

**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

(State or other jurisdiction of incorporation or organization)

98-1489389

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

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

(Address of principal executive offices)

Not Applicable

(Zip Code)

Registrant's telephone number, including area code: +44 203 283 4200
Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of 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.

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PART I - FINANCIAL INFORMATION

Item 1. Financial statements

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

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
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	<u>216,283</u>	<u>202,504</u>
Non-current assets:		
Furniture and equipment, net	89	107
Goodwill	545	545
Right-of-use assets	1,585	1,050
Total non-current assets	<u>2,219</u>	<u>1,702</u>
Total assets	<u>\$ 218,502</u>	<u>\$ 204,206</u>
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	<u>58,364</u>	<u>14,203</u>
Non-current liabilities:		
Term loan	4,767	4,635
Operating lease liability	974	514
Total non-current liabilities	<u>5,741</u>	<u>5,149</u>
Total liabilities	<u>64,105</u>	<u>19,352</u>
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	<u>154,397</u>	<u>184,854</u>
Total liabilities and shareholders' equity	<u>\$ 218,502</u>	<u>\$ 204,206</u>

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

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

	Three months ended 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	<u>488,304,446</u>	<u>\$ 31,794</u>	<u>\$ 375,261</u>	<u>\$ (1,670)</u>	<u>\$ (4,601)</u>	<u>\$ (228,370)</u>	<u>\$ 172,414</u>
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 agreement	434,704	30	353	—	—	—	383
Balance at June 30, 2021	<u>488,739,150</u>	<u>\$ 31,824</u>	<u>\$ 379,282</u>	<u>\$ (843)</u>	<u>\$ (4,601)</u>	<u>\$ (251,265)</u>	<u>\$ 154,397</u>

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	<u>106,213,718</u>	<u>\$ 7,317</u>	<u>\$ 181,402</u>	<u>\$ (4,437)</u>	<u>\$ (154,125)</u>	<u>\$ 30,157</u>
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	<u>106,481,006</u>	<u>\$ 7,333</u>	<u>\$ 182,352</u>	<u>\$ (4,601)</u>	<u>\$ (163,231)</u>	<u>\$ 21,853</u>

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)
<i>Adjustments to reconcile net income to net cash used in operating activities:</i>		
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
<i>Changes in operating assets and liabilities:</i>		
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	<u>(38,756)</u>	<u>(16,285)</u>
Cash flows from investing activities:		
Purchases of furniture and equipment	—	(5)
Sale of short-term investments	—	9,792
Net cash provided by investing activities	<u>—</u>	<u>9,787</u>
Cash flows from financing activities:		
Payments of withholding taxes from share-based awards	(3,782)	—
Proceeds from at-the-market sales agreement	383	—
Net cash used in financing activities	<u>(3,399)</u>	<u>—</u>
Effect of exchange rate changes on cash and cash equivalents	<u>204</u>	<u>(1,570)</u>
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	<u>\$ 146,035</u>	<u>\$ 22,360</u>
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.

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

Note 1 - Organization and description of business operations

Verona Pharma plc (the “Company”) is incorporated and domiciled in the United Kingdom. Verona Pharma plc has 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.

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

Note 3 - Prepaid expenses

Prepaid expenses consisted of the following (in thousands):

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

Note 4 - Tax and tax incentive receivables

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

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

Note 5 - Accrued expenses

Accrued expenses consisted of the following (in thousands):

	<u>June 30,</u>	<u>December 31,</u>
	2021	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	<u>\$ 17,188</u>	<u>\$ 10,863</u>

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

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.

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

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 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.

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

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

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

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 diluted	\$ (22,068)	\$ (9,038)	\$ (43,358)	\$ (21,384)
Denominator:				
Weighted-average shares outstanding - basic and diluted	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, 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,		Variance
	2021	2020	
Operating expenses			
Research and development	\$ 20,563	\$ 7,811	\$ 12,752
General and administrative	7,985	3,172	4,813
Total operating expenses	<u>28,548</u>	<u>10,983</u>	<u>17,565</u>
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	<u>6,505</u>	<u>1,960</u>	<u>4,545</u>
Loss before income taxes	(22,043)	(9,023)	(13,020)
Income tax expense	(25)	(15)	(10)
Net loss	<u>\$ (22,068)</u>	<u>\$ (9,038)</u>	<u>\$ (13,030)</u>

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,		Variance
	2021	2020	
Operating expenses			
Research and development	\$ 34,137	\$ 15,433	\$ 18,704
General and administrative	17,267	10,034	7,233
Total operating expenses	<u>51,404</u>	<u>25,467</u>	<u>25,937</u>
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	<u>8,151</u>	<u>4,149</u>	<u>4,002</u>
Loss before income taxes	(43,253)	(21,318)	(21,935)
Income tax expense	(105)	(66)	(39)
Net loss	<u>\$ (43,358)</u>	<u>\$ (21,384)</u>	<u>\$ (21,974)</u>

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,		Variance
	2021	2020	
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	<u>\$ 146,035</u>	<u>\$ 22,360</u>	<u>\$ 123,675</u>

