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 June 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 August 4, 2021, the registrant had 480,291,822 ordinary shares, nominal value £0.05 per share, outstanding, which if all held in ADS form, would be represented by 60,036,478 American Depositary Shares, each representing eight (8) ordinary shares.

		Page
PART I - FINANCIAL INFORMATION		
Item 1	Financial Statements	2
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3	Quantitative and Qualitative Disclosures About Market Risk	31
Item 4	Controls and Procedures	31
PART II - OTHER INFORMATION		
Item 1	Legal Proceedings	32
Item 1A.	Risk Factors	32
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	34
Item 3	Defaults Upon Senior Securities	34
Item 4	Mine Safety Disclosure	34
Item 5	Other Information	34
Item 6	Exhibits	35
Signatures		36

PART I - FINANCIAL INFORMATION

Item 1. Financial statements

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 146,035	$ 187,986
Accounts receivable	25,002	—
Prepaid expenses	9,817	4,538
Tax and tax incentive receivables	14,108	8,260
Contract asset	4,001	—
Equity interest receivable	15,000	—
Other current assets	2,320	1,720
Total current assets	216,283	202,504
Non-current assets:		
Furniture and equipment, net	89	107
Goodwill	545	545
Right-of-use assets	1,585	1,050
Total non-current assets	2,219	1,702
Total assets	$ 218,502	$ 204,206
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 34	$ 178
Accrued expenses	17,188	10,863
Deferred revenue	40,051	—
Operating lease liability	749	798
Warrants	42	2,246
Other current liabilities	300	118
Total current liabilities	58,364	14,203
Non-current liabilities:		
Term loan	4,767	4,635
Operating lease liability	974	514
Total non-current liabilities	5,741	5,149
Total liabilities	64,105	19,352
Commitments and contingencies		
Shareholders' equity:		
Ordinary £0.05 par value shares; 488,739,150 and 488,304,446 issued, and 471,839,302 and 463,304,446 outstanding, at June 30, 2021 and December 31, 2020, respectively	31,824	31,794
Additional paid-in capital	379,282	366,411
Ordinary shares held in treasury	(843)	(1,700)
Accumulated other comprehensive loss	(4,601)	(4,601)
Accumulated deficit	(251,265)	(207,050)
Total shareholders' equity	154,397	184,854
Total liabilities and shareholders' equity	$ 218,502	$ 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 Loss
(unaudited)
(in thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 20,563	$ 7,811	$ 34,137	$ 15,433
General and administrative	7,985	3,172	17,267	10,034
Total operating expenses	28,548	10,983	51,404	25,467
Operating loss	(28,548)	(10,983)	(51,404)	(25,467)
Other income / (expense)				
Benefit from research and development tax credit	3,836	1,786	5,906	3,471
Interest income	3	34	7	103
Interest expense	(85)	—	(169)	—
Fair value movement on warrants	2,711	89	2,204	231
Foreign exchange gain	40	51	203	344
Total other income, net	6,505	1,960	8,151	4,149
Loss before income taxes	(22,043)	(9,023)	(43,253)	(21,318)
Income tax expense	(25)	(15)	(105)	(66)
Net loss	$ (22,068)	$ (9,038)	$ (43,358)	$ (21,384)
Other comprehensive loss:				
Foreign currency translation adjustments	—	(164)	—	(2,321)
Total comprehensive loss attributable to shareholders of the Company	$ (22,068)	$ (9,202)	$ (43,358)	$ (23,705)
Loss per ordinary share - basic and diluted	$ (0.05)	$ (0.08)	$ (0.09)	$ (0.20)
Weighted-average shares outstanding - basic and diluted	470,786,767	106,360,580	469,036,978	105,908,648

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

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

	Ordinary shares		Additional paid-in capital	Ordinary shares held in treasury	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity
	Number	Amount					
Balance at January 1, 2021	488,304,446	$ 31,794	$366,411	$ (1,700)	$ (4,601)	$ (207,050)	$ 184,854
Net loss		—	—	—	—	(21,290)	(21,290)
Restricted share units vested		—	—	30	—	(30)	—
Share-based compensation		—	8,850	—	—	—	8,850
Balance at March 31, 2021	488,304,446	$ 31,794	$375,261	$ (1,670)	$ (4,601)	$ (228,370)	$ 172,414
Net loss	—	—	—	—	—	(22,068)	(22,068)
Common shares withheld for taxes on vested stock awards	—	—	(3,782)	—	—	—	(3,782)
Restricted share units vested	—	—	—	827	—	(827)	—
Share-based compensation	—	—	7,450	—	—	—	7,450
Issuance of common shares under at-the-market sales	434,704	30	353	—	—	—	383
Balance at June 30, 2021	488,739,150	$ 31,824	$379,282	$ (843)	$ (4,601)	$ (251,265)	$ 154,397

