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 September 30, 2022

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 November 3, 2022, the registrant had 604,980,598 ordinary shares, nominal value £0.05 per share, outstanding, which if all held in ADS form, would be represented by 75,622,575 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 per share amounts and par value of shares)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 231,701	$ 148,380
Prepaid expenses	3,355	4,037
Tax and tax incentive receivable	20,321	15,583
Other current assets	3,077	2,063
Total current assets	258,454	170,063
Non-current assets:		
Furniture and equipment, net	81	80
Goodwill	544	545
Equity interest	15,000	15,000
Right-of-use assets	793	899
Total non-current assets	16,418	16,524
Total assets	$ 274,872	$ 186,587
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,002	$ 10,044
Accrued expenses	22,978	22,256
Operating lease liability	569	648
Taxes payable	285	147
Other current liabilities	294	327
Total current liabilities	32,128	33,422
Non-current liabilities:		
Term loan	5,035	4,874
Operating lease liability	224	286
Total non-current liabilities	5,259	5,160
Total liabilities	37,387	38,582
Commitments and contingencies		
Shareholders' equity:		
Ordinary £0.05 par value shares; 608,138,246 and 489,177,550 issued, and 602,215,606 and 480,082,966 outstanding, at September 30, 2022 and December 31, 2021, respectively	39,119	31,855
Additional paid-in capital	525,858	385,070
Ordinary shares held in treasury	(449)	(603)
Accumulated other comprehensive loss	(4,601)	(4,601)
Accumulated deficit	(322,442)	(263,716)
Total shareholders' equity	237,485	148,005
Total liabilities and shareholders' equity	$ 274,872	$ 186,587

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 September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Revenue	$ —	$ 40,000	$ —	$ 40,000
Gross profit	—	40,000	—	40,000
Operating expenses				
Research and development	$ 9,838	$ 22,560	$ 42,445	$ 56,697
Selling, general and administrative	5,290	10,883	18,256	28,150
Total operating expenses	15,128	33,443	60,701	84,847
Operating (loss)/profit	(15,128)	6,557	(60,701)	(44,847)
Other (expense)/income				
Research and development tax credit	2,127	4,749	8,838	10,655
Interest income	779	4	959	11
Interest expense	(116)	(86)	(291)	(255)
Fair value movement on warrants	—	40	—	2,244
Foreign exchange (loss)/gain	(3,245)	(86)	(6,830)	117
Total other (expense)/income, net	(455)	4,621	2,676	12,772
(Loss)/profit before income taxes	(15,583)	11,178	(58,025)	(32,075)
Income tax expense	(64)	(127)	(225)	(232)
Net (loss)/profit	$ (15,647)	$ 11,051	$ (58,250)	$ (32,307)
(Loss)/profit per ordinary share - basic	$ (0.03)	$ 0.02	$ (0.12)	$ (0.07)
(Loss)/profit per ordinary share - diluted	$ (0.03)	$ 0.02	$ (0.12)	$ (0.07)
Weighted-average shares outstanding - basic	544,134,136	475,334,354	503,751,844	471,159,171
Weighted-average shares outstanding - diluted	544,134,136	515,819,439	503,751,844	471,159,171

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
Net loss	—	—	—	—	—	(17,766)	(17,766)
Restricted share units vested	—	—	—	148	—	(148)	—
Common shares withheld for taxes on vested stock awards	—	—	(689)	—	—	—	(689)
Equity settled share-based compensation reclassified as cash-settled	—	—	(25)	—	—	—	(25)
Share-based compensation	—	—	3,053	—	—	—	3,053
Balance at June 30, 2022	494,058,246	$ 32,182	$ 390,543	$ (591)	$ (4,601)	$ (306,653)	$ 110,880
Net loss	—	—	—	—	—	(15,647)	(15,647)
Issuance of ordinary shares, net of issuance costs	114,080,000	6,906	133,242	—	—	—	140,148
Restricted share units vested	—	—	—	142	—	(142)	—
Issuance of ordinary shares from restricted share units or share options	—	31	340	—	—	—	371
Common shares withheld for taxes on vested stock awards	—	—	(900)	—	—	—	(900)
Equity settled share-based compensation reclassified as cash-settled	—	—	(182)	—	—	—	(182)
Share-based compensation	—	—	2,815	—	—	—	2,815
Balance at September 30, 2022	608,138,246	$ 39,119	$ 525,858	$ (449)	$ (4,601)	$ (322,442)	$ 237,485

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, 2020	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
Net loss	—	—	—	—	—	(22,068)	(22,068)
Issuance of common shares under at-the-market sales agreement	434,704	30	353	—	—	—	383
Restricted share units vested	—	—	—	827	—	(827)	—
Common shares withheld for taxes on vested stock awards	—	—	(3,782)	—	—	—	(3,782)
Share-based compensation	—	—	7,450	—	—	—	7,450
Balance at June 30, 2021	488,739,150	$ 31,824	$ 379,282	$ (843)	$ (4,601)	$ (251,265)	$ 154,397
Net profit						11,051	11,051
Issuance of common shares under at-the-market sales agreement	438,400	31	319	—	—	—	350
Restricted share units vested	—	—	—	73	—	(73)	—
Common shares withheld for taxes on vested stock awards	—	—	(2,167)	—	—	—	(2,167)
Equity settled share-based compensation reclassified as cash-settled	—	—	(367)	—	—	—	(367)
Share-based compensation	—	—	4,938	—	—	—	4,938
Balance at September 30, 2021	489,177,550	$ 31,855	$ 382,005	$ (770)	$ (4,601)	$ (240,287)	$ 168,202

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)

	Nine months ended September 30,	
	2022	**2021**
Operating activities:		
Net loss:	$ (58,250)	$ (32,307)
Adjustments to reconcile net income to net cash used in operating activities:		
Foreign exchange loss	7,105	556
Amortization of debt issue costs	67	92
Accretion of redemption premium on debt	94	94
Fair value movement on warrants	—	(2,244)
Share-based compensation	9,617	21,238
Depreciation and amortization	485	467
Changes in operating assets and liabilities:		
Equity interest receivable	—	(15,000)
Prepaid expenses	682	(2,134)
Tax incentive receivable	(9,113)	(2,677)
Other current assets	(1,014)	1,053
Right-of-use asset	(351)	(823)
Accounts payable	(2,042)	(169)
Accrued expenses	722	15,595
Lease liabilities	(141)	177
Taxes payable	138	451
Other current liabilities	(123)	(300)
Net cash used in operating activities	(52,124)	(15,931)
Cash flows from investing activities:		
Purchases of furniture and equipment	(29)	(11)
Net cash used in investing activities	(29)	(11)
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares	149,730	—
Payment of offering costs in connection with the issuance of ordinary shares	(9,582)	—
Payments of withholding taxes from share-based awards	(2,382)	(5,949)
Proceeds from exercise of share options	371	—
Proceeds from at-the-market sales agreement	67	733
Net cash provided by/(used in) financing activities	138,204	(5,216)
Effect of exchange rate changes on cash and cash equivalents	(2,730)	(281)
Net change in cash and cash equivalents	83,321	(21,439)
Cash and cash equivalents at beginning of the period	148,380	187,986
Cash and cash equivalents at end of the period	$ 231,701	$ 166,547
Supplemental disclosure of cash flow information:		
Income taxes paid	$ 90	$ —
Interest paid	$ 190	$ 162

