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, 2021

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number: 001-38067

Verona Pharma plc

(Exact name of Registrant as specified in its Charter)

United Kingdom	**98-1489389**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3 More London Riverside London SE1 2RE United Kingdom	**Not Applicable**
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value £0.05 per share*	VRNA	The Nasdaq Stock Market LLC (Nasdaq Global Market)

* The ordinary shares are represented by American Depositary Shares (each representing 8 ordinary shares), which are exempt from the operation of Section 12(a) of the Securities Exchange Act of 1934, as amended, pursuant to Rule 12a-8 thereunder.

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

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

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

Large accelerated filer	☐	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 8, 2021, the registrant had 480,082,966 ordinary shares, nominal value £0.05 per share, outstanding, which if all held in ADS form, would be represented by 60,010,371 American Depositary Shares, each representing eight (8) ordinary shares.

PART I - FINANCIAL INFORMATION

Item 1. Financial statements

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 166,547	$ 187,986
Prepaid expenses	6,672	4,538
Tax and tax incentive receivable	10,606	8,260
Other current assets	667	1,720
Total current assets	184,492	202,504
Non-current assets:		
Furniture and equipment, net	88	107
Goodwill	545	545
Equity interest	15,000	—
Right-of-use assets	1,435	1,050
Total non-current assets	17,068	1,702
Total assets	$ 201,560	$ 204,206
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9	$ 178
Accrued expenses	26,457	10,863
Operating lease liability	690	798
Warrants	2	2,246
Taxes payable	397	—
Other current liabilities	185	118
Total current liabilities	27,740	14,203
Non-current liabilities:		
Term loan	4,821	4,635
Operating lease liability	797	514
Total non-current liabilities	5,618	5,149
Total liabilities	33,358	19,352
Commitments and contingencies		
Shareholders' equity:		
Ordinary £0.05 par value shares; 489,177,550 and 488,304,446 issued, and 477,649,646 and 463,304,446 outstanding, at September 30, 2021 and December 31, 2020, respectively	31,855	31,794
Additional paid-in capital	382,005	366,411
Ordinary shares held in treasury	(770)	(1,700)
Accumulated other comprehensive loss	(4,601)	(4,601)
Accumulated deficit	(240,287)	(207,050)
Total shareholders' equity	168,202	184,854
Total liabilities and shareholders' equity	$ 201,560	$ 204,206

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenue	$ 40,000	$ —	$ 40,000	$ —
Operating expenses				
Research and development	22,560	12,820	56,697	28,259
Selling, general and administrative	10,883	8,284	28,150	18,318
Total operating expenses	33,443	21,104	84,847	46,577
Operating profit/(loss)	6,557	(21,104)	(44,847)	(46,577)
Other income/(expense)				
Research and development tax credit	4,749	2,338	10,655	5,809
Interest income	4	13	11	116
Interest expense	(86)	—	(255)	—
Fair value movement on warrants	40	(978)	2,244	(747)
Foreign exchange (loss)/gain	(86)	844	117	1,188
Total other income, net	4,621	2,217	12,772	6,366
Profit/(loss) before income taxes	11,178	(18,887)	(32,075)	(40,211)
Income tax expense	(127)	(44)	(232)	(110)
Net profit/(loss)	11,051	(18,931)	(32,307)	(40,321)
Other comprehensive profit/(loss):				
Foreign currency translation adjustments	—	—	—	(2,321)
Total comprehensive profit/(loss) attributable to shareholders of the Company	$ 11,051	$ (18,931)	$ (32,307)	$ (42,642)
Profit/(loss) per ordinary share - basic	$ 0.02	$ (0.05)	$ (0.07)	$ (0.20)
Profit/(loss) per ordinary share - diluted	$ 0.02	$ (0.05)	$ (0.07)	$ (0.20)
Weighted-average shares outstanding - basic	475,334,354	344,809,792	471,159,171	197,049,240
Weighted-average shares outstanding - diluted	515,819,439	344,809,792	471,159,171	197,049,240

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

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

	Ordinary shares		Additional paid-in capital	Ordinary shares held in treasury	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity
	Number	Amount					
Balance at January 1, 2021	488,304,446	$ 31,794	$ 366,411	$ (1,700)	$ (4,601)	$ (207,050)	$ 184,854
Net loss	—	—	—	—	—	(21,290)	(21,290)
Share-based compensation	—	—	8,850	—	—	—	8,850
Restricted share units vested	—	—	—	30	—	(30)	—
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)
Share-based compensation	—	—	7,450	—	—	—	7,450
Restricted share units vested	—	—	—	827	—	(827)	—
Common shares withheld for taxes on vested stock awards	—	—	(3,782)	—	—	—	(3,782)
Issuance of common shares under at-the-market sales agreement	434,704	30	353	—	—	—	383
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
Share-based compensation	—	—	4,938	—	—	—	4,938
Restricted share units vested	—	—	—	73	—	(73)	—
Common shares withheld for taxes on vested stock awards	—	—	(2,167)	—	—	—	(2,167)
Issuance of common shares under at-the-market sales agreement	438,400	31	319	—	—	—	350
Equity settled share-based compensation reclassified as cash-settled	—	—	(367)	—	—	—	(367)
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 Shareholders' Equity
(unaudited)
(in thousands except share data)