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†	Collaboration and License Agreement, effective as of June 9, 2021, by and between 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

CERTAIN INFORMATION IN THIS DOCUMENT, MARKED BY [*], HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(b)(10)(iv). SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

COLLABORATION AND LICENSE AGREEMENT

BY AND BETWEEN

VERONA PHARMA PLC

AND

NUANCE PHARMA LIMITED

AND

NUANCE (SHANGHAI) PHARMA CO LTD

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COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (this “Agreement”) is deemed by the parties to be effective on June 9, 2021 (“Effective Date”) between Verona Pharma plc, with a principal place of business at 3 More London Riverside, London, SE1 2RE, United Kingdom (“Verona”), and Nuance Pharma Limited, with a principal place of business at Room 639, East Tower, Shanghai Centre, 1376 West Nanjing Road, Shanghai, the PRC (“Nuance”) and Nuance (Shanghai) Pharma Co Ltd, with a principal place of business at Room 639, East Tower, Shanghai Centre, 1376 West Nanjing Road, Shanghai, the PRC (“Nuance Shanghai”).

Verona and Nuance may be referred to herein individually as a “Party” and collectively as the “Parties”.

RECITALS

WHEREAS, Verona is the owner of, or otherwise controls, the Verona Technology in the Territory (each as defined below);

WHEREAS, Nuance is interested in obtaining an exclusive license to Develop and Commercialize the Licensed Products in the Territory (each as defined below); and

WHEREAS, the Parties desire for Verona to grant such license to Nuance to Develop and Commercialize the Licensed Products in the Territory, all under the terms and conditions as set forth in this Agreement.

NOW THEREFORE, the Parties agree as follows:

Article I.

DEFINITIONS

Section I.1 “Accounting Standards” means, with respect to Nuance, the then-current IFRS; with respect to any Nuance Entity established in the Mainland China, the then-current Generally Accepted Accounting Principles of the Mainland China; and with respect to Verona, the then-current U.S. Generally Accepted Accounting Principles, in each case as consistently applied.

Section I.2 “Affiliate” means, with respect to an entity, any corporation or other business entity controlled by, controlling, or under common control with such entity, with “control” meaning (a) direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of, or at least a fifty percent (50%) interest in the income of, the applicable entity (or such lesser percentage that is the maximum allowed to be owned by a foreign entity in a particular jurisdiction and is sufficient to grant the holder of such voting stock or interest the power to direct the management and policies of such entity) or (b) possession, directly or indirectly, of the power to direct the management and policies of an entity, whether through

ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise.

Section I.3 “Business Day” means a day other than (a) a Saturday or a Sunday or (b) a day on which banking institutions in London, UK, or in Shanghai, China, are authorized or required by Law to remain closed.

Section I.4 “Clinical Study” means human clinical trials for a Licensed Product and any other tests and studies for a Licensed Product in human subjects.

Section I.5 “CMO” means a contract manufacturing organization.

Section I.6 “Commercialization” or “Commercialize” means, with respect to a pharmaceutical product, any and all activities directed to the marketing, promotion, importation, distribution (including without limitation importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering the product to customers), pricing, Reimbursement Approval, offering for sale, sales force training, or sale of such pharmaceutical product, and interacting with Regulatory Authorities regarding the foregoing. Commercialization shall exclude Development and Manufacturing.

Section I.7 “Commercially Reasonable Efforts” means, with respect to the performing Party under this Agreement [***].

Section I.8 “Confidential Information” means, subject to Section 12.02(a)-(d), Know-How and any technical, scientific, trade, research, manufacturing, business, financial, compliance, marketing, product, supplier, intellectual property or other information that may be disclosed by one Party or any of its Affiliates to the other Party or any of its Affiliates, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form. Notwithstanding the foregoing, subject to Section 12.02(a)-(d), all information that (a) was disclosed prior to the Effective Date by or on behalf of either Party or any of its Affiliates under, and subject to, the Confidentiality Agreement dated April 19, 2021 between Nuance and Verona (“Confidentiality Agreement”) and (b) is “Confidential Information” as defined in the Confidentiality Agreement, shall be deemed “Confidential Information” hereunder.

Section I.9 “Controlled” means, with respect to a Party, and any Know-How, Patent Right, Regulatory Documents or other intellectual property right, that such Party or any of its Affiliates has the ability (other than pursuant to a license granted to such Party under this Agreement) to grant to the other Party a license or sublicense on the terms set out in this Agreement to such Know-How, Patent Right, Regulatory Documents or other intellectual property right without violating the terms of any pre-existing agreement or other pre-existing arrangement with any Third Party.

Section I.10 “COPD” means chronic obstructive pulmonary disease.