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 options exercised during the period	887,080	52	—	—	—	52
Share-based compensation	—	—	1,867	—	—	1,867
Balance at March 31, 2020	106,213,718	$ 7,317	$181,402	$ (4,437)	$ (154,125)	$ 30,157
Net loss	—	—	—	—	(9,038)	(9,038)
Retranslation of foreign operations	—	—	—	(164)	—	(164)
Share options exercised during the period	267,288	16	—	—	(68)	(52)
Share-based compensation	—	—	950	—	—	950
Balance at June 30, 2020	106,481,006	$ 7,333	$182,352	$ (4,601)	$ (163,231)	$ 21,853

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)

	Six months ended June 30,	
	2021	**2020**
Operating activities:		
Net loss:	$ (43,358)	$ (21,384)
Adjustments to reconcile net income to net cash used in operating activities:		
Foreign exchange gain	(186)	(214)
Amortization of debt issue costs	70	—
Accretion of redemption premium on debt	63	—
Fair value movement on warrants	(2,204)	(231)
Impairment of right-of-use asset	—	289
Share-based compensation	16,300	2,817
Depreciation and amortization	305	315
Changes in operating assets and liabilities:		
Accounts receivable	(25,002)	—
Equity interest receivable	(15,000)	—
Prepaid expenses	(5,279)	(2,873)
Tax and tax incentive receivables	(5,848)	5,894
Other current assets	(600)	713
Non-current assets	(4,823)	(716)
Accounts payable	(144)	(953)
Accrued expenses	6,325	(561)
Lease liabilities	393	406
Deferred revenue	40,051	—
Other liabilities	182	213
Net cash used in operating activities	(38,756)	(16,285)
Cash flows from investing activities:		
Purchases of furniture and equipment	—	(5)
Sale of short-term investments	—	9,792
Net cash provided by investing activities	—	9,787
Cash flows from financing activities:		
Payments of withholding taxes from share-based awards	(3,782)	—
Proceeds from at-the-market sales agreement	383	—
Net cash used in financing activities	(3,399)	—
Effect of exchange rate changes on cash and cash equivalents	204	(1,570)
Net decrease in cash and cash equivalents	(41,951)	(8,068)
Cash and cash equivalents at beginning of the period	187,986	30,428
Cash and cash equivalents at end of the period	$ 146,035	$ 22,360
Supplemental disclosure of cash flow information:		
Income taxes paid	$ —	$ —
Interest paid	$ 109	$ —

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 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 $251.3 million as of June 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 June 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 three months ended June 30, 2021, the Company sold 434,704 shares (equivalent to 54,338 ADSs) under the ATM Program, at an average price of approximately $0.90 per share (equivalent to $7.23 per ADS), raising aggregate net proceeds of approximately $0.4 million after deducting issuance costs. As of June 30, 2021, there remained $99.6 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 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 policy on revenue recognition is 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 stockholders' equity for the periods presented. Except as otherwise disclosed, all such adjustments are of a normal recurring nature. Operating results for the interim periods are not necessarily indicative of the results that may be expected for the full year.

Revenue recognition

The Company's deferred revenue arises from the Company's agreement for the development and commercialization of ensifentrine in Greater China. The terms of the 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 and liabilities

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 receivable

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

Equity receivable

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 recorded as a receivable at fair value on the date of the transaction and is classified as equity interest receivable in current assets. There are no observable market data to determine the fair value of this stock. Consequently, the receivable relating to the stock is classified under Level 3 of the fair value hierarchy. Management valued the stock on the date of the transaction using data from Nuance Pharma's latest funding round in November 2020 and there was no change or any new information for Nuance Biotech that would have impacted this valuation as of June 30, 2021.

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, estimation of contract consideration and revenue recognition, the fair value of share-based compensation and the fair value of warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from the Company's estimates.

Critically, management are required to identify the promises in the contract, determine whether these promises are distinct and determine when the Company has satisfied these obligations. The Company's consideration of these issues is discussed in Note 8.