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. Rhinopharma Limited, a Canadian company that was previously a non-operating, wholly-owned subsidiary, was dissolved in June 2021. 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 $322.4 million as of September 30, 2022. 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 September 30, 2022, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance.

In March 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 ordinary shares in the form of ADSs, with an aggregate offering price of up to $100.0 million.

During the nine months ended September 30, 2022, the Company sold 80,696 ordinary shares (equivalent to 10,087 ADSs) under the ATM Program, at an average price of approximately $0.86 per share (equivalent to $6.86 per ADS), raising aggregate net proceeds of approximately $0.1 million after deducting issuance costs. As of September 30, 2022, there remained ordinary shares, in the form of ADSs, with a value up to $99.2 million available for sale under the ATM Program.

On August 15, 2022, the Company completed an upsized public offering of 14,260,000 ADSs, each representing eight ordinary shares of the Company, nominal value £0.05 per share, at a price to the public of $10.50 per ADS, which includes the exercise in full by the underwriters of their option to purchase an additional 1,860,000 ADSs. The aggregate net proceeds from the offering were approximately $140.1 million after deducting underwriting discounts and commissions and estimated offering expenses payable.

Subsequent to the quarter end, on October 14, 2022, the Company entered into a term loan of up to $150.0 million (the "Oxford Term Loan") with Oxford Finance Luxembourg S.À R.L. ("Oxford"). This Oxford Term Loan replaced the Company's existing $30.0 million facility with Silicon Valley Bank under the Prior Loan Agreement (as defined below). See Note 11 for further details.

The Company's commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for several years, 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 require additional capital to commercialize ensifentrine in other markets, to continue the clinical development of 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.

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").

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 March 3, 2022 (the "2021 Form 10-K"). The Consolidated Balance Sheet as of December 31, 2021, was derived from audited consolidated financial statements included in the 2021 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, the fair value of share-based compensation, the fair value of warrants, research and development tax credit and the carrying value of the equity interest in Nuance Pharma (as defined below). 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 - Tax and tax incentive receivables

Tax and tax incentive receivables consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Research and development tax credit receivable - U.K.	$ 20,321	$ 15,583
Total tax receivable	$ 20,321	$ 15,583

The Company conducts research and development activities including, but not limited to, developing ensifentrine for various indications and delivery methods, and as a result the Company benefits in the U.K. from the HM Revenue and Customs, or HMRC, small and medium sized enterprises research and development relief, or SME R&D credit, which provides relief against U.K. Corporation Tax.

The tax and tax incentive receivable as of September 30, 2022 includes the accumulated nine months ended September 30, 2022 and twelve months ended December 31, 2021 credits, compared to the receivable as of December 31, 2021 which includes the twelve months ended December 31, 2021 credit. The Company is expecting to receive the 2021 credit in the fourth quarter of 2022.

Note 4 - Accrued expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Clinical trial and other development costs	$ 19,677	$ 21,336
Professional fees and general corporate costs	1,746	919
People related costs	1,555	1
Total accrued expenses	$ 22,978	$ 22,256

Note 5 - Term loan

In November 2020, the Company entered into a term loan facility of up to $30.0 million (the “SVB 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 of September 30, 2022, the Company had $5.0 million principal outstanding under the SVB Term Loan. Additional detail surrounding the SVB Term Loan can be found in the Company’s 2021 Form 10-K.

As of September 30, 2022, the carrying value of the SVB Term Loan was approximately $5.0 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 of the balance sheet date.

Subsequent to the quarter end, on October 14, 2022, the Company entered into the Oxford Term Loan, which replaced the existing $30.0 million SVB Term Loan with Silicon Valley Bank under the Prior Loan Agreement. See Note 11 for further details.

Note 6 - 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 Company follows guidance from ASC 321-10-35-2 and uses the fair value measurement alternative and measures the securities at cost, which is deemed to be the value indicated by the last observable transaction in Nuance Biotech's stock, subject to impairment. The valuation will be adjusted for any observable price changes in orderly transactions for an identical or similar investment in Nuance Biotech, or if there is an indicator of impairment. As of September 30, 2022, there had been no observable transactions to indicate any price changes in the value of Nuance Biotech's stock, nor had there been any indications of impairment. The equity interest is therefore recorded at a value of $15.0 million.

Note 7 - Significant agreements

Ligand agreement

In 2006 the Company acquired Rhinopharma and assumed contingent liabilities owed to Ligand UK Development Limited ("Ligand") (formerly Vernalis Development Limited). The Company refers to the assignment and license agreement as the Ligand Agreement.

Ligand assigned to the Company 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 "Ligand Licensed Products") developed using Ligand Patents, Ligand know-how and the physical stock of certain compounds.

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

At the time of the acquisition the contingent liability was not recognized as part of the acquisition accounting as it was immaterial. The Company will therefore record as a research and development expense the Milestone Payment or royalties when they are probable.

In March 2022, the Company entered into an Amendment Agreement (the "Amendment") with Ligand whereby the Ligand Agreement was amended to clarify certain ambiguous terms in the Ligand Agreement. Pursuant to the Amendment:

- the Company agreed to pay to Ligand (i) $2.0 million within five business days of the date of the Amendment and (ii) $15.0 million upon the first commercial sale of ensifentrine by the Company or a sub-licensee, which amount is payable in cash or, at the Company's discretion, by the issuance of Company equity of equivalent value, as determined based on the volume-weighted average price of the Company's American Depositary Shares on the Nasdaq Global Market over the ten (10) trading days including and prior to such milestone event;
- the Ligand Agreement shall expire on March 24, 2042 unless terminated earlier by either party in accordance with its terms;
- upon termination of the Ligand Agreement, any Sub-licensee (as defined in the Amendment) shall have the right to enter into a direct license agreement with Ligand for the portion of the Program IP (as defined in the Amendment) that was sub-licensed by such Sub-licensee;
- the Milestone Payment may be paid in cash or, at the Company's discretion, by issuing to Ligand shares in the Company of equivalent value; and
- each party's right to terminate the Ligand Agreement is conditioned upon such party obtaining a final judgment of the English High Court declaring that the other party is in material breach of its obligations under the Ligand Agreement.