Section I.11 “Cost of Goods Sold” or “COGS” means, with respect to particular Licensed Product, the reasonable internal and Out-of-Pocket Costs of Verona or any of its Affiliates incurred in Manufacturing such Licensed Product, including:

(a) to the extent that the Licensed Product is Manufactured by Verona or any of its Affiliates, Verona’s or its Affiliates’ fully burdened costs including direct material and direct labor costs, logistics costs, plus manufacturing overhead directly attributable only to the Licensed Product (including quality assurance and quality control activities, sales, excise or other taxes imposed thereon, customs duties, import, export and other charges levied by Government Authorities, all costs of shipping and insuring such materials, facility start-up costs, directly incurred manufacturing variances, warehousing costs, costs to maintain inventory and a reasonable allocation of related manufacturing, corporate, administrative and facilities costs (including depreciation) and a reasonable allocation of the costs of failed batches and validation batches to be further described in the applicable Supply Agreement, to be provided for the Licensed Product, but excluding costs associated with excess capacity), all determined in accordance with the books and records of Verona or its applicable Affiliate(s) maintained in accordance with the Accounting Standards, consistently applied and as supported by reasonable evidence (such as contracts or invoice) that shall be provided to Nuance upon Nuance’s request; and

(b) to the extent that the Licensed Product is Manufactured for Verona by a Third Party CMO for provision by Verona to Nuance, the Out-of-Pocket Costs paid by Verona or any of its Affiliates to the Third Party CMO for the Manufacture of the Licensed Product, plus all reasonably allocated costs of Verona and its Affiliates as described in the foregoing clause (a) incurred in managing or overseeing the sourcing of such Licensed Product from such Third Party CMO, determined in accordance with the books and records of Verona or its applicable Affiliate(s) maintained in accordance with the Accounting Standards, consistently applied and as supported by reasonable evidence (such as contracts or invoice) that shall be provided to Nuance upon Nuance’s request.

Section I.12 “Cover”, “Covering” or “Covered” means, with respect to a product, composition, technology, process or method and a Patent Right, that, in the absence of ownership of, or a license granted under, a claim in such Patent Right, the manufacture, use, offer for sale, sale or importation of such product or composition or the practice of such technology, process or method would infringe such claim (or, in the case of a claim of a pending patent application, would infringe such claim if it were to issue as a claim of an issued patent).

Section I.13 “Develop” or “Development” means pre-clinical research, clinical development activities and other non-clinical testing, test method development and stability testing, including (i) clinical trials of a pharmaceutical compound or product, investigator sponsored trials and registry studies and (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct clinical trials or obtain Regulatory Approval of a pharmaceutical product. Development shall include clinical trials initiated prior to or following receipt of Regulatory Approval, but shall exclude Manufacturing and Commercialization.

Section I.14 “Development Plan” means the draft plan based on preliminary information provided by Verona prior to the execution of this Agreement, setting out activities to be undertaken in Developing the Licensed Products in the Field in the Territory, attached hereto as Schedule 2.05, which draft plan will be revised based on the information and documents to be provided by Verona in accordance with Section 2.02 and subject to approval of JSC and as may be amended from time to time in accordance with Section 4.01 (Development in the Field in the Territory; Diligence).

Section I.15 “Dollars” or “\$” means the legal tender of the U.S.

Section I.16 “Drug Approval Application” means a New Drug Application as defined in the FD&C Act, or an equivalent application filed with any Regulatory Authority in any country other than the United States.

Section I.17 “FDA” means the U.S. Food and Drug Administration or any successor agency thereto.

Section I.18 “FD&C Act” means the U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time.

Section I.19 “Field” means any and all uses in humans.

Section I.20 “First Commercial Sale” means, for each Licensed Product in the Field in a Jurisdiction, the first sale for end use or consumption of such Licensed Product in the Field in such Jurisdiction by any Nuance Entity in an arms’ length transaction to a Third Party following receipt of applicable Regulatory Approval of such Licensed Product in such Jurisdiction. Sales for test marketing, compassionate use prior to Regulatory Approval, or clinical trial purposes shall not constitute a First Commercial Sale.

Section I.21 “Generic Product” means, with respect to a Licensed Product in a particular Jurisdiction, any pharmaceutical product that (a) is approved, or sought to be approved, by a Regulatory Authority in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Licensed Product as determined by the applicable Regulatory Authority, including any product authorized for sale (i) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FDCA (21 U.S.C. § 355(b)(2) and 21 U.S.C. § 355(j), respectively), (ii) in the EU pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or (iii) in any other country or jurisdiction pursuant to all equivalents of such provisions, including any amendments and successor statutes with respect to the subsections (i) through (iii) thereto; (b) is sold in such Jurisdiction by a Third Party that is not a sublicensee of Nuance and did not purchase such product, or a component thereof, in a chain of distribution that included any of Nuance or its Affiliates or sublicensees; and (c) causes at least fifty percent (50%) decline in sales unit of such Licensed Product as measured over the preceding four (4) months.

Section I.22 “Governmental Authority” means any federal, national, multinational, state, provincial, county, city or local government or any court, arbitrational tribunal, administrative agency or commission or government authority acting under the authority of any federal, national, multinational, state, provincial, county, city or local government.