	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity
	Number	Amount				
Balance at January 1, 2020	105,326,638	$ 7,265	$ 179,535	$ (2,280)	$ (141,779)	$ 42,741
Net loss	—	—	—	—	(12,346)	(12,346)
Retranslation of foreign operations	—	—	—	(2,157)	—	(2,157)
Share-based compensation	—	—	1,867	—	—	1,867
Issuance of ordinary shares from restricted share units	887,080	52	—	—	—	52
Balance at March 31, 2020	106,213,718	$ 7,317	$ 181,402	$ (4,437)	$ (154,125)	$ 30,157
Net loss	—	—	—	—	(9,044)	(9,044)
Retranslation of foreign operations	—	—	—	(164)	—	(164)
Share-based compensation	—	—	950	—	—	950
Issuance of ordinary shares from restricted share units	267,288	16	—	—	(68)	(52)
Balance at June 30, 2020	106,481,006	$ 7,333	$ 182,352	$ (4,601)	$ (163,237)	$ 21,847
Net loss	—	—	—	—	(18,931)	(18,931)
Share-based compensation	—	—	6,486	—	—	6,486
Issuance of ordinary shares from restricted share units	322,296	21	—	—	(21)	—
Issuance of ordinary shares, net of issuance costs	355,831,184	22,700	164,660	—	—	187,360
Balance at September 30, 2020	462,634,486	$ 30,054	$ 353,498	$ (4,601)	$ (182,189)	$ 196,762

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,	
	2021	**2020**
Operating activities:		
Net loss:	$ (32,307)	$ (40,321)
Adjustments to reconcile net income to net cash used in operating activities:		
Foreign exchange loss/(gain)	556	(1,282)
Amortization of debt issue costs	92	—
Accretion of redemption premium on debt	94	—
Fair value movement on warrants	(2,244)	747
Impairment of right-of-use asset	—	289
Share-based compensation	21,238	9,303
Depreciation and amortization	467	472
Equity interest	(15,000)	—
Changes in operating assets and liabilities:		
Prepaid expenses	(2,134)	(2,444)
Tax incentive receivable	(2,677)	3,336
Other current assets	1,053	1,151
Right-of-use asset	(823)	—
Accounts payable	(169)	(983)
Accrued expenses	15,595	3,916
Lease liabilities	177	(461)
Taxes payable	451	—
Other current liabilities	(300)	(4)
Net cash used in operating activities	(15,931)	(26,281)
Cash flows from investing activities:		
Purchases of furniture and equipment	(11)	(73)
Sale of short-term investments	—	9,792
Net cash (used in)/provided by investing activities	(11)	9,719
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares	—	200,156
Payment of offering costs in connection with the issuance of ordinary shares	—	(11,763)
Payments of withholding taxes from share-based awards	(5,949)	—
Proceeds from at-the-market sales agreement	733	—
Net cash (used in)/provided by financing activities	(5,216)	188,393
Effect of exchange rate changes on cash and cash equivalents	(281)	(291)
Net change in cash and cash equivalents	(21,439)	171,540
Cash and cash equivalents at beginning of the period	187,986	30,428
Cash and cash equivalents at end of the period	$ 166,547	$ 201,968
Supplemental disclosure of cash flow information:		
Income taxes paid	$ —	$ —
Interest paid	$ 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 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 $240.3 million as of September 30, 2021. The Company expects to incur additional losses and negative cash flows from operations until its products potentially gain regulatory approval and reach commercial profitability, if at all.

The Company expects that its cash and cash equivalents as of September 30, 2021, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance.

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, 2021, the Company sold 873,104 ordinary shares (equivalent to 109,138 ADSs) under the ATM Program, at an average price of approximately $0.86 per share (equivalent to $6.91 per ADS), raising aggregate net proceeds of approximately $0.7 million after deducting issuance costs. As of September 30, 2021, there remained $99.2 million of ordinary shares, in the form of ADSs, available for sale under the ATM Program.

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 February 25, 2021 (the "2020 Form 10-K"). The Consolidated Balance Sheet as of December 31, 2020, was derived from audited consolidated financial statements included in the 2020 Form 10-K but does not include all disclosures required by U.S. GAAP for complete financial statements. The Company's significant accounting policies are described in Note 2 to those consolidated financial statements. In addition, the Company's policies on revenue recognition, contract assets, trade receivables and the equity interest are set out below.

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.

Revenue recognition

The Company's deferred revenue and revenue arise from the Company's agreement for the development and commercialization of ensifentrine in Greater China (the "Nuance Agreement"). The terms of the Nuance Agreement include non-refundable upfront fees, payments based upon achievement of developmental and regulatory milestones, commercial milestones, royalties payable on sales, and manufacturing and supply. These payments are viewed as both fixed and variable consideration. Non-refundable upfront fees are considered fixed, while milestone payments and revenue from the commercialized product are identified as variable consideration. The Company follows the five-step model in ASC 606 "Revenue from Contracts with Customers":

Step 1: Identify the contract(s) with a customer.