The Company paid the $2.0 million to Ligand in March, 2022 and accounted for the $2.0 million payment at execution as selling, general and administrative expense in the condensed consolidated statements of operations as the payment is related to a contract modification.

Nuance agreement

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 Company is eligible to receive future milestone payments of up to $179.0 million triggered upon achievement of certain clinical, regulatory, and commercial milestones, as well as tiered double-digit royalties as a percentage of net sales of the products in Greater China.

As of September 30, 2021, the $25.0 million cash payment and $15.0 million equity interest had been received and the holding in Nuance Biotech was recorded as Equity Interest on our unaudited condensed consolidated balance sheets. The Company follows guidance from ASC 321-10-35-2 and uses the fair value measurement alternative and measures the securities at cost, which is deemed to be the value indicated by the last observable transaction in Nuance Biotech's stock, subject to impairment. The valuation will be adjusted for any observable price changes in orderly transactions for an identical or similar investment in Nuance Biotech, or if there is an indicator of impairment. As of September 30, 2022, there had been no other transactions to indicate any price changes in the value of Nuance Biotech's stock, nor had there been any indications of impairment. The Equity Interest is therefore recorded at a value of $15 million.

Under the terms of the Nuance Agreement, at any time until three months prior to the expected submission of the first New Drug Application in Greater China, if (i) a third party is interested in partnering with the Company, either globally or in territory covering at least the United States or Europe, for the development and/or commercialization of ensifentrine or (ii) the Company undergoes a change of control, the Company will have an exclusive option right to buy back the license granted to Nuance Pharma and all related assets. The price is agreed to be equal to the aggregate of (i) all prior amounts paid by Nuance Pharma to the Company in cash under the agreement and (ii) all development and regulatory costs incurred and paid by Nuance Pharma in connection with the development and commercialization of ensifentrine under the Nuance Agreement multiplied by a single-digit factor range dependent upon achievement of certain milestones, subject to a specified maximum amount.

The Nuance Agreement will continue on a jurisdiction-by-jurisdiction and product-by-product basis until the expiration of royalty payment obligations with respect to such product in such jurisdiction unless earlier terminated by the parties. Either party may terminate the Nuance Agreement for an uncured material breach or bankruptcy of the other party. Nuance Pharma may also terminate the Nuance Agreement at will upon 90 days' prior written notice.

The Company reviewed the buy-back option and determined that because it is conditional on a third party the Company does not have the practical ability to exercise it and, accordingly, the contract is accounted for under ASC 606.

The transaction price at the Effective Date of the Nuance Agreement was $40.0 million consisting of the $25.0 million upfront cash payment and $15.0 million equity interest. Developmental and regulatory milestones, and the manufacture and supply of ensifentrine drug product, were not included in the transaction price as management determined that it is not probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Commercial milestones and sales royalties were also excluded and will be recognized when the milestones are achieved or the sales occur in Greater China.

The performance obligations in the Nuance Agreement include the grant of the license (including the right to commercialize ensifentrine until the end of the term, the sharing of certain know how, and the sharing of certain clinical and regulatory data), and manufacture and supply of ensifentrine drug product.

The Company has determined that the license and the know how shared with Nuance Pharma constitutes functional intellectual property and that revenue relating to this should be recognized at a point in time. Consequently, the Company determined that it fulfilled its obligations to Nuance Pharma after it delivered the know how that will allow Nuance Pharma to file an investigational new drug application in Greater China. This know how was delivered in the year ended December 31, 2021, and the $40.0 million revenue was therefore recognized as revenue in the year ended December 31, 2021. Revenue relating to the manufacture and supply obligations will be recognized when the drug product is delivered.

Note 8 - 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 September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Research and development	$ 916	$ 1,466	$ 3,785	$ 8,132
Selling, general and administrative	1,900	3,472	5,832	13,106
Total	$ 2,816	$ 4,938	$ 9,617	$ 21,238

Share options

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

	2022	
	Number of share options outstanding	Weighted average exercise price
Balance as of December 31, 2021	12,695,200	$ 1.38
Granted	608,000	0.62
Balance as of March 31, 2022	13,303,200	$ 1.34
Granted	1,760,000	0.51
Balance as of June 30, 2022	15,063,200	$ 1.24
Granted	4,520,000	0.82
Forfeited	(301,168)	0.77
Exercised	(502,232)	$ 0.74
Balance as of September 30, 2022	18,779,800	$ 1.16

Restricted stock units activity

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

	2022	
	Number of RSUs outstanding	Weighted average remaining contractual term (years)
Balance as of December 31, 2021	38,347,352	1.2
Granted	468,224	
Vested	(3,943,144)	
Balance as of March 31, 2022	34,872,432	1.1
Vested	(3,752,488)	
Balance as of June 30, 2022	31,119,944	1.0
Granted	12,409,640	
Forfeited	(906,264)	
Vested	(3,752,488)	
Balance as of September 30, 2022	38,870,832	1.3

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 net loss per share for the three and nine months ended September 30, 2022 and 2021 (net loss in thousands, loss per share in dollars):

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (15,647)	$ 11,051	$ (58,250)	$ (32,307)
Denominator:				
Weighted-average shares outstanding - basic	544,134,136	475,334,354	503,751,844	471,159,171
Net (loss)/profit per share - basic	$ (0.03)	$ 0.02	$ (0.12)	$ (0.07)
Weighted-average shares outstanding - diluted	544,134,136	515,819,439	503,751,844	471,159,171
Net (loss)/profit per share - diluted	$ (0.03)	$ 0.02	$ (0.12)	$ (0.07)

During the three months ended September 30, 2022 and 2021, outstanding share options, RSUs and warrants over 57,650,632 and 25,139,377 ordinary shares, respectively, were not included in the computation of diluted earnings per ordinary share, because to do so would be antidilutive.

During the nine months ended September 30, 2022 and 2021, outstanding share options, RSUs and warrants over 57,650,632 and 65,624,462 ordinary shares, respectively, were not included in the computation of diluted earnings per ordinary share, because to do so would be antidilutive.