Section I.23 “Improvement” means any Inventions that (a) improve or otherwise offer advantages in respect of development, manufacture and/or performance of the Licensed Products, or (b) are specific to the Licensed Products.

Section I.24 “IND” means an Investigational New Drug application for submission to the FDA, the NMPA or any equivalent counterpart application in any country other than the United States (including a clinical trial application in Mainland China), including all supplements and amendments thereto.

Section I.25 “Inventions” means any developments, discoveries, inventions or other intellectual property rights, whether patentable or not, made by a Party (either solely or jointly), its Affiliates or (sub)licensees, or on behalf of any of the foregoing entities by their respective employees, agents, and independent contractors during the performance of activities under this Agreement.

Section I.26 “Jurisdiction” means each of the following: (a) Mainland China, (b) Taiwan, (c) Hong Kong, and (d) Macau.

Section I.27 “Know-How” means inventions (whether patentable or not), discoveries, trade secrets, technology, information, formulae, practices, methods, knowledge, know-how, processes, procedures, results and test data (including physical, chemical, biological, toxicological, pharmacological, clinical, veterinary, analytical and quality control data), dosage regimens, control assays, product specifications, and marketing, pricing, distribution cost and sales data and descriptions; but excluding Patent Rights.

Section I.28 “Law” means any law, statute, rule, regulation, order, judgment, standard or ordinance of any Governmental Authority.

Section I.29 “Licensed Compound” means the dual inhibitor of the phosphodiesterase 3 (PDE3) and phosphodiesterase 4 (PDE4) enzymes developed and controlled by Verona, known as Ensifentrine.

Section I.30 “Licensed Product” means any pharmaceutical product, in any dosage strength or formulation, containing a Licensed Compound as an active ingredient, alone or in combination with one or more other active ingredients.

Section I.31 “Mainland China” means the People’s Republic of China (“PRC”), for the purposes of this Agreement, excluding Taiwan, Hong Kong and Macau.

Section I.32 “Manufacture” or “Manufacturing” means, as applicable, all activities associated with the production, manufacture, process of formulating, processing, filling,

finishing, packaging, labeling, shipping, importing or storage of pharmaceutical compounds or materials, including process development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release.

Section I.33 “Net Sales” means the gross invoice price of a particular Licensed Product sold or otherwise transferred to a Third Party (other than a Nuance Entity or any of its sublicensees and (sub)contractors) by any Nuance Entity or any of its sublicensees for consideration, reduced by the following amounts actually taken and specifically allocated to the Licensed Product, all as calculated in accordance with and to the extent acceptable under Accounting Standards, consistently applied:

(a) discounts (including trade, quantity and cash discounts) actually allowed, cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any Third Party (including to governmental authorities, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations or entities (and other similar entities and institutions));

(b) credits or allowances, if any, on account of price adjustments, recalls, claims, damaged goods, rejections or returns of items previously sold (including Licensed Product returned in connection with recalls or withdrawals) and amounts written off by reason of uncollectible debt; *provided* that, if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid;

(c) rebates (or their equivalent), administrative fees, chargebacks and retroactive price adjustments and any other similar allowances granted by a Nuance Entity or any of its sublicensees (including to governmental authorities, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations or entities (and other equivalent entities and institutions)) which effectively reduce the selling price or gross sales of the Licensed Product, normal and customary inventory management fees and other bona fide services paid to distributors and wholesalers;

(d) insurance, customs charges, freight, postage, shipping, handling, and other transportation costs incurred by a Nuance Entity or any of its sublicensees in shipping Licensed Product to a Third Party, provided that such amounts shall not exceed [***] of the gross invoiced amounts net of the amounts described in subsections (a)-(c) and (e) of such Licensed Product; and

(e) import taxes, export taxes, excise taxes, sales tax, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined or imposed with respect to such sales (excluding income or net profit taxes or franchise taxes of any kind);

provided that the aggregate amounts under subsections (a)-(e) shall not exceed[***] of the gross invoiced amounts of such Licensed Product.

If non-monetary consideration is received by a Nuance Entity or any of its sublicensees for any Licensed Product in the relevant Jurisdiction, Net Sales will be calculated based on the average price charged for such Licensed Product, as applicable, during the preceding royalty period, or in the absence of such sales, the fair market value of the Licensed Product, as applicable, as determined by the Parties in good faith. Notwithstanding the foregoing, Net Sales shall not be imputed to transfers of Licensed Products, as applicable, for use in clinical trials, non-clinical Development activities or other Development activities with respect to Licensed Products by or on behalf of the Parties, for *bona fide* charitable purposes or for compassionate use or for Licensed Product samples, if no monetary consideration is received for such transfers. For clarity, Net Sales shall include monetary consideration received for the transfer of Licensed Product in connection with any named patient sales.

Section I.34 “NMPA” means China’s National Medical Products Administration, including its divisions and the Center for Drug Evaluation, and local counterparts thereto, and any successor agency or authority thereto having substantially the same function.

