered into a strategic collaboration with Nuance Pharma Limited, a Shanghai-based specialty pharmaceutical company ("Nuance Pharma"), to develop and commercialize ensifentrine in Greater China.

In Phase 2 clinical trials, ensifentrine has demonstrated positive results in patients with COPD, asthma and cystic fibrosis ("CF"). Two additional formulations of ensifentrine have been evaluated in Phase 2 trials for the treatment of COPD: dry powder inhaler ("DPI") and pressurized metered-dose inhaler ("pMDI").

We have incurred recurring losses and negative cash flows from operations since inception, and have an accumulated deficit of $350.1 million as of March 31, 2023. 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 significant expenses in connection with our ongoing activities, if and as we:

- establish a sales, marketing and distribution infrastructure, ramp up production to commercial scale with our manufacturing and other Chemistry, Manufacturing and Controls activities to potentially commercialize any products for which we may obtain regulatory approval;
- 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;
- 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; and

- 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.

We believe that our cash and cash equivalents as of March 31, 2023, together with expected cash receipts from U.K. tax credit program and funding expected to become available under the $150.0 million debt financing facility secured in October 2022 (the "Oxford Term Loan"), will enable us to fund our planned operating expenses and capital expenditure requirements through at least the end of 2025, including the planned commercial launch of ensifentrine in the U.S., if approved. The Oxford Term Loan advances are contingent upon achievement of certain clinical and regulatory milestones and other specified conditions. Refer to Note 5 - Term Loan to the condensed consolidated financial statements for additional information on the Oxford Term Loan.

Clinical development update

Phase 3 ENHANCE program

We reported positive top-line results from ENHANCE-2 and ENHANCE-1, in August and December 2022, respectively. Ensifentrine successfully met the primary endpoints in both trials, demonstrating statistically significant and clinically meaningful improvements in measures of lung function in moderate to severe COPD patients. Improvements in symptoms and quality of life measures were shown in both trials, which reached statistical significance in ENHANCE-1. Ensifentrine substantially reduced the rate and risk of moderate to severe COPD exacerbations and was well tolerated in both trials.

The ENHANCE trials were designed to evaluate ensifentrine as monotherapy and added onto a single bronchodilator. Each trial enrolled approximately 800 subjects, for a total of approximately 1,600 subjects, at sites primarily in the U.S. and Europe. The two trials provided replicate evidence of efficacy and safety data over 24 weeks and ENHANCE-1 also evaluated longer-term safety in approximately 400 subjects over 48 weeks.

Subject demographics and disease characteristics were well balanced between treatment groups in both trials.

- In ENHANCE-1 approximately 69% of subjects received background COPD therapy, either a long-acting muscarinic antagonist ("LAMA") or a long-acting beta-antagonist ("LABA"). Additionally, approximately 20% of all subjects received inhaled corticosteroids ("ICS") with concomitant LAMA or LABA.
- In ENHANCE-2 approximately 55% of subjects received background COPD therapy, either a LAMA or a LABA. Additionally, approximately 15% of all subjects received ICS with concomitant LAMA or LABA.

Highlights

Primary endpoint met (FEV_1*AUC 0-12 hr)

- Placebo corrected, change from baseline in average FEV_1 area under the curve 0-12 hours post dose at week 12 was 87 mL ($p<0.0001$) for ensifentrine in ENHANCE-1 and 94 mL ($p<0.0001$) for ensifentrine in ENHANCE-2.
- Demonstrated consistent improvements with ensifentrine in all subgroups including gender, age, smoking status, COPD severity, background medication, ICS use, chronic bronchitis, FEV_1 reversibility and geographic region.

Secondary endpoints evaluating lung function met:

- Placebo corrected, increase in peak FEV_1 of 147 mL ($p<0.0001$) 0-4 hours post dose at week 12 in ENHANCE-1 and 146 mL ($p<0.0001$) in ENHANCE-2.
- Placebo corrected, increase in morning trough FEV_1 of 35 mL ($p=0.0413$) at week 12 in ENHANCE-1 and 49 mL ($p=0.0016$) in ENHANCE-2, supporting twice daily dosing regimen.