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):

	June 30, 2021	December 31, 2020
Clinical trial and other development costs	$ 5,643	$ 2,551
Insurance	3,864	1,701
Other	310	286
Total prepaid expenses	$ 9,817	$ 4,538

Note 4 - Tax and tax incentive receivables

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

	June 30, 2021	December 31, 2020
Research and development tax credit receivable - U.K.	$ 14,108	$ 8,202
Tax receivable - U.S.	—	58
Total tax receivable	$ 14,108	$ 8,260

Note 5 - Accrued expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Clinical trial and other development costs	$ 11,227	$ 8,607
Professional fees and general corporate costs	4,925	2,149
People related costs	1,036	107
Total accrued expenses	$ 17,188	$ 10,863

Note 6 - Warrants

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

There have been no changes in valuation techniques or transfers between fair value measurement levels during the period ended June 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:

	June 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	0.10 %	— %
Expected term to exercise	0.84	1.33
Annualized volatility	53.6 %	105.4 %
Dividend rate	— %	— %
Calculated value of the warrants, in thousands of U.S. dollars	$ 42	$ 2,246

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

10% volatility increase	$ 125
Base case, reported fair value	42
10% volatility decrease	$ 8

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 June 30, 2021, the Company had $5.0 million principal outstanding under the Term Loan.

As of June 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 with Nuance Pharma Limited ("Nuance Pharma") effective June 9, 2021 (the "Effective Date") (the "Nuance Agreement") 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 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 June 30, 2021, as the $25.0 million cash payment and $15.0 million equity interest were due on signing the contract, they were recorded as receivables on the Company's balance sheet. The $25.0 million cash payment was received in July 2021.

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 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.

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 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 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 has determined that it will have fulfilled its obligations to Nuance Pharma when it has delivered the know how that will allow Nuance Pharma to file an investigational new drug application in Greater China. This know how is expected to be delivered in the three months ended September 30, 2021, and the $40.0 million revenue is expected to be recognized in that 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.

The equity interest in Nuance Biotech was recorded as a receivable at fair value on the Effective Date and is classified as equity interest receivable in current assets. There are no observable market data to determine the fair value of this equity interest. Consequently, the receivable relating to the equity interest is classified under Level 3 of the fair value hierarchy. Management valued the equity interest using data from Nuance Pharma's latest funding round in November 2020. As of June 30, 2021, the Company had no information to indicate that this valuation is not still appropriate.

On the Effective Date, the $40.0 million fixed consideration was recognized and recorded in deferred revenue. As of June 30, 2021, $nil had been recognized in the Statement of Operations and Comprehensive Loss. As of June 30, 2021, $25.0 million cash receivable and $15.0 million equity interest were recorded in current assets.

On the Effective Date, $4.0 million of costs of obtaining a contract were recorded as a contract asset. As of June 30, 2021, $nil had been amortized into the Statement of Operations and Comprehensive Loss and it will be recognized in line with the revenue from the grant of the license.

Subsequent to the Effective Date, Ligand has 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 general and administrative costs (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Research and development	$ 3,234	$ 498	$ 6,666	$ 991
General and administrative	4,217	452	9,634	1,826
Total	$ 7,451	$ 950	$ 16,300	$ 2,817

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

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

Note 10 - Net loss per share

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (22,068)	$ (9,038)	$ (43,358)	$ (21,384)
Net loss available to ordinary shareholders - basic and	$ (22,068)	$ (9,038)	$ (43,358)	$ (21,384)
Denominator:				
Weighted-average shares outstanding - basic and	470,786,767	106,360,580	469,036,978	105,908,648
Net loss per share - basic and diluted	$ (0.05)	$ (0.08)	$ (0.09)	$ (0.20)

During the periods ended June 30, 2021 and 2020, outstanding share options, RSUs and warrants over 75,713,291 and 34,504,825 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, the duration of our patent portfolio, our estimates regarding expenses, future revenues, capital requirements, debt service obligations and our need for additional financing, the funding we expect to become available from cash receipts from U.K. tax credits, and the sufficiency of our cash and cash equivalents to fund operations, are forward-looking statements.

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

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

Overview

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

We have incurred recurring losses and negative cash flows from operations since inception, and have an accumulated deficit of $251.3 million as of June 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
- enhance our commercial insights and capabilities.

We believe that our cash and cash equivalents as of June 30, 2021, together with the $25 million upfront payment received from Nuance Pharma in July 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 2023.