Note 10 - Commitments and contingencies

Management is currently negotiating a matter with a supplier that has an estimated exposure of approximately $1.5 million. Management does not currently consider it probable that a payment will be made and therefore no accrual is recorded at September 30, 2022. This matter is expected to be resolved within the next 12 months.

Note 11 - Subsequent events

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 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, which are available as described below and subject to terms of the Loan Agreement. The proceeds from the Oxford Term Loan will be used for general corporate and working capital purposes, and a portion of the proceeds of the Oxford Term A Loan are being used to repay in full the existing outstanding indebtedness owed to SVB as discussed in Note 5 – Term Loan. The Oxford Term Loan has a maturity date of October 1, 2027.

The four additional term loan advances under the Oxford Term Loan consists of: a $10.0 million term loan advance (the "Oxford Term B Loan") which is available at the option of the Company from the Effective Date up to and including March 31, 2023; a $20.0 million term loan advance (the "Oxford Term C Loan") available during the period commencing on the later of January 1, 2024 and the date on which the Company receives positive ENHANCE-1 data in the Phase 3 clinical trial for ensifentrine sufficient to support the submission of a New Drug Application ("NDA") with the United States Food and Drug Administration (the "FDA") for ensifentrine through and including March 29, 2024; a $60.0 million term loan advance (the "Oxford Term D Loan") available during the period commencing on the later of October 1, 2024 and the date on which the Company receives final approval from the FDA for the Company's NDA for ensifentrine up to and including December 31, 2024; and a $50.0 million term loan advance (the "Oxford Term E Loan") available during the interest-only period at the Company's request and at Oxford's sole discretion.

Each advance under the Oxford Term Loan accrues interest at a floating per annum rate equal to (a) the greater of (i) the 1-Month CME Term SOFR reference rate on the last business 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"). In no event shall the Basic Rate (x) for the Oxford Term A Loan be less than 7.88% and (y) for each other advance be less than the Basic Rate on the business day immediately prior to the funding date of such term advance. The Basic Rate for the Term A Loan for the period from the Effective Date through and including October 31, 2022 shall be 8.54205% and the Basic Rate for each Term Loan shall not increase by more than 2.00% above the applicable Basic Rate as of the funding date of each such term loan. The Oxford Term Loan provides for interest-only payments on a monthly basis until the payment date immediately preceding December 1, 2025, if the Oxford Term D Loan is not made, and December 1, 2026, if the Oxford Term D Loan is made. Thereafter, amortization payments will be payable monthly in equal installments of principal plus accrued interest.

Upon repayment, whether at maturity, upon acceleration or by prepayment or otherwise, the Company shall make a final payment to the lenders in an amount ranging from 1.30% to 3.00% of the aggregate principal balance, depending on the advances received under the Oxford Term Loan. The Company may prepay the Oxford Term Loan in full, or in part, in accordance with the terms of the Loan Agreement, which is subject to a prepayment fee of up to 2.00%, depending on the timing of the prepayment.

The Oxford Term Loan is secured by a lien on substantially all of the assets of the Company, other than intellectual property, but including any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. The Company has also granted Oxford a negative pledge with respect to its intellectual property. The Loan Agreement contains customary covenants and representations, including but not limited to financial reporting obligations and limitations on dividends, dispositions, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, transactions with affiliates and subsidiaries. The Loan Agreement also contains other customary provisions, such as expense reimbursement, non-disclosure obligations as well as indemnification rights for the benefit of Oxford.

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, 2021 filed with the Securities and Exchange Commission on March 3, 2022 (the "2021 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, 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 2021 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 ("PDE3" and "PDE4"), which 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 evaluating nebulized ensifentrine for the maintenance treatment of chronic obstructive pulmonary disease ("COPD"). In August 2022, we announced positive top-line results from the ENHANCE-2 trial. ENHANCE-2 successfully met its primary endpoint, as well as secondary endpoints demonstrating improvements in lung function, and significantly reduced the rate and risk of COPD exacerbations. Ensifentrine was well tolerated with safety results similar to placebo.

We expect to report top-line results from ENHANCE-1 around the end of 2022. Conditional upon positive results, we plan to submit a New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") in the first half of 2023 for inhaled ensifentrine for the maintenance treatment of COPD.

We have incurred recurring losses and negative cash flows from operations since inception, and have an accumulated deficit of $322.4 million as of September 30, 2022. 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, as we:

- build out infrastructure and prepare for potential commercial launch;
- continue to invest in the clinical development of ensifentrine for the treatment of COPD or other indications;
- manufacture ensifentrine and engage in other Chemistry, Manufacturing and Controls activities; and
- maintain, expand and protect our intellectual property portfolio.

We believe that our cash and cash equivalents as of September 30, 2022, together with expected cash receipts from U.K. tax credits and additional funding expected to become available under the new Oxford Term Loan secured in October 2022, 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. See "Indebtedness" for additional information.

Clinical development update

ENHANCE-2

In August 2022, we announced positive top-line results from our Phase 3 ENHANCE-2 clinical trial evaluating nebulized ensifentrine for the maintenance treatment of COPD. ENHANCE-2 successfully met its primary endpoint, as well as secondary endpoints demonstrating improvements in lung function, and significantly reduced the rate and risk of COPD exacerbations.

Highlights

- **Study population (n=789):**
  - Subject demographics and disease characteristics were well balanced between treatment groups.
  - Approximately 52% of subjects received background COPD therapy, either a long-acting muscarinic antagonist ("LAMA") or a long-acting beta-agonist ("LABA"). Additionally, approximately 15% of all subjects also received inhaled corticosteroids ("ICS") with concomitant LAMA or LABA.
- **Primary endpoint met (FEV_1* AUC 0-12 hr):**
  - Placebo corrected, the change from baseline in average FEV_1 area under the curve 0-12 hours post dose at week 12 was 94 mL ($p<0.0001$) for ensifentrine.
  - Statistically significant and clinically meaningful improvements with ensifentrine demonstrated across all subgroups including gender, age, smoking status, COPD severity, background medication, ICS use, chronic bronchitis, FEV_1 reversibility, and geographic region.
- **Secondary endpoints of lung function met:**
  - Placebo corrected, increase in peak FEV_1 of 146 mL ($p<0.0001$) 0-4 hours post dose at week 12.
  - Placebo corrected, increase in morning trough FEV_1 of 49 mL ($p=0.0017$) at week 12, confirming twice daily dosing regimen.
- **Exacerbation rate reduced:**
  - Subjects receiving ensifentrine demonstrated a 42% reduction in the rate of moderate to severe COPD exacerbations over 24 weeks compared to those receiving placebo ($p=0.0109$).
  - Treatment with ensifentrine significantly decreased the risk of a moderate/severe exacerbation as measured by time to first exacerbation when compared with placebo by 42% ($p=0.0088$).
- **COPD symptoms and Quality of Life ("QOL"):**
  - Daily symptoms and QOL as measured by E-RS** Total Score and SGRQ** Total Score in the ensifentrine group improved from baseline to greater than the minimal clinically important difference ("MCID") of -2 units and -4 units, respectively, at week 24. Improvements in these measures were seen as early as 6 weeks and showed continued improvement at 12 and 24 weeks, numerically exceeding placebo at each measurement. Statistical significance was not achieved due to improvements observed in the placebo group over time.
- **Favorable safety profile:**
  - Ensifentrine was well tolerated with safety results similar to placebo, including occurrence of pneumonia, gastrointestinal and cardiovascular adverse events.