Section I.35 “Nuance Entity” means, as applicable, (a) Nuance, (b) any of Nuance’s Affiliates or (c) any direct sublicensee or (sub)contractor of Nuance or any of Nuance’s Affiliates with respect to any Licensed Product. Nuance shall be responsible for the breach of this Agreement by any Nuance Entity.

Section I.36 “Nuance Know-How” means all Know-How that is both (a) Controlled as of the Effective Date or during the Term by Nuance and (b) necessary or reasonably useful for the Development, Manufacture or Commercialization of any Licensed Product.

Section I.37 “Nuance Patent Rights” means all Patent Rights that are both (a) Controlled as of the Effective Date or during the Term by Nuance and (b) necessary or reasonably useful for the Development, Manufacture or Commercialization of any Licensed Product.

Section I.38 “Nuance Regulatory Documents” means Regulatory Documents Controlled by Nuance at any time during the Term that relate to a Licensed Product in the Territory.

Section I.39 “Nuance Technology” means Nuance Know-How and Nuance Patent Rights.

Section I.40 “Out-of-Pocket Costs” means amounts paid by a Party or any of its Affiliates to a Third Party for goods or services but shall not include such Party’s, or any of its Affiliates’, internal or general overhead costs or expenses.

Section I.41 “Patent Right(s)” means (a) all patents and patent applications (including provisional applications) in any country or jurisdiction, and (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like.

Section I.42 “Phase III Clinical Study” means a Clinical Study of a Licensed Product that meets the definition of a Phase III study in the Clinical Trial Regulation EU No 536/2014 and for the United States as described in 21 C.F.R. §312.21(c), or its successor regulation, or the equivalent regulation in any other country.

Section I.43 “Regulatory Approval” means, with respect to a particular regulatory jurisdiction, an approval, license, registration or authorization of any Governmental Authority (including Reimbursement Approval) that provides marketing approval for the commercial sale of a pharmaceutical product in one or more specified indications in such regulatory jurisdiction.

Section I.44 “Regulatory Authority” means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including (a) in the United States, the FDA and any other applicable Governmental Authority in the United States having jurisdiction over pharmaceutical products, (b) in Europe Union, the European Medicines Agency (“EMA”), (c) in Mainland China, the NMPA and (d) any other applicable Governmental Authority in the Territory having jurisdiction over pharmaceutical products.

Section I.45 “Regulatory Documents” means, all (a) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations, approvals (including Regulatory Approvals) and marketing or regulatory exclusivities; (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files and complaint files; and (c) preclinical, clinical and other data, results, analyses, publications, and reports contained or referred to in any of the foregoing. For the avoidance of doubt, Regulatory Documents include Regulatory Approvals and Regulatory Filings.

Section I.46 “Regulatory Filings” means all applications, filings, dossiers and the like submitted to a Regulatory Authority for the purpose of Developing, Manufacturing or Commercializing a product, including obtaining Regulatory Approval from that Regulatory Authority. Regulatory Filings include all INDs, Drug Approval Applications and other Regulatory Approval and Reimbursement Approval applications.

Section I.47 “Reimbursement Approval” means an approval, agreement, determination, or other decision by any applicable Regulatory Authority or other Governmental Authority that establishes prices at which a pharmaceutical product may be priced, or will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities, in a particular country or jurisdiction.

Section I.48 “Safety Data Exchange Agreement” means that agreement to be entered by and between the Parties regarding receipt, investigation and reporting of product complaints, adverse events, product recalls, and any other information related to the safety of the Licensed Products as set forth in Section 10.02 (Adverse Drug Events).

Section I.49 “Supply Price” means [***].

Section I.50 “Territory” means any Jurisdiction, or, collectively, all Jurisdictions, as the context requires.

Section I.51 “Third Party” means any person or entity other than the Parties and their Affiliates.

Section I.52 “Trademark” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

Section I.53 “U.S.” or “United States” means the United States of America, including its districts, territories and possessions.

Section I.54 “Valid Claim” means (a) any claim of any Patent Right that has issued, is unexpired and has not been rejected, revoked or held unenforceable or invalid by a final, non-appealable (or unappealed within the time allowable for appeal) decision of a court or other Governmental Authority of competent jurisdiction or (b) any claim of any patent application that has (i) been pending for [***] or less from the date of issuance of the first substantive patent office action considering the patentability of such claim by the applicable patent office in the applicable country or jurisdiction and (ii) not been cancelled, lapsed, revoked, withdrawn, abandoned, dedicated to the public, or finally rejected by an administrative agency action from which no appeal can be taken.

Section I.55 “Verona Entity” means, as applicable, (a) Verona or (b) any of Verona’s Affiliates. Verona shall be responsible for the breach of this Agreement by any Verona Entity.

Section I.56 “Verona Know-How” means all Know-How that is both (a) Controlled as of the Effective Date or during the Term by Verona and (b) necessary or reasonably useful for the Development or Commercialization of any Licensed Product in the Field in the Territory.

Section I.57 “Verona Marks” means (a) the Trademarks, names and logos to be developed by Verona, (b) the Trademarks (in their native language or any translation thereof) with respect to any Licensed Product outside the Territory, and (c) such other Trademarks, names and logos as Verona may designate in writing from time to time.