Clinical development update

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

During the second quarter of 2021, we continued steady progress on patient recruitment in our Phase 3 ENHANCE clinical program and patient enrollment in both ENHANCE-1 and ENHANCE-2 continues across our international clinical trial sites. During the second quarter of 2021, numerous COVID-19 related challenges, including new variants and increased infection and hospitalization rates across a number of countries, have put pressure on our recruitment timelines. We have implemented various mitigation strategies to address these challenges including revising our study inclusion criteria to allow for up to 20% of patients taking inhaled corticosteroids (ICS) in addition to their daily LAMA or LABA maintenance bronchodilator to enroll in ENHANCE-1 and ENHANCE-2. This change is aligned with treatment practices during the COVID-19 pandemic. In our Phase 2 trials, ensifentrine demonstrated clinically and statistically significant dose-dependent improvements in lung function and progressive improvements in quality of life as well as a favorable safety profile similar to placebo, with or without the use of ICS. Approximately 40% of patients in our 400-patient Phase 2b study were taking ICS.

Based on our current models, our projections for reporting top-line data are in-line with previous guidance, with ENHANCE-2 expected to report in the first half of 2022 and ENHANCE-1 in the second half of 2022. Should COVID-19 related challenges continue to increase, we predict top-line data from ENHANCE-2 would be expected in the third quarter of 2022 and from ENHANCE-1 in the fourth quarter 2022.

Intellectual property update

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

As of June 30, 2021, our patent portfolio consisted of nine issued U.S. patents, three pending U.S. patent applications, fifty-three issued foreign patents and fifty-four pending foreign applications including two patent applications made under the Patent Cooperation Treaty. These patents and patent applications include claims directed to certain respirable formulations comprising ensifentrine, a crystalline form of ensifentrine, combinations of ensifentrine with certain respiratory drugs, certain salts of ensifentrine, ensifentrine for use in the treatment of cystic fibrosis, and a method of making ensifentrine, with expected expiry dates up to 2041.

COVID-19 impact

We are closely monitoring the potential impact of the COVID-19 pandemic on our operations and clinical trials, in particular the timelines and costs of our Phase 3 clinical program. The pandemic and associated individual government and country 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.

We are closely monitoring activities at our contract manufacturers associated with clinical supply for our ongoing clinical trials, and are satisfied that appropriate plans and procedures are in place to ensure uninterrupted future supply of ensifentrine to the clinical trial sites, subject to potential limitations on their operations and on the supply chain due to the COVID-19 pandemic. We continue to monitor this situation and will provide an update if we become aware of any meaningful disruption caused by the pandemic to the clinical supply of ensifentrine for our clinical trials.

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 with 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.

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 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 the ensifentrine under the 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 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 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 will have fulfilled our obligations to Nuance Pharma when we have delivered the know how that will allow Nuance Pharma to file an investigational new drug application in Greater China. This know how is expected to be delivered in the three months ended September 30, 2021, and the $40.0 million revenue is expected to be recognized in that period. Revenue relating to the manufacture and supply obligations will be recognized when the drug product is delivered.

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

The equity interest in Nuance Biotech was recorded as a receivable at fair value on the Effective Date and is classified as equity interest receivable in current assets. There are no observable market data to determine the fair value of this equity interest. Consequently, the receivable relating to the equity interest is classified under Level 3 of the fair value hierarchy. Management valued the equity interest using data from Nuance Pharma's latest funding round in November 2020. As of June 30, 2021, the we had no information to indicate that this valuation is not still appropriate.

On the Effective Date, the $40.0 million fixed consideration was recognized and recorded in deferred revenue. As of June 30, 2021, $nil had been recognized in the Statement of Operations and Comprehensive Loss. As of June 30, 2021, $25.0 million cash receivable and $15.0 million equity interest were recorded in current assets.

On the Effective Date, $4.0 million of costs of obtaining a contract were recorded as a contract asset. As of June 30, 2021, $nil had been amortized into the Statement of Operations and Comprehensive Loss and it will be recognized in line with the revenue from the grant of the license.

Since the Effective Date, Ligand has 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 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 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 six months ended June 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 deferred revenue arises from the Nuance Agreement. The terms of the 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 and liabilities

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 receivable

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 recorded as a receivable at fair value on the date of the transaction and is classified as equity interest receivable in current assets. There are no observable market data to determine the fair value of this stock. Consequently, the receivable relating to the stock is classified under Level 3 of the fair value hierarchy. Management valued the stock on the date of the transaction using data from Nuance Pharma's latest funding round in November 2020 and there was no change or any new information for Nuance Biotech that would have impacted this valuation as of June 30, 2021.