Step 2: Identify the performance obligations in the contract.

Step 3: Determine the transaction price.

Step 4: Allocate the transaction price to the performance obligations in the contract.

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

All of the Company's revenue is derived from contracts with customers.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. The Company's performance obligations include intellectual property rights, (which include the license, patents and developmental and regulatory data) and manufacturing and supply. Management are required to judge when performance obligations are satisfied and consequently when revenue is recognized.

If the right to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the right when the right is transferred to the customer, and the customer can use and benefit from the right.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the

Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later

of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

Contract assets

The Company recognizes incremental costs of obtaining a contract such as commission costs as an asset and amortizes the asset on a basis that is consistent with the satisfaction of the performance obligations to which the asset relates. Consideration receivable that is in excess of the value of satisfied, or part satisfied, performance obligations is recognized as a deferred revenue liability.

Trade receivables

Accounts receivable relate to amounts billed to customers. Management determine the likelihood of uncollectible accounts and provide for this accordingly.

Equity interest

As of June 30, 2021, as part of the Nuance Agreement, the Company recorded a $15 million equity receivable, relating to an equity interest in Nuance Biotech, the parent company of Nuance Pharma (see note 8). This equity interest was received in the three months ended September 30, 2021. As Nuance Biotech is not publicly listed the equity interest's fair value is not readily determinable. The Company therefore 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.

Segment reporting

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 initial recognition of the value of the equity interest and the fair value of warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from the Company's estimates.

Recently adopted accounting standards and recent accounting standards not yet adopted

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

Note 3 - Prepaid expenses

Prepaid expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Clinical trial and other development costs	$ 3,568	$ 2,551
Insurance	2,713	1,701
Other	391	286
Total prepaid expenses	$ 6,672	$ 4,538

Note 4 - Tax and tax incentive receivables

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

	September 30, 2021	December 31, 2020
Research and development tax credit receivable - U.K.	$ 10,606	$ 8,202
Tax receivable - U.S.	—	58
Total tax receivable	$ 10,606	$ 8,260

Note 5 - Accrued expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Clinical trial and other development costs	$ 24,063	$ 8,607
Professional fees and general corporate costs	995	2,149
People related costs	1,399	107
Total accrued expenses	$ 26,457	$ 10,863

Note 6 - Warrants

In the periods ended September 30, 2021, and December 31, 2020, no warrants were exercised or forfeited. The warrants had no intrinsic value as of September 30, 2021.

There have been no changes in valuation techniques or transfers between fair value measurement levels during the period ended September 30, 2021. They are measured at fair value and included at level 3 in the fair value hierarchy. The warrants are valued using the Black-Scholes model and the table below presents the assumptions used:

	September 30, 2021	December 31, 2020
Shares potentially issued under warrants	12,401,262	12,401,262
Exercise price in pounds sterling	£ 1.7238	£ 1.7238
Risk-free interest rate	0.07 %	— %
Expected term to exercise	0.6	1.3
Annualized volatility	51.6 %	105.4 %
Dividend rate	— %	— %
Calculated value of the warrants, in thousands of U.S. dollars	$ 2	$ 2,246

For the amount recognized at September 30, 2021, the effect when the following parameter deviates up or down is presented in the below table (in thousands):

10% volatility increase	$ 11
Base case, reported fair value	2
10% volatility decrease	$ —

Note 7 - Term loan

In November 2020, the Company entered into a term loan facility of up to $30.0 million (the “Term Loan”), consisting of advances of $5.0 million funded at closing and $10.0 million and $15.0 million contingent upon achievement of certain clinical development milestones and other specified conditions. As of September 30, 2021, the Company had $5.0 million principal outstanding under the Term Loan.

As of September 30, 2021, the carrying value of the Term Loan was approximately $4.8 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.

Note 8 - 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 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.

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 the 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, 2021, 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 three months ended September 30, 2021, and the $40.0 million revenue was therefore recognized as revenue in this period. Revenue relating to the manufacture and supply obligations will be recognized when the drug product is delivered.

The Company has reviewed the two performance obligations in the Nuance Agreement and has determined that these are priced at fair value.

On the Effective Date, $4.0 million of costs of obtaining the contract were recorded as a contract asset. As of September 30, 2021, the entire cost had been recognized in the Condensed Consolidated Statement of Operations.

Subsequent to the Effective Date, Ligand notified the Company that it believes that Nuance Pharma is a sub-licensee under the Ligand Agreement and that the Company is therefore under an obligation to make a sublicense payment to Ligand equal to 25% of the $40.0 million upfront transaction price. The Company does not believe it has granted a sublicense of or otherwise transferred to Nuance any Ligand intellectual property or know how and therefore the Company believes that it is not under any obligation to pay the requested sum to Ligand.