Section I.58 “Verona Patent Rights” means all Patent Rights that are both (a) Controlled as of the Effective Date or during the Term by Verona in the Territory and (b) necessary or reasonably useful for the Development or Commercialization of any Licensed Product in the Field in the Territory. The list of Verona Patent Rights existing as of the Effective Date is attached hereto as Exhibit A.

Section I.59 “Verona Regulatory Documents” means Regulatory Documents Controlled by Verona as of the Effective Date or at any time during the Term that relate to a Licensed Product.

Section I.60 “Verona Technology” means Verona Know-How, Verona Marks and Verona Patent Rights. For clarity, Verona Technology shall include Improvements.

Additional Defined Terms	Section
Acquiring Party	Section 2.04
Alliance Manager	Section 3.10
Arbitration Request	Section 15.01(a)
Bankrupt Party	Section 14.04(a)
Breaching Notice	Section 14.03
Breaching Party	Section 14.03
Buy-Back Notice	Section 2.04
Buy-Back Option	Section 2.04
Buy-Back Price	Section 2.04
Confidentiality Agreement	Section 1.08
EMA	Section 1.44
Event of Bankruptcy	Section 14.04(a)
Executive Officer	Section 3.06
FCPA	Section 11.04(b)(i)
Global Partner	Section 2.04
Global Partnership	Section 2.04
Government Official	Section 11.04(a)
ICC	Section 15.01(c)
ICH	Section 10.01
Indemnified Party	Section 13.03
Indemnifying Party	Section 13.03
Infringement Activity	Section 9.03(a)
Joint Inventions	Section 9.01(d)
Joint Patent Rights	Section 9.01(d)
JSC	Section 3.01(a)
Losses	Section 13.01
Non-breaching Party	Section 14.03
Nuance Indemnitee	Section 13.01
Nuance License Investment	Section 2.04
Nuance Product Data	Section 5.01(e)
Other Covered Party	Section 11.04(a)
Other Party	Section 14.04(a)
Payment	Section 8.09
Public Statement	Section 12.04
Recipient	Section 12.02
Representatives	Section 12.01
Royalty Term	Section 8.04(b)

Rules	Section 15.01
Severed Clause	Section 17.03
Supply Agreement	Section 7.01
Supply Request	Section 7.01
Term	Section 14.01
Verona Indemnitee	Section 13.02
Verona Product Data	Section 2.02(c)

Section I.61 Interpretation. (a) Whenever any provision of this Agreement uses the word “including,” “include,” “includes,” or “e.g.,” such word shall be deemed to mean “including without limitation” and “including but not limited to”; (b) “herein,” “hereby,” “hereunder,” “hereof” and other equivalent words shall refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) a capitalized term not defined herein but reflecting a different part of speech from that of a capitalized term which is defined herein shall be interpreted in a correlative manner; (d) wherever used herein, any pronoun or pronouns shall be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the Schedules and the Exhibits to this Agreement, and the terms and conditions incorporated in such recitals and Schedules and Exhibits, shall be deemed integral parts of this Agreement and all references in this Agreement to this Agreement shall encompass such recitals and Schedules and Exhibits and the terms and conditions incorporated in such recitals and Schedules and Exhibits; *provided* that, in the event of any conflict between the terms and conditions of the body of this Agreement and any terms and conditions set forth in the recitals, Schedules or Exhibits, the terms of the body of this Agreement shall control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement or otherwise, the terms and conditions of this Agreement shall govern; (g) this Agreement shall be construed as if both Parties drafted it jointly, and shall not be construed against either Party as principal drafter; (h) unless otherwise provided, all references to Sections, Articles and Schedules in this Agreement are to Sections, Articles, Exhibits and Schedules of and to this Agreement; (i) any reference to any Law shall mean such Law as in effect as of the relevant time, including all rules and regulations thereunder and any successor Law in effect as of the relevant time, and including the then-current amendments thereto; (j) wherever used, the word “shall” and the word “will” are each understood to be imperative or mandatory in nature and are interchangeable with one another; (k) references to a Party’s knowledge shall be taken to refer to the actual knowledge of such Party’s CEO and his/her direct reports as of the Effective Date; (l) the captions and table of contents used herein are inserted for convenience of reference only and shall not be construed to create obligations, benefits or limitations; and (m) the word “year” means any consecutive twelve (12) month period, unless otherwise specified.

Article II.

LICENSES

Section II.01 Grants of Licenses.

(a) Subject to the terms and conditions of this Agreement, Verona hereby grants to Nuance an exclusive (including as to Verona and its Affiliates), royalty-bearing, sublicensable (in accordance with Section 2.03 (Sublicense)), non-transferable (except in accordance with Section 16.01 (Assignment)) license under the Verona Technology to Develop and Commercialize Licensed Products in the Field in the Territory.