*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

In October 2022, we announced positive additional analyses from the ENHANCE-2 trial demonstrating that ensifentrine reduced rates of exacerbation across all subgroups analyzed over 24 weeks, including background medication, ICS use, smoking status and geographic region. Results of the subgroup analyses confirmed positive effects consistent with the 42% reduction in the rate of moderate to severe exacerbations observed in the overall population. ENHANCE-2 was not powered for exacerbation rate.

We plan to release additional information from ENHANCE-2 at upcoming scientific conferences.

ENHANCE-1

In June 2022, we completed enrollment in our Phase 3 ENHANCE-1 clinical trial with more than 800 patients randomized. Based on our current models of study progress, we expect to report top-line data for ENHANCE-1 around the end of 2022.

The two randomized, double-blind placebo-controlled studies (ENHANCE-1 and ENHANCE-2) evaluate the efficacy and safety of nebulized ensifentrine in subjects with COPD as monotherapy and added onto a single bronchodilator, either a LAMA or a LABA, compared to placebo, and up to approximately 20% of subjects may receive ICS. The two study designs replicate measurements of efficacy and safety data over 24 weeks and ENHANCE-1 also evaluates longer-term safety over 48 weeks. The primary endpoint of both studies is improvement in lung function, as measured by FEV_1 area under curve ("AUC") 0-12 hours post dose at week 12. Key secondary endpoints comprise measurements of COPD symptoms and health-related quality of life measures, including SGRQ and E-RS.

The design of the ENHANCE program was based on analysis of our two Phase 2b clinical trials, which each enrolled 400 subjects with moderate to severe COPD. The attributes of the patient population enrolled in the ENHANCE program are consistent with those enrolled in prior Phase 2b trials of ensifentrine including demographics and baseline COPD characteristics, including smoking history, lung function, symptoms and quality of life measures.

Nuance Pharma

In August 2022, our development partner, Nuance Pharma, received clearance from China's Center for Drug Evaluation to begin Phase 1 and Phase 3 studies with ensifentrine for COPD in mainland China. In 2021, we entered into an agreement with Nuance Pharma with a potential value of up to $219 million, granting Nuance Pharma exclusive rights to develop and commercialize ensifentrine in Greater China. See "Significant Agreements" for additional information.

COVID-19 pandemic impact

Whilst the impact of the COVID-19 pandemic and government and other measures in response have substantially reduced, we continue to monitor the pandemic and any potential impact on our operations and clinical trials. In addition, we continue to follow guidance from the FDA and other health regulatory authorities regarding the conduct of clinical trials during the pandemic to ensure the safety of study participants, minimize risks to study integrity, and maintain compliance with good clinical practice.

Russia-Ukraine conflict

We are conducting ENHANCE-1 at a number of clinical trial sites in Russia. The sanctions and other restrictions imposed by the U.S. and other countries as a result of the current conflict between Russia and Ukraine are impacting our outsourced clinical research vendor's ability to pay the clinical trial sites and investigators in Russia and may impact our clinical trial activities at sites in Russia. Management is closely monitoring the Russia-Ukraine conflict and will provide an update if we become aware of any meaningful disruption to the completion of our Phase 3 program or our plans to submit an NDA for ensifentrine.

Management update

Following the positive data from ENHANCE-2, we accelerated our commercial launch preparation activities. We are executing on our strategy and, in September and October 2022, we added senior leadership across marketing, market access, commercial operations, IT, HR and finance.

Significant agreements

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 "Ligand Licensed Products") developed using Ligand Patents, Ligand know-how and the physical stock of certain compounds.

The contingent liability comprises a milestone payment (the "Milestone Payment") on obtaining the first approval of any regulatory authority for the commercialization of a Ligand Licensed Product, low single digit royalties based on the future sales performance of all Ligand Licensed Products and a portion equal to a mid-twenty percent of any consideration received from any sub-licensees 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 probable.

In March 2022 we entered into an Amendment Agreement (the "Amendment") with Ligand whereby the Ligand Agreement was amended to clarify certain ambiguous terms in the Ligand Agreement. Pursuant to the Amendment:

- we agreed to pay to Ligand (i) $2.0 million within five business days of the date of the Amendment and (ii) $15.0 million upon the first commercial sale of ensifentrine by us or a sub-licensee, which amount is payable in cash or, at the our discretion, by the issuance of Company equity of equivalent value, as determined based on the volume-weighted average price of the our American Depositary Shares on the Nasdaq Global Market over the ten (10) trading days including and prior to such milestone event;
- the Ligand Agreement shall expire on March 24, 2042 unless terminated earlier by either party in accordance with its terms;
- upon termination of the Ligand Agreement, any Sub-licensee (as defined in the Amendment) shall have the right to enter into a direct license agreement with Ligand for the portion of the Program IP (as defined in the Amendment) that was sub-licensed by such Sub-licensee;
- the Milestone Payment may be paid in cash or, at our discretion, by issuing to Ligand shares in the Company of equivalent value; and
- each party's right to terminate the Ligand Agreement is conditioned upon such party obtaining a final judgment of the English High Court declaring that the other party is in material breach of its obligations under the Ligand Agreement.

Nuance agreement

We 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 we granted Nuance Pharma the exclusive rights to develop and commercialize ensifentrine in Greater China (China, Taiwan, Hong Kong and Macau). In return, we 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. We are eligible to receive future milestone payments of up to $179.0 million, triggered upon achievement of certain clinical, regulatory, and commercial milestones as well as tiered double-digit royalties on net sales in Greater China.