Note 9 - 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,	
	2021	2020	2021	2020
Research and development	$ 1,466	$ 2,747	$ 8,132	$ 3,738
Selling, general and administrative	3,472	3,739	13,106	5,565
Total	$ 4,938	$ 6,486	$ 21,238	$ 9,303

Share options

The following table shows share option activity in the period:

	2021	
	Number of share options outstanding	Weighted average exercise price
Outstanding at January 1	13,125,672	$ 1.41
Forfeited	(996,720)	1.17
Outstanding at March 31	12,128,952	$ 1.43
Granted	800,000	0.73
Outstanding at June 30	12,928,952	$ 1.38
Granted	576,000	0.78
Forfeited	(638,112)	0.75
Outstanding at September 30	12,866,840	$ 1.39

Restricted stock units activity

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

	2021	
	Number of RSUs outstanding	Weighted average remaining contractual term (years)
Outstanding at January 1	61,992,360	1.5
Granted	750,928	
Vested	(441,304)	
Outstanding at March 31	62,301,984	1.3
Vested	(11,920,928)	
Outstanding at June 30	50,381,056	1.3
Forfeited	(1,572,176)	
Vested	(8,452,520)	
Outstanding at September 30	40,356,360	1.3

Note 10 - Net profit/(loss) per share

Net profit/(loss) per share is calculated on an ordinary share basis. The Company's ADSs that are listed on the Nasdaq Global Market each represent eight ordinary shares. The following table shows the computation of basic and diluted earnings per share for the periods ended September 30, 2021 and 2020 (net profit/(loss) in thousands, profit/(loss) per share in dollars):

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net profit/(loss)	$ 11,051	$ (18,931)	$ (32,307)	$ (40,321)
Denominator:				
Weighted-average shares outstanding - basic	475,334,354	344,809,792	471,159,171	197,049,240
Net profit/(loss) per share - basic	$ 0.02	$ (0.05)	$ (0.07)	$ (0.20)
Weighted-average shares outstanding - diluted	515,819,439	344,809,792	471,159,171	197,049,240
Net profit/(loss) per share - diluted	$ 0.02	$ (0.05)	$ (0.07)	$ (0.20)

During the three months ended September 30, 2021 and 2020, outstanding share options, RSUs and warrants over 25,139,377 and 88,402,414 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, 2021 and 2020, outstanding share options, RSUs and warrants over 65,624,462 and 88,402,414 ordinary shares, respectively, were not included in the computation of diluted earnings per ordinary share, because to do so would be antidilutive.

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

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

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

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

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

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

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical need. Our product candidate, ensifentrine, is an investigational, potential first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4, or PDE3 and PDE4, 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 and, if approved, we intend to commercialize ensifentrine for the maintenance treatment of chronic obstructive pulmonary disease ("COPD") for the nebulized formulation in the United States.

We have incurred recurring losses and negative cash flows from operations since inception, and have an accumulated deficit of $240.3 million as of September 30, 2021. We expect to incur additional losses and negative cash flows from operations until our product candidates potentially gain regulatory approval and reach commercial profitability, if at all.

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

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

We believe that our cash and cash equivalents as of September 30, 2021, expected cash receipts from U.K. tax credits and funding expected to become available under the $30.0 million debt financing facility secured in November 2020, will enable us to fund our planned operating expenses and capital expenditure requirements through at least the end of 2023. The Term Loan advances are contingent upon achievement of certain clinical development milestones and other specified conditions. See "Indebtedness" for additional information.

Clinical development update

During the third quarter of 2021, we continued to make substantial progress on patient recruitment in our Phase 3 ENHANCE clinical program. Patient enrollment is nearing completion and, by the end of November, we expect both the 800 patient ENHANCE-2 trial and the 400 patient 48-week subset of the ENHANCE-1 trial will be approximately 95% enrolled. Although the pace of enrollment is expected to slow due to the approaching holiday season and the continued effects of the COVID-19 pandemic, we still expect to complete enrollment in ENHANCE-2 and the 48-week subset of ENHANCE-1 around year-end 2021.

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

The 48-week subset of ENHANCE-1 is a critical driver of delivering top-line data. As of November 8, 2021, this subset had approximately 95% of patients randomized into the study. Enrollment in the full ENHANCE-1 trial is expected to complete in the second quarter of 2022.

Based on our current models of forecasted recruitment and study progress, we expect to report top-line data for ENHANCE-2 mid-year 2022 and for ENHANCE-1 around the end of 2022. Should COVID-19 related challenges increase further, our models predict top-line data for ENHANCE-2 would be expected in the third quarter of 2022 and for ENHANCE-1 in the first quarter of 2023. With the COVID-19 pandemic and government and other measures continuing to impact a number of clinical trial activities, including contractor staffing issues and disruptions to supply chains globally, we continue to closely monitor these timelines.

In September, 2021, we presented an abstract describing the results of a Phase 1 study assessing the effect of CYP2C9 inhibitor, fluconazole, on the pharmacokinetics of ensifentrine in healthy individuals at the European Respiratory Society International Congress (“ERS”) 2021. Ensifentrine is primarily metabolized via the hepatic route by the cytochrome P450 enzyme, CYP2C9. Results from the study demonstrated co-administration of fluconazole had a less than 2-fold, not clinically relevant, effect on pharmacokinetic measures of the maximum concentration and area under the curve for ensifentrine.