Components of results of operations

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

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

Operating expenses

Research and development costs

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

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

General and administrative costs

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

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

Other income / (expense)

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

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

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

Taxation

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

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

Results of operations for the three months ended June 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. 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 and expressed in U.S. dollars from that date. 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.

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

	Three months ended June 30,		
	2021	2020	Variance
Operating expenses			
Research and development	$ 20,563	$ 7,811	$ 12,752
General and administrative	7,985	3,172	4,813
Total operating expenses	28,548	10,983	17,565
Operating loss	(28,548)	(10,983)	(17,565)
Other income / (expense)			
Benefit from research and development tax credit	3,836	1,786	2,050
Interest income	3	34	(31)
Interest expense	(85)	—	(85)
Fair value movement on warrants	2,711	89	2,622
Foreign exchange gain	40	51	(11)
Total other income, net	6,505	1,960	4,545
Loss before income taxes	(22,043)	(9,023)	(13,020)
Income tax expense	(25)	(15)	(10)
Net loss	$ (22,068)	$ (9,038)	$ (13,030)

Research and development costs

Research and development costs were $20.6 million for the three months ended June 30, 2021, compared to $7.8 million for the three months ended June 30, 2020, an increase of $12.8 million. This increase was primarily due to a $10.1 million increase in clinical trial and other development costs, as we progressed our Phase 3 ENHANCE program, as well as a $2.7 million increase in share-based compensation.

Development costs were higher during the three months ended June 30, 2021 due to costs associated with dosing patients in our ongoing Phase 3 clinical trials. In the comparative period we had no trials in progress, and only startup costs for Phase 3 trials and close down costs for certain Phase 2 trials.

General and administrative costs

General and administrative costs were $8.0 million for the three months ended June 30, 2021 compared to $3.2 million for the three months ended June 30, 2020, an increase of $4.8 million.

This increase was driven primarily by a $3.7 million increase in share-based compensation charges, as well as increased costs for Directors' and Officers' insurance.

Other income / (expense)

The research and development tax credit for the three months ended June 30, 2021 was $3.8 million compared to a credit of $1.8 million for the three months ended June 30, 2020, an increase of $2.0 million. This increase is attributable to our higher qualifying expenditure on research and development in the three months ended June 30, 2021, compared to the comparative 2020 period, as we dosed patients in our Phase 3 trials.

We recorded income of $2.7 million in the three months ended June 30, 2021, compared to $0.1 million in the comparative period relating to the fair value movements of the warrants. The income recorded in the three months ended June 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 June 30, 2020, the income was lower as the fall in the share price in that period was partly offset by greater volatility.

Net loss

Net loss was $22.1 million for the three months ended June 30, 2021, compared to $9.0 million for the three months ended June 30, 2020. The increase in net loss was primarily the result of the increase in operating costs partially offset by the increase in other income, net.

Results of operations for the six months ended June 30, 2021 and 2020

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

	Six months ended June 30,		
	2021	2020	Variance
Operating expenses			
Research and development	$ 34,137	$ 15,433	$ 18,704
General and administrative	17,267	10,034	7,233
Total operating expenses	51,404	25,467	25,937
Operating loss	(51,404)	(25,467)	(25,937)
Other income / (expense)			
Benefit from research and development tax credit	5,906	3,471	2,435
Interest income	7	103	(96)
Interest expense	(169)	—	(169)
Fair value movement on warrants	2,204	231	1,973
Foreign exchange gain	203	344	(141)
Total other income, net	8,151	4,149	4,002
Loss before income taxes	(43,253)	(21,318)	(21,935)
Income tax expense	(105)	(66)	(39)
Net loss	$ (43,358)	$ (21,384)	$ (21,974)

Research and development costs

Research and development costs were $34.1 million for the six months ended June 30, 2021, compared to $15.4 million for the six months ended June 30, 2020, an increase of $18.7 million. This increase was primarily due to a $13.6 million increase in clinical trial and other development costs, as we progressed our Phase 3 ENHANCE program, as well as a $5.7 million increase in share-based compensation charges.

Development costs were higher during the three months ended June 30, 2021 due to costs associated with enrolling patients in our ongoing Phase 3 clinical trials. In the comparative period we had only one, smaller, trial in progress as well as startup costs for Phase 3 trials and close down costs for certain Phase 2 trials.*General and administrative costs*

General and administrative costs were $17.3 million for the six months ended June 30, 2021 compared to $10.0 million for the six months ended June 30, 2020, an increase of $7.3 million.