As of September 30, 2021, the $25.0 million cash payment and $15.0 million equity interest had been received and the holding in Nuance Biotech was recorded as Equity Interest on our unaudited condensed consolidated balance sheet. The equity interest is recorded at the fair value indicated by the last observable transaction in Nuance Biotech's stock, which was a fund raising in November, 2020. As of September 30, 2022, there had been no other observable transactions to indicate any price changes in the value of Nuance Biotech's stock, nor had there been any indications of impairment. The equity interest is therefore recorded at a value of $15.0 million.

Nuance Pharma will be responsible for all costs related to clinical development and commercialization of ensifentrine in Greater China. A joint steering committee has been established between us and Nuance Pharma to

oversee and coordinate the overall conduct of such clinical development and commercialization. We intend to use the joint steering committee to help ensure the clinical development of ensifentrine in Greater China aligns with our overall global development and commercialization strategy.

Under the terms of the Nuance Agreement, at any time until three months prior to the expected submission of the first New Drug Application in Greater China, if (i) a third party is interested in partnering with us, either globally or in territory covering at least the United States or Europe, for the development and/or commercialization of ensifentrine or (ii) we undergo a change of control, we will have an exclusive option right to buy back the license granted to Nuance Pharma and all related assets. The price is agreed to be equal to the aggregate of (i) all prior amounts paid by Nuance Pharma to us in cash under the agreement and (ii) all development and regulatory costs incurred and paid by Nuance Pharma in connection with the development and commercialization of the ensifentrine under the Nuance Agreement multiplied by a single-digit factor range dependent upon achievement of certain milestones, subject to a specified maximum amount.

The Nuance Agreement will continue on a jurisdiction-by-jurisdiction and product-by-product basis until the expiration of royalty payment obligations with respect to such product in such jurisdiction unless earlier terminated by the parties. Either party may terminate the Nuance Agreement for an uncured material breach or bankruptcy of the other party. Nuance Pharma may also terminate the Nuance Agreement at will upon 90 days' prior written notice.

We reviewed the buy-back option and determined that because it is conditional on a third party we do not have the practical ability to exercise it and, accordingly, the contract is accounted for under ASC 606.

The transaction price at the Effective Date of the Nuance Agreement was $40.0 million consisting of the $25.0 million upfront cash payment and $15.0 million equity interest. Developmental and regulatory milestones, and the manufacture and supply of ensifentrine drug product, were not included in the transaction price as we determined that it is not probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Commercial milestones and sales royalties were also excluded and will be recognized when the milestones are achieved or the sales occur in Greater China.

The performance obligations in the Nuance Agreement include the grant of the license (including the right to commercialize ensifentrine until the end of the term, the sharing of certain know how, and the sharing of certain clinical and regulatory data), and manufacture and supply of ensifentrine drug product. We have determined that the manufacturing and supply was not at a discount.

We have determined that the license and the know how shared with Nuance Pharma constitutes functional intellectual property and that revenue relating to this should be recognized at a point in time. Consequently, we have determined that we fulfilled our obligations to Nuance Pharma when we delivered the know how that will allow Nuance Pharma to file an investigational new drug application in Greater China. We delivered this know-how in the year ended December 31, 2021, and the $40.0 million revenue was therefore recognized as revenue in the year ended December 31, 2021. Revenue relating to the manufacture and supply obligations will be recognized when the drug product is delivered.

For additional information regarding the Nuance Agreement, see Note 6 to our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Warrants

On July 29, 2016, as part of a private placement we issued warrants to investors. The warrant holders could subscribe for an ordinary share at a per share exercise price of £1.7238. They could also opt for a cashless exercise of their warrants whereby they could 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 were able to demand a cash payment instead of the delivery of the underlying securities. Accordingly, they were 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 were exercisable by the holders until May 2, 2022. None of the warrants were exercised prior to their expiration.

Loan and security agreement

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 “SVB Term Loan”). Subsequent to the quarter end, on October 14, 2022, we and Verona Pharma, Inc. entered into a term loan (the “Oxford Term Loan”) of up to $150.0 million with Oxford Finance Luxembourg

S.À R.L. (“Oxford”). This Oxford Term Loan replaced the existing term loan with Silicon Valley Bank. See “Indebtedness” for additional information.

Critical accounting estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. (“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 consolidated financial statements include, but are not limited to, the recognition of revenue, the accrual and prepayment of research and development expenses, the fair value of share-based compensation, the carrying value of the equity interest in Nuance Pharma, research and development tax credit 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 2021 Form 10-K. There have been no material changes to that information disclosed in our 2021 Form 10-K during the nine months ended September 30, 2022.

Components of results of operations

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

- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to potentially commercialize any products for which we may obtain regulatory approval;
- 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 or combinations with 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; 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.

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, the fair value movement of the warrant liability until they expired on May 2, 2022, 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 2021 financial year are expected to be received in the fourth quarter of 2022.

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 September 30, 2022 and 2021

The following table shows our statements of operations for the three months ended September 30, 2022 and 2021, (in thousands):

	Three months ended September 30,		
	2022	2021	Change
Revenue	$ —	$ 40,000	$ (40,000)
Gross profit	—	40,000	(40,000)
Operating expenses			
Research and development	9,838	22,560	(12,722)
Selling, general and administrative	5,290	10,883	(5,593)
Total operating expenses	15,128	33,443	(18,315)
Operating (loss)/profit	(15,128)	6,557	(21,685)
Other (expense)/income			
Research and development tax credit	2,127	4,749	(2,622)
Interest income	779	4	775
Interest expense	(116)	(86)	(30)
Fair value movement on warrants	—	40	(40)
Foreign exchange loss	(3,245)	(86)	(3,159)
Total other (expense)/income, net	(455)	4,621	(5,076)
(Loss)/profit before income taxes	(15,583)	11,178	(26,761)
Income tax expense	(64)	(127)	63
Net (loss)/profit	$ (15,647)	$ 11,051	$ (26,698)

Revenue

Revenue of $40.0 million for the three months ended September 30, 2021 is related to upfront consideration received under the Nuance Agreement. There was no revenue for the three months ended September 30, 2022.

Research and development costs

Research and development costs were $9.8 million for the three months ended September 30, 2022, compared to $22.6 million for the three months ended September 30, 2021, a decrease of $12.8 million. This decrease was primarily due to a $12.5 million decrease in clinical trial and other development costs, as we progressed to later stages of our Phase 3 ENHANCE program and a $0.6 million decrease in share-based compensation.

Selling, general and administrative costs

Selling, general and administrative costs were $5.3 million for the three months ended September 30, 2022, compared to $10.9 million for the three months ended September 30, 2021, a decrease of $5.6 million, primarily due to a $4.0 million broker fee relating to the Nuance Agreement in 2021 and a $1.6 million decrease in share-based compensation.