(b) Subject to the terms and conditions of this Agreement, Nuance hereby grants to Verona (i) an exclusive, sublicensable, royalty-free, non-transferable (except in accordance with Section 16.01 (Assignment)) license under the Nuance Technology to Develop, Manufacture and Commercialize Licensed Products in the Field outside the Territory; and (ii) a non-exclusive, sublicensable, royalty-free, non-transferable (except in accordance with Section 16.01 (Assignment)) license under the Nuance Technology to Manufacture Licensed Product in the Territory solely for use in the Development or Commercialization of Licensed Products in the Field outside the Territory.

(c) As between the Parties, all rights not expressly licensed to Nuance under the Verona Technology in Section 2.01(a) shall be expressly retained by Verona, including the right to Develop and Commercialize the Licensed Product outside the Territory and the right to Manufacture the Licensed Product anywhere in the world for use in the Development or Commercialization of Licensed Products outside the Territory. As between the Parties, all rights not expressly licensed to Verona under the Nuance Technology in Section 2.01(b) shall be expressly retained by Nuance.

Section II.02 Technology Sharing.

(a) Verona shall provide to Nuance electronic copies of the documents relating to Licensed Products set forth on Exhibit B hereto promptly after the Effective Date but in any event within ninety (90) days of the Effective Date.

(b) To the extent not included in Exhibit B, Verona shall also provide to Nuance all Verona Know-How, and all other additional data and documents existing as of the Effective Date that are Controlled by the Verona Entity and reasonably necessary for the Nuance Entity to Develop or Commercialize Licensed Product in the Field in the Territory in accordance with this Agreement, which Nuance did not and could not reasonably know of.

(c) Throughout the Term, Verona shall provide Nuance with an update of any material regulatory developments (e.g., NDA filed, meetings with Regulatory Authority, or Regulatory Approval) relating to a Licensed Product made by the Verona Entity, and upon Nuance's request, Verona shall make available to Nuance copies of Regulatory Documents, clinical and preclinical data, and efficacy, safety and pharmacovigilance data, in each case that are related to Licensed Product in the Field and Controlled by the Verona Entity (collectively, the "Verona Product Data"), to the extent such Verona Product Data is reasonably necessary for any Nuance Entity to Develop or Commercialize Licensed Product in the Field in the Territory in accordance with this Agreement.

(d) No provision of this Agreement shall require Verona to provide to Nuance any intellectual property or information (including Know-How, data, documents or files) licensed to, or provided to, Verona by Ligand UK Development Limited (formerly Vernalis Development Limited).

(e) Throughout the Term, Verona shall provide reasonable technical assistance as reasonably requested by Nuance in support of the Development and Commercialization of the Licensed Product in the Field in the Territory, at Nuance's costs and expenses.

Section II.03 Sublicenses. Nuance shall have the right to sublicense its rights under Section 2.01(a) to Develop and Commercialize any Licensed Product in all or part of the Territory in the Field, provided that (a) Nuance shall remain ultimately responsible to Verona for the performance of all its obligations under this Agreement, (b) each such sublicense shall be in writing and shall be consistent with the terms and conditions of this Agreement; (c) Nuance shall provide a copy of the proposed sublicense agreement (including the sublicense agreements with third-party contract research organizations) to Verona with respect to each such sublicense and obtain Verona's prior written consent; provided that no such consent shall be required for any sublicense to an Affiliate of Nuance; and (d) Nuance shall provide Verona with a true and complete copy of such sublicense after execution. If Nuance entrusts certain activities related to Commercialization of the Licensed Product to third party distributors, sub-distributors or sales agents (collectively, "Distributors"), and grants such sublicense to the Distributors to the extent necessary or appropriate for them to conduct the so entrusted activities, the prior written approval from Verona shall be waived, provided, that, Nuance shall disclose the list of the Distributors so engaged to Verona and shall update such list on a quarterly basis, and such Distributors shall comply with all applicable law, including without limitation all anti-corruption laws, in all material respects. Verona shall have the right to object to the use of any particular Distributor for compliance purpose, in which case Nuance shall either cause such Distributor to remedy the relevant compliance issue within a reasonable time period or switch to a different Distributor reasonably acceptable to Nuance for compliance purpose.

Section II.04 Verona Buy-Back Option. At any time after the Effective Date until three (3) months prior to the expected submission of the first New Drug Application for a Licensed Product in the Field in the Territory pursuant to the China clinical development timeline attached hereto as Schedule 2.05, if (i) a Third Party ("Global Partner") is interested in partnering with Verona, either globally or in territory covering at least U.S. or Europe, for the Development and/or Commercialization of the Licensed Product ("Global Partnership"), or (ii) Verona undergoes a Change of Control (the acquiring or successor entity in such Change of Control, the "Acquiring Party"), Verona will have an exclusive option right (the "Buy-Back Option") to buy back the license granted to Nuance pursuant to Section 2.01(a) (including any sublicenses granted by Nuance pursuant to Section 2.03) and all related assets including all preclinical and clinical data, Clinical Study files, Regulatory Documents and Regulatory Approvals relating to the Licensed Product, taking into account the progress made by Nuance in the Development of the Licensed Product. At any time between [***] and [***], Verona may notify Nuance in writing ("Buy-Back Notice") and Verona shall pay Nuance the following amount (such amount the "Buy-Back Price"): (x) all amounts paid by Nuance to Verona in cash under this Agreement up to the date of