Exacerbation rate and risk reduced

- Subjects receiving ensifentrine demonstrated a 36% reduction in the rate of moderate to severe COPD exacerbations over 24 weeks ($p=0.0503$) compared to those receiving placebo in ENHANCE-1 and a 43% reduction ($p=0.0090$) in ENHANCE-2.
- In pooled exacerbation data from ENHANCE-1 and ENHANCE-2, ensifentrine demonstrated a 40% reduction in the rate of moderate to severe COPD exacerbations over 24 weeks ($p=0.0012$) compared to those receiving placebo.
- Treatment with ensifentrine significantly decreased the risk of a moderate/severe exacerbation as measured by time to first exacerbation when compared with placebo by 38% ($p=0.0382$) in ENHANCE-1 and by 42% ($p=0.0089$) in ENHANCE-2.
- In pooled exacerbation data from ENHANCE-1 and ENHANCE-2, ensifentrine significantly decreased the risk of a moderate/severe exacerbation as measured by time to first exacerbation when compared with placebo by 41% ($p=0.0009$).

COPD symptoms and Quality of Life ("QOL")

- In ENHANCE-1, daily symptoms as measured by E-RS** Total Score in the ensifentrine group improved from baseline to greater than the minimal clinically important difference ("MCID") of -2 units with a statistically significant improvement compared to placebo at week 24. Improvements in symptoms were early and sustained with statistical significance versus placebo at weeks 6, 12 and 24. Similar improvements were demonstrated in ENHANCE-2 but statistical significance was not achieved due to improvements observed in the placebo group over time.
- In ENHANCE-1, QOL as measured by SGRQ** Total Score in the ensifentrine group improved from baseline to greater than the MCID of -4 units with a statistically significant improvement compared to placebo at week 24. Improvements in QOL were early and sustained with statistical significance versus placebo at weeks 6, 12 and 24. In ENHANCE-2, QOL as measured by SGRQ* Total Score in the ensifentrine group also improved from baseline to greater than the MCID of -4 units at weeks 12 and 24, numerically exceeding placebo at each measurement, but statistical significance was not achieved due to improvements observed in the placebo group over time.

Favorable safety profile

- Ensifentrine was well tolerated with very few adverse events occurring in more than 1% of subjects and greater than placebo over 24 and 48 weeks.

*FEV_1: Forced Expiratory Volume in one second, a standard measure of lung function

**E-RS, Evaluating Respiratory Symptoms, and SGRQ, St. George's Respiratory Questionnaire, are validated patient reported outcome tools

ENHANCE Program summary

ENHANCE-1 and ENHANCE-2 provide consistent efficacy and safety in COPD patients

Top-line Measurement	ENHANCE-1	ENHANCE-2
Average FEV_1 AUC (0-12 hours)	+87 mL (p<0.0001) vs placebo	+94 mL (p<0.0001) vs placebo
Peak FEV_1	+147 mL (p<0.0001) vs placebo	+146 mL (p<0.0001) vs placebo
Morning Trough FEV_1	+35 mL (p=0.0413) vs placebo	+49 mL (p=0.0016) vs placebo
Symptoms (E-RS Total Score)	-1.0 units (p=0.0111) vs placebo	-0.6 units (NS) vs placebo
Quality of Life (SGRQ Total Score)	-2.3 units (p=0.0253) vs placebo	-0.5 units (NS) vs placebo
Exacerbation rate	36% (p=0.0503) reduction in rate	43% (p=0.0090) reduction in rate
Time to first COPD exacerbation	38% (p=0.0382) reduction in risk	42% (p=0.0089) reduction in risk
Pooled exacerbation rate	40% (p=0.0012) reduction in rate	
Pooled time to first COPD exacerbation	41% (p=0.0009) reduction in risk	
Incidence of adverse events	Low incidence of adverse events at 24 and 48 weeks No safety signals associated with ensifentrine	