In December 2021, we expect to report results from a 32-patient thorough QT study to evaluate the effect of ensifentrine on measures of cardiac conduction, which we are carrying out in support of a potential NDA submission.

Management update

In mid-November, Caroline Diaz will join Verona Pharma as Senior Vice President of Regulatory Affairs, bringing more than 18 years of experience in both large and small pharmaceutical companies across key regions. Ms. Diaz has served at ReViral as Vice President, Regulatory Affairs, and, previously, as Vice President, Regulatory and Quality at Dova Pharmaceuticals where she built the regulatory function from the ground up and led regulatory strategy development and implementation efforts resulting in the first marketing approvals for the company.

COVID-19 impact

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

To help protect the health and safety of the patients, caregivers and healthcare professionals involved in our clinical trials, as well as our employees and independent contractors, we continue to follow guidance from the FDA and other health regulatory authorities regarding the conduct of clinical trials during the COVID-19 pandemic to ensure the safety of study participants, minimize risks to study integrity, and maintain compliance with good clinical practice.

The COVID-19 pandemic is disrupting supply chains, and employee retention and recruitment, globally and we are closely monitoring this situation and will provide an update if we become aware of any meaningful disruption caused by the pandemic to the supply of ensifentrine and drug-related products, equipment and services for our clinical trials.

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 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.

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 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 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 the Condensed Consolidated Balance Sheet, included elsewhere in this Quarterly Report on Form 10-Q. 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, subject to impairment. As of September 30, 2021, 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 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 three months ended September 30, 2021, and the $40.0 million revenue was therefore recognized as revenue in this period. Revenue relating to the manufacture and supply obligations will be recognized when the drug product is delivered.

We reviewed the two performance obligations in the Nuance Agreement and have determined that these were priced at fair value.

On the Effective Date, $4.0 million of costs of obtaining the contract were recorded as a contract asset. As of September 30, 2021, the entire cost had been recognized in the Condensed Statement of Operations, in line with recognition of the revenue relating to the contract.

Subsequent to the Effective Date, Ligand notified us that it believes that Nuance Pharma is a sub-licensee under the Ligand Agreement and that we are therefore under an obligation to make a sublicense payment to Ligand equal to 25% of the $40.0 million upfront transaction price. We do not believe we have granted a sublicense of or otherwise transferred to Nuance Pharma any Ligand intellectual property or know how and therefore we believe that we are not under any obligation to pay the requested sum to Ligand.

For additional information regarding the Nuance Agreement, see Note 8 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 can subscribe for an ordinary share at a per share exercise price of £1.7238. They can also opt for a cashless exercise of their warrants whereby they can choose to exchange the warrants held for a reduced number of warrants exercisable at nil consideration.

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

Loan and security agreement

In November 2020 we and Verona Pharma Inc. entered into a term loan facility of up to $30.0 million with Silicon Valley Bank (the “Term Loan”). See “Indebtedness” for additional information.

Critical accounting policies and significant judgments and estimates

The preparation of consolidated financial statements in conformity with 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 value of the equity interest and the fair value of warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from our estimates. The accounting policies considered to be critical to the judgments and estimates used in the preparation of our financial statements are disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operations included in our 2020 Form 10-K. Except as described below there have been no material changes to that information disclosed in our 2020 Form 10-K during the nine months ended September 30, 2021.

Critically, management are required to identify the promises in the Nuance Agreement, determine whether these promises are distinct and determine when we have satisfied these obligations. Our consideration of these issues is discussed in Note 8 to our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Revenue recognition

Our revenue arises from the Nuance Agreement. The terms of the Nuance Agreement include non-refundable upfront fees, payments based upon achievement of developmental and regulatory milestones, commercial milestones, royalties payable on sales, and manufacturing and supply. These payments are viewed as both fixed and variable consideration. Non-refundable upfront fees are considered fixed, while milestone payments and revenue from the commercialized product are identified as variable consideration. We follow the five-step model in ASC 606 "Revenue from Contracts with Customers":

Step 1: Identify the contract(s) with a customer.

Step 2: Identify the performance obligations in the contract.

Step 3: Determine the transaction price.

Step 4: Allocate the transaction price to the performance obligations in the contract.

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

All of our revenue is derived from contracts with customers.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. Our performance obligations include intellectual property rights, (which include the license, patents and developmental and regulatory data) and manufacturing and supply. Management are required to judge when performance obligations are satisfied and consequently when revenue is recognized.

If the right to the our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, upfront fees allocated to the right when the right is transferred to the customer, and the customer can use and benefit from the right.

If an arrangement includes development and regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

Contract assets

We recognize incremental costs of obtaining a contract such as commission costs as an asset and amortize the asset on a basis that is consistent with the satisfaction of the performance obligations to which the asset relates. Consideration receivable that is in excess of the value of satisfied, or part satisfied, performance obligations is recognized as a deferred revenue liability.

Trade receivable

Accounts receivable relate to amounts billed to customers. Management determine the likelihood of uncollectible accounts and provide for this accordingly.