Other (expense)/income

The research and development tax credit for the three months ended September 30, 2022 was $2.1 million compared to $4.7 million for the three months ended September 30, 2021, a decrease of $2.6 million. This decrease was primarily due to a reduction in clinical trial and other development costs, as we progressed to later stages of our Phase 3 ENHANCE program.

Foreign exchange loss for the three months ended September 30, 2022 was $3.2 million compared to $0.1 million for the three months ended September 30, 2021, an increase of $3.1 million. This loss was primarily due to a fall in the value of the British pound against the U.S. dollar affecting pound sterling bank balances and the R&D tax credit receivable.

Net loss

Net loss was $15.6 million for the three months ended September 30, 2022, compared to a net profit of $11.1 million for the three months ended September 30, 2021, because of the factors outlined above.

Results of operations for the nine months ended September 30, 2022 and 2021

The following table shows our statements of operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine months ended September 30,		
	2022	2021	Change
Revenue	$ —	$ 40,000	$ (40,000)
Gross profit	—	40,000	(40,000)
Operating expenses			
Research and development	$ 42,445	$ 56,697	$ (14,252)
Selling, general and administrative	18,256	28,150	(9,894)
Total operating expenses	60,701	84,847	(24,146)
Operating loss	(60,701)	(44,847)	(15,854)
Other (expense)/income			
Research and development tax credit	8,838	10,655	(1,817)
Interest income	959	11	948
Interest expense	(291)	(255)	(36)
Fair value movement on warrants	—	2,244	(2,244)
Foreign exchange (loss)/gain	(6,830)	117	(6,947)
Total other income, net	2,676	12,772	(10,096)
Loss before income taxes	(58,025)	(32,075)	(25,950)
Income tax expense	(225)	(232)	7
Net loss	$ (58,250)	$ (32,307)	$ (25,943)

Revenue

Revenue of $40.0 million for the nine months ended September 30, 2021 is related to upfront consideration received under the Nuance Agreement. There was no revenue for the nine months ended September 30, 2022.

Research and development costs

Research and development costs were $42.4 million for the nine months ended September 30, 2022, compared to $56.7 million for the nine months ended September 30, 2021, a decrease of $14.3 million. This decrease was primarily due to a $11.1 million decrease in clinical trial and other development costs and a $4.3 million decrease in share-based compensation charges partially offset by a $1.1 million increase in consultant costs mainly relating to an increase in clinical trial site audit and NDA filing preparation costs.

Selling, general and administrative costs

Selling, general and administrative costs were $18.3 million for the nine months ended September 30, 2022 compared to $28.2 million for the nine months ended September 30, 2021, a decrease of $9.9 million. This decrease was driven primarily by a $7.3 million decrease in share-based compensation charges and a $2.0 million decrease due to a $4.0 million broker fee relating to the Nuance Agreement in 2021 offset by a $2.0 million charge related to the modification of the Ligand Agreement in 2022.

Other income/(expense)

The research and development tax credit for the nine months ended September 30, 2022 was $8.8 million compared to $10.7 million for the nine months ended September 30, 2021, a decrease of $1.9 million. This decrease is attributable to lower qualifying research and development expenditures in the nine months ended September 30, 2022, compared to the comparative 2021 period.

We recorded no income in the nine months ended September 30, 2022, compared to an income of $2.2 million in the comparative period relating to the fair value movements of the warrants. In the nine months ended September 30, 2021, there was a reduction in liability due to a decrease in the share price in that period and reduced volatility.

Foreign exchange loss for the nine months ended September 30, 2022 was $6.8 million compared to a gain of $0.1 million gain for the nine months ended September 30, 2021, an increase of $6.9 million. This loss was primarily due to a fall in the value of the British pound against the U.S. dollar affecting pound sterling bank balances and the R&D tax credit receivable.

Net loss

Net loss was $58.3 million for the nine months ended September 30, 2022, compared to $32.3 million for the nine months ended September 30, 2021, because of the factors outlined above.

Cash flows

The following table summarizes our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine months ended September 30,		
	2022	2021	Change
Cash and cash equivalents at beginning of the period	$ 148,380	$ 187,986	$ (39,606)
Net cash used in operating activities	(52,124)	(15,931)	(36,193)
Net cash used in investing activities	(29)	(11)	(18)
Net cash provided by/(used in) financing activities	138,204	(5,216)	143,420
Effect of exchange rate changes on cash and cash equivalents	(2,730)	(281)	(2,449)
Cash and cash equivalents at end of the period	$ 231,701	$ 166,547	$ 65,154

Operating activities

Net cash used in operating activities was $52.1 million in the nine months ended September 30, 2022, compared to $15.9 million during the nine months ended September 30, 2021, an increase of $36.2 million. In 2021, as part of the Nuance Agreement, we received $25.0 million cash. In 2022, clinical trial and other development costs decreased as we progressed to later stages of our Phase 3 ENHANCE program.

Financing activities

Net cash provided by financing activities was $138.2 million in the nine months ended September 30, 2022, compared to $5.2 million net cash used in the nine months ended September 30, 2021. This increase in net cash received is driven primarily by the net proceeds from the August 2022 follow-on equity offering.

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. See "Significant Agreements" and "Indebtedness" for additional information.

We have incurred recurring losses since inception, including net losses of $58.3 million for the nine months ended September 30, 2022, and $55.6 million for the year ended December 31, 2021. As of September 30, 2022, we had an accumulated deficit of $322.4 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 Oxford. See "Indebtedness" for details on the Term Loan.

August 2022 follow-on equity offering

On August 15, 2022, we completed an upsized public offering of 14,260,000 ADSs, each representing eight of our ordinary shares, nominal value £0.05 per share, at a price to the public of $10.50 per ADS, which includes the exercise in full by the underwriters of their option to purchase an additional 1,860,000 ADSs. The aggregate net proceeds from the offering were approximately $140.1 million after deducting underwriting discounts and offering expenses.

Open market sale agreement

In March 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").

During the nine months ended September 30, 2022, we sold 80,696 ordinary shares (equivalent to 10,087 ADSs) under the ATM Program, at an average price of approximately $0.86 per share (equivalent to $6.86 per ADS), raising aggregate net proceeds of approximately $0.1 million after deducting issuance costs. As of September 30, 2022, $99.2 million of ordinary shares, in the form of ADSs, remained available for sale 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, which we refer to as 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 $15.0 million contingent upon achievement of a specific clinical development milestone and other specified conditions. As of September 30, 2022, we 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 2021 Form 10-K. There have been no material changes to that information disclosed in our 2021 Form 10-K during the nine months ended September 30, 2022.