NS = not significant

Nuance Pharma

In April 2023, our development partner, Nuance Pharma, dosed the first subject in its pivotal Phase 3 clinical trial evaluating ensifentrine for the maintenance treatment of COPD in mainland China. In August 2022, Nuance Pharma received clearance from the Center of Drug Evaluation for its Investigational New Drug application to conduct both Phase 1 and Phase 3 studies with ensifentrine for the maintenance treatment of COPD in mainland China. Nuance Pharma initiated a Phase 1 trial with ensifentrine in healthy volunteers in March 2023. In 2021, we entered into an agreement with Nuance Pharma for exclusive rights to develop and commercialize ensifentrine in Greater China, with future potential milestone payments up to $179 million plus royalties.

Critical accounting estimates

There were no material changes to the Company's critical accounting estimates described in the Company's 2022 Form 10-K during the three months ended March 31, 2023.

Components of results of operations

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.

As the Phase 3 ENHANCE program is nearing completion, we expect our research and development costs to decrease over the next several quarters until we add new compounds or develop ensifentrine further in other delivery methods or indications. Due to the nature of research and development, the expected costs are inherently uncertain and may vary significantly from our current expectations.

Selling, general and administrative costs

Selling, 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 commercial operations, prepare for a potential launch and, in the event of successful regulatory approval, 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, foreign exchange movements on cash and cash equivalents and taxes receivable, and the U.K. research and development tax credits.

We 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 us. Credits recorded in the 2022 financial year are expected to be received in the fourth quarter of 2023.

Taxation

We are subject to corporate taxation in the U.S. 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 Condensed Consolidated Statements of Operations and Comprehensive Loss represent the tax impact from our operating activities in the U.S., 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, 2023 and 2022

The following table shows our statements of operations for the three months ended March 31, 2023 and 2022 (in thousands):

	Three months ended March 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 12,610	$ 17,625	$ (5,015)
Selling, general and administrative	9,589	7,440	2,149
Total operating expenses	22,199	25,065	(2,866)
Operating loss	(22,199)	(25,065)	2,866
Other income/(expense):			
Research and development tax credit	2,313	1,302	1,011
Interest income	2,677	15	2,662
Interest expense	(293)	(84)	(209)
Foreign exchange gain/(loss)	932	(923)	1,855
Total other income, net	5,629	310	5,319
Loss before income taxes	(16,570)	(24,755)	8,185
Income tax expense	(173)	(82)	(91)
Net loss	$ (16,743)	$ (24,837)	$ 8,094

Research and development costs

Research and development costs were $12.6 million for the three months ended March 31, 2023, compared to $17.6 million for the three months ended March 31, 2022, a decrease of $5.0 million. This decrease was primarily due to a $5.1 million decrease in clinical trial and other development costs as the Phase 3 ENHANCE program is in the final stages of completing data analysis whereas in the same period in the prior year significant costs were incurred associated with active enrollment. Research and development costs for the three months ended March 31, 2023 include the impact of the accrual related to the supplier matter as discussed in Note 8.

Selling, general and administrative costs

Selling, general and administrative costs were $9.6 million for the three months ended March 31, 2023, compared to $7.4 million for the three months ended March 31, 2022, an increase of $2.1 million. This increase was primarily due to a $2.7 million increase in people related costs, inclusive of share-based compensation, as well as an increase of $0.8 million for costs related to the build out of commercial infrastructure in preparation for a potential commercial launch. The increases were partially offset by a non-recurring $2.0 million charge related to the modification of the assignment and license agreement with Ligand UK Development Limited, which was incurred in the three months ended March 31, 2022.

Other income/(expense)

Other income/(expense) for the three months ended March 31, 2023 was income of $5.6 million compared to income of $0.3 million for the three months ended March 31, 2022, an increase of $5.3 million. This increase was primarily due to increases of $2.7 million in interest income on higher cash balances and higher interest rates, $1.9 million related to the strengthening of the pound sterling and $1.0 million relating to the R&D tax credit and was partially offset by an increase in interest expense.