This increase was driven primarily by a $7.8 million increase in share-based compensation charges, as well as increased costs for Directors' and Officers' insurance, partially offset by severance and other executive change costs incurred in the six months ended June 30, 2020.

Other income / (expense)

The research and development tax credit for the six months ended June 30, 2021 was $5.9 million compared to a credit of $3.5 million for the six months ended June 30, 2020, an increase of $2.4 million. This increase was attributable to our higher qualifying expenditure on research and development in the six months ended June 30, 2021, compared to the comparative 2020 period, as we dosed patients in our Phase 3 trials.

We recorded income of $2.2 million in the six months ended June 30, 2021, compared to $0.2 million in the comparative period relating to the fair value movements of the warrants. The income recorded in the six months ended June 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 six months ended June 30, 2020. the income was lower as the fall in the share price in that period was partly offset by greater volatility.

Net loss

Net loss was $43.4 million for the six months ended June 30, 2021, compared to $21.4 million for the six months ended June 30, 2020. The increase in net loss was primarily the result of the increase in operating costs partially offset by the increase in other income, net.

Cash flows

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

	Six months ended June 30,		
	2021	2020	Variance
Cash and cash equivalents at beginning of the period	$ 187,986	$ 30,428	$ 157,558
Net cash used in operating activities	(38,756)	(16,285)	(22,471)
Net cash provided by investing activities	—	9,787	(9,787)
Net cash used in financing activities	(3,399)	—	(3,399)
Effect of exchange rate changes on cash and cash equivalents	204	(1,570)	1,774
Cash and cash equivalents at end of the period	$ 146,035	$ 22,360	$ 123,675

Operating activities

Net cash used in operating activities increased to $38.8 million in the six months ended June 30, 2021, from $16.3 million during the six months ended June 30, 2020, an increase of $22.5 million. Operating expenses increased by $25.9 million, of which $13.5 million was related to non-cash share-based compensation expenses. In the six months ended June 30, 2020, we received $9.0 million from the U.K. cash research and development tax credit. The remaining variance was due to the timing of supplier payments.

Investing activities

Net cash provided by investing activities decreased to nil in the six months ended June 30, 2021 from $9.8 million in the six months ended June 30, 2020, as in the prior period all funds were moved from short-term investments to money market mutual funds that are classified as cash equivalents..

Financing activities

Net cash used in financing activities increased to $3.4 million in the six months ended June 30, 2021, from nil during the six months ended June 30, 2020. This consisted of $3.8 million for payment of withholding taxes due on the net-settling of certain employees' RSU awards, partially offset by $0.4 million provided by the issuance of ADSs under the ATM Program.

Liquidity and capital resources

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

We have incurred recurring losses since inception, including net losses of $43.4 million for the six months ended June 30, 2021, and $65.1 million for the year ended December 31, 2020. As of June 30, 2021, we had an accumulated deficit of $251.3 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 three months ended June 30, 2021, the Company sold 434,704 shares (equivalent to 54,338 ADSs) under the ATM Program, at an average price of approximately $0.90 per share (equivalent to $7.23 per ADS), raising aggregate net proceeds of approximately $0.4 million after deducting issuance costs. As of June 30, 2021, there remained $99.6 million of ordinary shares, in the form of ADSs, 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 million contingent upon achievement of a specific clinical development milestone and other specified conditions. As of June 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 six months ended June 30, 2021.

Funding requirements

We believe that our cash and cash equivalents as of June 30, 2021, and together with the $25 million upfront payment received from Nuance Pharma in July 2021, recent and 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 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 June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

In the quarter ended June 30, 2021, we entered into the Nuance Agreement. Consequently we will be required to implement certain controls over financial reporting in the year ended December 31, 2021. Beyond this exception 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 June 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

		Incorporated by Reference to Filings Indicated				
Exhibit Number	Exhibit Description	Form	File No.	Exhibit No.	Filing date	Filed / Furnished Herewith
3.1	Articles of Association, as amended and as currently in effect	6-K	001-38067	1	12/30/2020	
10.1†	Verona Pharma plc, Nuance Pharma Limited and Nuance (Shanghai) Pharma Co Ltd					*
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.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and the registrant customarily and actually treats such information as private or confidential. Additionally, schedules and attachments to this exhibit have been omitted pursuant to Regulation S-K, Items 601(a)(5).

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: August 5, 2021	By:	/s/ David Zaccardelli David Zaccardelli, Pharm. D. President and Chief Executive Officer
Date: August 5, 2021	By:	/s/ Mark W. Hahn Mark W. Hahn Chief Financial Officer