Equity interest

As of June 30, 2021, as part of the Nuance Agreement, we recorded a $15.0 million equity receivable, relating to an equity interest in Nuance Biotech, the parent company of Nuance Pharma. This equity interest was received in the three months ended September 30, 2021. As Nuance Biotech is not publicly listed the equity interest's fair value is not readily determinable. We therefore use the fair value measurement alternative and measure 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.

Components of results of operations

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

- conduct our ongoing Phase 3 clinical trials for ensifentrine for the maintenance treatment of COPD;
- continue the clinical development of our DPI and pMDI formulations of ensifentrine and research and develop other formulations of ensifentrine;
- initiate and conduct further clinical trials for ensifentrine for the treatment of acute COPD, CF or any other indication;
- initiate and progress pre-clinical studies relating to other potential indications of ensifentrine;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our continuing operations as a U.S. public company; or
- experience any delays or encounter any issues from any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Revenue

Revenue relates to the Nuance Agreement. We have recognized the $40.0 million upfront consideration in the three months ended September 30, 2021. We expect that we will generate revenue from the manufacturing and supply agreement and potentially from the milestone payments defined in the Nuance Agreement.

Operating expenses

Research and development costs

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

We expect our research and development costs to increase through at least the first quarter of 2022 as we progress our ENHANCE program. Unless we add new compounds or develop ensifentrine further in other delivery methods or indications, we expect our research and development costs to begin to decrease in mid-2022. 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 potential commercial operations and, in the event of successful regulatory approval, we expect to incur sales force, marketing and other launch related costs. As we develop our knowledge of the market and refine our commercialization plans, expected costs may vary significantly from our current expectations.

Other income/(expense)

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

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

Effective January 1, 2022, this tax credit will be subject to a cap equal to a multiple of employment taxes the entity pays in the year in question. We are currently reviewing the impact these changes could have on our tax credit for the 2022 financial year, payable in 2023.

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, 2021 and 2020

In prior periods we prepared our financial information in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"), in pounds sterling, until July 1, 2020, when our functional and presentational currency changed to U.S. dollars. As a consequence of becoming a U.S. domestic issuer as of January 1, 2021, we are required to present our financial information in accordance with U.S. GAAP. The below financial information has been prepared in accordance with U.S. GAAP. The financial information should not be expected to correspond to figures we have previously presented under IFRS, in pounds sterling or in U.S. dollars.

The following table shows our statements of operations for the three months ended September 30, 2021 and 2020, (in thousands):

	Three months ended September 30,		
	2021	2020	Change
Revenue	$ 40,000	$ —	$ 40,000
Operating expenses			
Research and development	22,560	12,820	9,740
Selling, general and administrative	10,883	8,284	2,599
Total operating expenses	33,443	21,104	12,339
Operating profit/(loss)	6,557	(21,104)	27,661
Other income/(expense)			
Research and development tax credit	4,749	2,338	2,411
Interest income	4	13	(9)
Interest expense	(86)	—	(86)
Fair value movement on warrants	40	(978)	1,018
Foreign exchange (loss)/gain	(86)	844	(930)
Total other income, net	4,621	2,217	2,404
Profit/(loss) before income taxes	11,178	(18,887)	30,065
Income tax expense	(127)	(44)	(83)
Net profit/(loss)	$ 11,051	$ (18,931)	$ 29,982

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, 2020.

Research and development costs

Research and development costs were $22.6 million for the three months ended September 30, 2021, compared to $12.8 million for the three months ended September 30, 2020, an increase of $9.8 million. This increase was primarily due to an $11.0 million increase in clinical trial and other development costs, as we progressed our Phase 3 ENHANCE program, partially offset by a $1.3 million decrease in share-based compensation.

Selling, general and administrative costs

Selling, general and administrative costs were $10.9 million for the three months ended September 30, 2021, compared to $8.3 million for the three months ended September 30, 2020, an increase of $2.6 million. This increase was driven primarily by professional fees associated with the Nuance Agreement, partially offset by non-recurring costs relating to the $200 million PIPE financing in July 2020.

Other income/(expense)

The research and development tax credit for the three months ended September 30, 2021 was $4.7 million compared to $2.3 million for the three months ended September 30, 2020, an increase of $2.4 million. This increase is attributable to our higher qualifying research and development expenditures in the three months ended September 30, 2021, compared to the comparative 2020 period, as we treated more patients in our ENHANCE trials.

We recorded income of $40 thousand in the three months ended September 30, 2021, compared to a loss of $1.0 million in the comparative period relating to the fair value movements of the warrants. The income recorded in the three months ended September 30, 2021 was driven by the fall of our share price, as well as lower volatility and a shorter term of the warrants. In the three months ended September 30, 2020, the loss was driven by a rise in the share price in that period as well as greater volatility.

Net profit/(loss)

Net profit was $11.1 million for the three months ended September 30, 2021, compared to a net loss of $18.9 million for the three months ended September 30, 2020, because of the factors outlined above.