Subsequent to the quarter end, on October 14, 2022 (the "Effective Date"), we and Verona Pharma, Inc. ("Verona U.S." and together with us, the "Borrowers") entered into the Debt Facility 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 to be 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, which are available as described below and subject to terms of the loan and security agreement ("Loan Agreement"). The proceeds from the Oxford Term Loan will be used for general corporate and working capital purposes, and a portion of the proceeds of the Oxford Term A Loan are being used to repay in full the existing outstanding indebtedness owed to SVB as discussed in Note 5 – Term Loan. The Oxford Term Loan has a maturity date of October 1, 2027.

The four additional term loan advances under the Oxford Term Loan consists of a $10.0 million term loan advance (the "Oxford Term B Loan") which is available at the option of Company from the Effective Date up to and including March 31, 2023; a $20.0 million term loan advance (the "Oxford Term C Loan") available during the period commencing on the later of January 1, 2024 and the date on which we receive positive ENHANCE-1 data in

the Phase 3 clinical trial for ensifentrine sufficient to support the submission of a New Drug Application ("NDA") with the United States Food and Drug Administration (the "FDA") for ensifentrine through and including March 29, 2024; a $60.0 million term loan advance (the "Oxford Term D Loan") available during the period commencing on the later of October 1, 2024 and the date on which we receive final approval from the FDA for our NDA for ensifentrine up to and including December 31, 2024; and a $50.0 million term loan advance (the "Oxford Term E Loan") available during the interest-only period at our request and at Oxford's sole discretion.

Each advance under the Oxford Term Loan accrues interest at a floating per annum rate equal to (a) the greater of (i) the 1-Month CME Term SOFR reference rate on the last business 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"). In no event shall the Basic Rate (x) for the Term A Loan be less than 7.88% and (y) for each other term loan be less than the Basic Rate on the business day immediately prior to the funding date of such term loan. The Basic Rate for the Term A Loan for the period from the Effective Date through and including October 31, 2022 shall be 8.54205% and the Basic Rate for each Term Loan shall not increase by more than 2.00% above the applicable Basic Rate as of the funding date of each such term loan. The Oxford Term Loan provides for interest-only payments on a monthly basis until the payment date immediately preceding December 1, 2025, if the Term D Loan is not made, and December 1, 2026, if the Term D Loan is made. Thereafter, amortization payments will be payable monthly in equal installments of principal plus accrued interest.

Upon repayment, whether at maturity, upon acceleration or by prepayment or otherwise, we shall make a final payment to the lenders in an amount ranging from 1.30% to 3.00% of the aggregate principal balance, depending on the advances received under the Oxford Term Loan. We may prepay the Oxford Term Loan in full, or in part, in accordance with the terms of the Loan Agreement, which is subject to a prepayment fee of up to 2.00%, depending on the timing of the prepayment.

The Oxford Term Loan is secured by a lien on substantially all our assets, other than intellectual property, but including any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. We have also granted Oxford a negative pledge with respect to our intellectual property. The Loan Agreement contains customary covenants and representations, including but not limited to financial reporting obligations and limitations on dividends, dispositions, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, transactions with affiliates and subsidiaries. The Loan Agreement also contains other customary provisions, such as expense reimbursement, non- disclosure obligations as well as indemnification rights for the benefit of Oxford.

Funding requirements

We believe that our cash and cash equivalents as of September 30, 2022, 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.

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 for several years, if ever. Accordingly, we may need to obtain substantial additional funds to achieve our business objectives.

Recent accounting pronouncements

For a discussion of pending and recently adopted accounting pronouncements, see Note 2 to our consolidated financial statements included in the 2021 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 September 30, 2022, 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 September 30, 2022 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 disclosed below, our risk factors have not changed materially from those described in Part I, Item 1A of the 2021 Form 10-K under the heading "Risk Factors".

The terms of our credit facility place restrictions on our operating and financial flexibility, and our existing and any future indebtedness could adversely affect our ability to operate our business.

In October 2022, we and Verona Pharma, Inc. ("Verona U.S.") entered into a loan and security agreement (the "Loan Agreement"), with Oxford Finance Luxembourg S.À R.L. ("Oxford"), pursuant to which a term loan facility in an aggregate amount of up to $150.0 million (the "Term Loan") is available to us in five tranches. We received the first tranche of $10.0 million (the "Term A Loan") at closing. Each advance under the Term Loan accrues interest at a floating per annum rate equal to (a) the greater of (i) the 1-Month CME Term SOFR reference rate on the last business 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"); provided, however, that in no event shall the Basic Rate (x) for the Term A Loan be less than 7.88% and (y) for each other advance be less than the Basic Rate on the business day immediately prior to the funding date of such advance.

Our outstanding indebtedness, including any additional indebtedness beyond our borrowings from Oxford, combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product candidate development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our then existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under the Loan Agreement or any other debt instruments. Failure to make payments or comply with other covenants under the Loan Agreement or such other debt instruments could result in an event of default and acceleration of amounts due. For example, the affirmative covenants under our Loan Agreement include, among others, covenants requiring us (and us to cause our subsidiaries) to maintain our legal existence and governmental approvals, deliver certain financial reports and notifications, maintain proper books of record and account, timely file and pay tax returns, and maintain inventory and insurance coverage. Under the Loan Agreement, the occurrence of a material adverse change in our business, operations, or condition is an event of default. If an event of default occurs and Oxford accelerates the amounts due, we may not be able to make accelerated payments and Oxford could seek to enforce security interests in the collateral securing such indebtedness, which could potentially require us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of holders of our American Depositary Shares ("ADS") or of our shareholders to receive any proceeds from the liquidation. Any declaration by Oxford of an event of default could significantly harm our business and prospects and could cause the price of our ADSs to decline. In addition, the covenants under the Loan Agreement, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing. If we raise

any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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	Loan and Security Agreement, dated as of October 14, 2022, by and among Verona Pharma plc, Verona Pharma, Inc., Oxford Finance Luxembourg S.A R.L.	8-K	001-38067	10.1	10/17/2022	
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: November 9, 2022 By: /s/ David Zaccardelli

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

Date: November 9, 2022 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: November 9, 2022 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: November 9, 2022 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 September 30, 2022 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: November 9, 2022

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 September 30, 2022 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: November 9, 2022 By: /s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (*principal financial officer)*