Cash flows

The following table summarizes our cash flows for the three months ended March 31, 2023 and 2022 (in thousands):

	Three months ended March 31,		
	2023	2022	Change
Cash and cash equivalents at beginning of the period	$ 227,827	$ 148,380	$ 79,447
Net cash used in operating activities	(5,782)	(14,512)	8,730
Net cash provided by investing activities	—	—	—
Net cash provided by/(used in) financing activities	68,685	(726)	69,411
Effect of exchange rate changes on cash and cash equivalents	685	(378)	1,063
Cash and cash equivalents at end of the period	$ 291,415	$ 132,764	$ 158,651

Operating activities

Net cash used in operating activities was $5.8 million in the three months ended March 31, 2023, compared to $14.5 million during the three months ended March 31, 2022, a decrease of $8.7 million. The decrease in cash used in operating activities was primarily due to the decrease in clinical trial and other development costs as we are in the final stages of completing data analysis related to our Phase 3 ENHANCE program whereas in the same period in the prior year we had significant costs associated with active enrollment as well as the timing of payments.

Financing activities

Net cash provided by financing activities was $68.7 million in the three months ended March 31, 2023, compared to $0.7 million net cash used in the three months ended March 31, 2022, an increase of $69.4 million. The increase of cash provided by financing activities was primarily due to the proceeds from issuance of ordinary shares of $56.9 million and the proceeds from draw under the Oxford Term Loan of $10.0 million.

Liquidity and capital resources

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily through the issuances of our equity securities, including warrants, from borrowings under term loan facilities and from upfront payments from the Nuance Agreement.

We have incurred recurring losses since inception, including net losses of $16.7 million for the three months ended March 31, 2023, and $68.7 million for the year ended December 31, 2022. As of March 31, 2023, we had an accumulated deficit of $350.1 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 Oxford Term Loan.

2023 Financing and Capital Transactions

During the three months ended March 31, 2023, we completed the following financing and capital transactions

- Received $10.0 million under the second term loan advance related to the Oxford Term Loan;
- Sold 20,321,384 ordinary shares (equivalent to 2,540,173 ADSs) under the at-the-market offering program entered into in March 2021 (the "2021 ATM Program"), at an average price of approximately $2.88 per share (equivalent to $23.08 per ADS), raising aggregate net proceeds of approximately $56.9 million after deducting issuance costs;
- Replaced the 2021 ATM Program, with an open market sale agreement with Jefferies LLC ("Jefferies") to sell our ordinary shares, in the form of ADSs, with aggregate gross proceeds of up to $200.0 million.

Refer also to Note 5 - Term Loan to the condensed consolidated financial statements for additional information on the Oxford Term Loan and to Note 1 - Organization and description of business operations to the condensed consolidated financial statements for additional information on 2023 activity under the 2021 ATM Program.

Funding requirements

We believe that our cash and cash equivalents as of March 31, 2023, together with, expected cash receipts from U.K. tax credits and additional funding expected to become available under the Oxford Term Loan, will enable us to fund our planned operating expenses and capital expenditure requirements through at least the end of 2025, including the planned commercial launch of nebulized ensifentrine for COPD maintenance treatment in the U.S. Future advances under the Oxford Term Loan are contingent upon achievement of certain clinical and regulatory milestones and other specified conditions. Our cash and cash equivalents are maintained at financial institutions in amounts that exceed federally insured limits. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

We may require additional capital to commercialize ensifentrine, to continue the clinical development of our DPI and pMDI formulations of ensifentrine and to research and develop additional formulations of or with ensifentrine. In addition, we may seek to initiate or conduct preclinical or clinical studies with ensifentrine in additional indications or to discover or in-license and develop additional product candidates. We may 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 capital 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 revenue, 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 revenue, if any, will be derived from sales of products that we do not expect to be commercially available within the next year, if ever. Accordingly, we may need to obtain substantial additional funds to achieve our business objectives.

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, 2023, 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, 2023 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. Except as discussed below, our risk factors have not changed materially from those described in Part I, Item 1A of the 2022 Form 10-K under the heading "Risk Factors".