Results of operations for the nine months ended September 30, 2021 and 2020

The following table shows our statements of operations for the nine months ended September 30, 2021 and 2020, (in thousands):

	Nine months ended September 30,		
	2021	2020	Change
Revenue	$ 40,000	$ —	$ 40,000
Operating expenses			
Research and development	56,697	28,259	28,438
Selling, general and administrative	28,150	18,318	9,832
Total operating expenses	84,847	46,577	38,270
Operating loss	(44,847)	(46,577)	1,730
Other income/(expense)			
Research and development tax credit	10,655	5,809	4,846
Interest income	11	116	(105)
Interest expense	(255)	—	(255)
Fair value movement on warrants	2,244	(747)	2,991
Foreign exchange (loss)/gain	117	1,188	(1,071)
Total other income, net	12,772	6,366	6,406
Loss before income taxes	(32,075)	(40,211)	8,136
Income tax expense	(232)	(110)	(122)
Net loss	$ (32,307)	$ (40,321)	$ 8,014

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, 2020.

Research and development costs

Research and development costs were $56.7 million for the nine months ended September 30, 2021, compared to $28.3 million for the nine months ended September 30, 2020, an increase of $28.4 million. This increase was primarily due to a $24.6 million increase in clinical trial and other development costs, as we progressed our Phase 3 ENHANCE program, as well as a $4.4 million increase in share-based compensation charges.

Selling, general and administrative costs

Selling, general and administrative costs were $28.2 million for the nine months ended September 30, 2021 compared to $18.3 million for the nine months ended September 30, 2020, an increase of $9.9 million. This increase was driven primarily by a $7.5 million increase in share-based compensation charges and professional fees associated with the Nuance Agreement, partially offset by severance, executive change costs and non-recurring costs relating to the $200.2 million PIPE financing in July 2020.

Other income/(expense)

The research and development tax credit for the nine months ended September 30, 2021 was $10.7 million compared to $5.8 million for the nine months ended September 30, 2020, an increase of $4.9 million. This increase was attributable to our higher qualifying research and development expenditures in the nine months ended September 30, 2021, compared to the comparative 2020 period, as we enrolled more patients in our Phase 3 trials.

We recorded income of $2.2 million in the nine months ended September 30, 2021, compared to a charge of $0.7 million in the comparative period relating to the fair value movements of the warrants. The income recorded in the nine months ended September 30, 2021, is driven by the fall of our share price, as well as lower volatility and a shorter term of the warrants. In the nine months ended September 30, 2020, there was a loss due to a rise in the share price in that period and greater volatility.

Net loss

Net loss was $32.3 million for the nine months ended September 30, 2021, compared to $40.3 million for the nine months ended September 30, 2020, because of the factors outlined above.

Cash flows

The following table summarizes our cash flows for the nine months ended September 30, 2021 and 2020 (in thousands):

	Nine months ended September 30,		
	2021	2020	Change
Cash and cash equivalents at beginning of the period	$ 187,986	$ 30,428	$ 157,558
Net cash used in operating activities	(15,931)	(26,281)	10,350
Net cash (used in)/provided by investing activities	(11)	9,719	(9,730)
Net cash (used in)/provided by financing activities	(5,216)	188,393	(193,609)
Effect of exchange rate changes on cash and cash equivalents	(281)	(291)	10
Cash and cash equivalents at end of the period	$ 166,547	$ 201,968	$ (35,421)

Operating activities

Net cash used in operating activities was $15.9 million in the nine months ended September 30, 2021, compared to $26.3 million during the nine months ended September 30, 2020, a decrease of $10.4 million. The $25.0 million upfront payment related to the Nuance Agreement and $11.8 million related to timing of supplier payments offset a $26.4 million increase in cash based operating expenses.

Investing activities

Net cash used in investing activities was $11 thousand in the nine months ended September 30, 2021 compared to $9.7 million provided in the nine months ended September 30, 2020. In the prior period all funds that were held on deposit, classified as short-term investments, were transferred to money market mutual funds that are classified as cash equivalents.

Financing activities

Net cash used in financing activities was $5.2 million in the nine months ended September 30, 2021, compared to $188.4 million provided in the nine months ended September 30, 2020. This consisted of $5.9 million for payment of withholding taxes due on the net-settling of certain employees' RSU awards, partially offset by $0.7 million generated from the issuance of ADSs under the ATM Program. The $188.4 million provided in the nine months ended September 30, 2020, related to net funds received from the $200.2 million PIPE financing in July 2020.

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 the Term Loan and 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 $32.3 million for the nine months ended September 30, 2021, and $65.1 million for the year ended December 31, 2020. As of September 30, 2021, we had an accumulated deficit of $240.3 million. We expect to continue to generate operating losses for the foreseeable future.

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

Open market sale agreement

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, 2021, we sold 873,104 ordinary shares (equivalent to 109,138 ADSs) under the ATM Program, at an average price of approximately $0.86 per share (equivalent to $6.91 per ADS), raising aggregate net proceeds of approximately $0.7 million after deducting issuance costs. As of September 30, 2021, $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, 2021, the Company had $5.0 million principal outstanding under the Term Loan. Additional detail surrounding the Term Loan is included under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2020 Form 10-K. There have been no material changes to that information disclosed in our 2020 Form 10-K during the nine months ended September 30, 2021.