We will need additional funding to complete development and commercialization of any future product candidates, or development and commercialization of other formulations or target indications of ensifentrine, if approved. If we are unable to raise capital when needed, or if a failure of any financial institution where we maintain our cash and cash equivalents prevents or delays us from accessing uninsured funds, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing and planned activities, particularly as we conduct further clinical trials of ensifentrine, and develop ensifentrine in other formulations or for other indications. In addition, if we obtain regulatory approval for ensifentrine or any other product candidates, we expect to incur significant commercialization expenses related to activities including product positioning studies, product manufacturing, medical affairs, marketing, sales and distribution. Furthermore, we expect to incur ongoing costs associated with operating as a public company in the United States and maintaining a listing on the Nasdaq Global Market, or Nasdaq. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

If we obtain regulatory approval for ensifentrine for the treatment of COPD in the US, we estimate that our existing cash resources, expected cash receipts from the UK tax credit program and funding expected to become available under the $150.0 million debt facility will enable the Company to fund planned operating expenses and capital expenditure requirements through at least the end of 2025 including the commercial launch of ensifentrine in the US. Future advances under the Oxford Term Loan are contingent upon achievement of certain clinical and regulatory milestones and other specified conditions. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. In addition, our operating plan may change as a result of many factors unknown to us. These factors, among others, may necessitate that we seek additional capital sooner than currently planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of the regulatory submission and review of ensifentrine for the treatment of COPD in the US and other regions, including any post-marketing studies that could be required by regulatory authorities, if regulatory approval is received;
- the cost, progress and results of any other studies required to support the commercial positioning of ensifentrine for the treatment of COPD, if regulatory approval is received;
- the cost, progress and results of any clinical trials for the treatment of CF, asthma or other indications, or for other formulations of ensifentrine including fixed-dose combination products;
- the cost of manufacturing clinical and, if approved, commercial supplies of the ensifentrine active ingredient and derived formulated drug products;

- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for ensifentrine in other indications and of the development of DPI and pMDI formulations of ensifentrine, or fixed-dose combination formulations of ensifentrine for the maintenance treatment of COPD and potentially asthma and other respiratory diseases;
- the costs, timing and outcome of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for ensifentrine;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the timing and amount of revenue, if any, received from commercial sales of ensifentrine;
- the sales price and availability of adequate third-party coverage and reimbursement for ensifentrine;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for ensifentrine, although we currently have no commitments or agreements to complete any such transactions.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize ensifentrine. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect our business, the holdings or the rights of our shareholders, or the value of our ordinary shares or ADSs.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue our research and development programs relating to ensifentrine or any commercialization efforts, be unable to expand our operations, or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business and potentially cause us to discontinue operations.

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

Exhibit Number	Exhibit Description	Incorporated by Reference to Filings Indicated				Filed/Furnished Herewith
		Form	File No.	Exhibit No.	Filing date	
3.1	Articles of Association, as amended and as currently in effect	6-K	001-38067	1	12/30/2020	
10.1	Second Amendment and Restated 2017 Incentive Award Plan	8-K	001-38067	10.1	05/01/2023	
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
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: May 9, 2023 By: /s/ David Zaccardelli

David Zaccardelli, Pharm. D.
President and Chief Executive Officer

Date: May 9, 2023 By: /s/ Mark W. Hahn

Mark W. Hahn
Chief Financial Officer

Exhibit 31.1

CERTIFICATION

I, David Zaccardelli, Pharm.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verona Pharma plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2023 By: /s/ David Zaccardelli, Pharm.D.

David Zaccardelli, Pharm.D.

Chief Executive Officer

(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Mark W. Hahn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verona Pharma plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2023 By: /s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (*principal financial officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Verona Pharma plc (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2023

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

David Zaccardelli, Pharm.D.

Chief Executive Officer

(*principal executive officer*)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Verona Pharma plc (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2023 By: /s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (*principal financial officer)*