Funding requirements

We believe that our cash and cash equivalents as of September 30, 2021, expected cash receipts from U.K. tax credits and funding expected to become available under the Term Loan, will enable us to fund our planned operating expenses and capital expenditure requirements through at least the end of 2023. The Term Loan advances are contingent upon achievement of certain clinical development milestones and other specified conditions.

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

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

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

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

- the progress, timing and completion of pre-clinical testing and clinical trials for ensifentrine or any future product candidates and the potential that we may be required to conduct additional clinical trials for ensifentrine;
- the number of potential new product candidates we decide to in-license and develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of ensifentrine or any future product candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the time and costs involved in obtaining regulatory approvals for ensifentrine or any future product candidate we develop and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to ensifentrine or any future product candidates;
- any licensing or milestone fees we might have to pay during future development of ensifentrine or any future product candidates;
- selling and marketing activities undertaken in connection with the anticipated commercialization of ensifentrine or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of ensifentrine or any future product candidates, if approved.

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

Off-balance sheet arrangements

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

Recent accounting pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

In June 2021, we entered into the Nuance Agreement. Consequently we are implementing certain controls over financial reporting in the year ending December 31, 2021, with regards to obligations to supply drug product to Nuance, and other related accounting matters. Apart from the foregoing changes 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, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

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

The collaboration and license agreement with Nuance Pharma is important to our business. If Nuance Pharma is unable to develop and commercialize products containing ensifentrine in Greater China, if we or Nuance Pharma fail to adequately perform under the Nuance Agreement, or if we or Nuance Pharma terminate the Nuance Agreement, our business would be adversely affected.

We entered into a collaboration and license agreement with Nuance Pharma Limited (“Nuance Pharma”) effective June 9, 2021 (the “Nuance Agreement”) under which we granted Nuance Pharma the exclusive rights to develop and commercialize products containing ensifentrine (the “Nuance Licensed Products”) in Greater China (China, Taiwan, Hong Kong and Macau).

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.

Termination of the Nuance Agreement could cause significant setbacks in our ability to develop and commercialize the Nuance Licensed Products in Greater China. Any suitable alternative collaboration or license agreement would take considerable time to negotiate and could also be on less favorable terms to us. In addition, under the Nuance Agreement, Nuance Pharma agreed to assume all costs related to clinical development and commercialization of the Nuance Licensed Products in Greater China. If the Nuance Agreement were to be terminated, and whether or not we identify another suitable collaborator, we may need to seek additional financing to support the clinical development and commercialization of the Nuance Licensed Products in Greater China, which could have a material adverse effect on our business.

Under the Nuance Agreement, we are dependent upon Nuance Pharma to successfully develop and commercialize Nuance Licensed Products. Although we have formed a joint steering committee with Nuance Pharma to oversee and coordinate the overall conduct of the clinical development and commercialization of the Nuance Licensed Products in Greater China, we do not control all aspects of Nuance Pharma’s development and commercialization or the resources it allocates to the development of the Nuance Licensed Products identified under the Nuance Agreement. Our interests and Nuance Pharma’s interests may differ or conflict from time to time, or we may disagree with Nuance Pharma’s level of effort or resource allocation. Nuance Pharma may internally prioritize programs under development within the collaboration differently than we would, or it may not allocate sufficient resources to effectively or optimally develop or commercialize the Nuance Licensed Products. If these events were to occur, our ability to receive revenue from the commercialization of the Nuance Licensed Products would be reduced, and our business would be adversely affected.

If we fail to enter into new strategic relationships for ensifentrine, our business, research and development and commercialization prospects could be adversely affected.

Our development program for ensifentrine and the potential commercialization of ensifentrine will require substantial additional cash to fund expenses. Therefore, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of ensifentrine. For example, we may seek a collaborator for development of our DPI or MDI formulation of ensifentrine for the maintenance treatment of COPD and potentially asthma and other respiratory diseases.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of ensifentrine, reduce or delay its development program, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring ensifentrine to market and generate product revenue. If we do enter into a collaboration agreement, we could be subject to the following risks, among others, any of which could adversely affect our ability to develop and commercialize ensifentrine:

- we may not be able to control the amount and timing of resources that the collaborator devotes to the development of ensifentrine;
- the collaborator may experience financial difficulties;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- safety and/or efficacy data from a collaborator's clinical development activities may conflict with our data and could potentially impact our global clinical development activities;
- a collaborator may unlawfully use or disclose confidential information and materials in breach of confidentiality obligations to us;
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement;
- we or a collaborator could fail to adequately perform our obligations under the agreement and/or the agreement could fall into dispute;
- we may be involved in lawsuits to protect or enforce patents covering ensifentrine, or relating to the terms of our collaborations, which could be expensive, time consuming and unsuccessful; or
- the collaboration may not provide sufficient funds to be profitable for us after we fulfill any payment liabilities under the Ligand Agreement.

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	
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 , 2021 By: /s/ David Zaccardelli

David Zaccardelli, Pharm. D.

President and Chief Executive Officer

Date: November 9 , 2021 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, 2021 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, 2021 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, 2021 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, 2021 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, 2021 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, 2021 By: /s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (*principal financial officer)*