the Buy-Back Notice, and (y) [***] times the amount of all development and regulatory costs incurred and paid by Nuance in connection with the Development and Commercialization of the Licensed Products under this Agreement and costs incurred and paid by Nuance to transfer to Verona the license granted to Nuance pursuant to Section 2.01(a) and all related assets (the “Nuance License Investment”), if Nuance receives the Buy-Back Notice before the earlier of [***] or [***], or [***] times the Nuance License Investment if Nuance receives the Buy-Back Notice after [***]; provided that in no event shall Verona be required to pay Nuance under this subsection (y) more than [***]. Verona shall have the right to examine Nuance’s books and records to be examined, at its own costs and expenses, through an independent accounting firm selected by Verona and reasonably acceptable to Nuance, to verify the accuracy of the Nuance License Investment, upon reasonable notice and during regular business hours and subject to a reasonable confidentiality agreement. Verona will pay Nuance the Buy-Back Price [***]. Upon Verona’s payment of the Buy-Back Price, this Agreement shall terminate and Section 14.06 (Effect of Termination) shall apply. For clarity, Verona shall have the right to determine whether to exercise the Buy-Back Option, at its sole discretion, and if Verona exercises the Buy-Back Option, Verona shall have the rights to retain the equity interests received under Section 8.01(b). For further clarity, after delivering a Buy-Back Notice to Nuance pursuant to this Section 2.04, Verona may at its sole discretion withdraw such Buy-Back Notice any time before it pays Nuance the Buy-Back Price, in which case this Agreement shall remain effective.

Section II.05 Non-Compete. During the Term, Nuance shall not, and shall cause any Nuance Entity to not, engage in (independently or for or with any Third Party) any Development, Manufacture or Commercialization of any product that (a) is not a Licensed Product, and (b) has the same active pharmaceutical ingredient or essentially the same mechanism of action as the Licensed Product and for any respiratory indication(s).

Article III.

GOVERNANCE

Section III.01 General.

(a) The Parties shall establish a Joint Steering Committee (“JSC”) to oversee and coordinate the overall conduct of the Development and Commercialization of Licensed Products in the Field in the Territory. The JSC shall have decision-making authority with respect to the matters within its purview to the extent expressly provided herein.

Section III.02 Joint Steering Committee.

- (a) Within thirty (30) days following the Effective Date, the Parties shall establish the JSC. The JSC shall:
- (i) review and approve the Development Plan and protocols for Clinical Studies;

(ii) discuss and approve any material variations (i.e., variations greater than [***]) with respect to any element or line item of the China clinical development timeline attached hereto as Schedule 2.05;

(iii) discuss the strategic direction of the Development (including the Development Plan) and Commercialization of the Licensed Products in the Field in the Territory;

(iv) monitor and discuss the progress of the Development (including the Development Plan) and Commercialization of the Licensed Products in the Field in the Territory and serve as a forum for exchanging information regarding the conduct of the Development and Commercialization of the Licensed Products in the Field in the Territory;

(v) discuss and approve pricing of the Licensed Products in the Field in the Territory and strategies for price negotiations with Governmental Authorities and Reimbursement Approval in the Territory;

(vi) determine whether to create any additional subcommittee(s) or working group(s);

(vii) serve as a forum for dispute resolution in accordance with Section 3.05 (JSC Decision Making); and

(viii) perform such other duties as are specifically assigned to the JSC under this Agreement.

Section III.03 Membership. The JSC shall be composed of two (2) representatives from each of Verona and Nuance, each of which representatives shall be of the seniority and experience appropriate for service on the JSC in light of the functions, responsibilities and authority of such committee and the status of activities within the scope of the authority and responsibility of such committee. Each Party may replace any of its representatives on the JSC at any time with written notice to the other Party; *provided* that such replacement meets the standard described in the preceding sentence and the Executive Officer of each Party will consult with the Executive Officer of the other Party regarding the individual selected as the replacement prior to that individual being appointed. Each Party's representatives and any replacement of a representative shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in Article XII (Confidentiality). Each Party may invite a reasonable number of its or its Affiliates' employees as required or useful to discuss the applicable agenda items. The JSC shall appoint a chairperson from among its members, with the first chairperson of the JSC being a representative of Nuance. Each chairperson (whether initially appointed or any successor therefor) shall serve a term of one (1) year, at which time, the JSC shall select a successor chairperson who is a representative of the Party other than the Party represented by the outgoing chairperson (*e.g.*, the second chairperson of the JSC shall be a representative of Verona, the third chairperson of the JSC shall be a representative of Nuance, etc.). Within fifteen (15) days following each JSC meeting, the chairperson shall circulate to all committee members a draft of the minutes of such meeting. The JSC shall then approve, by mutual agreement, such minutes within fifteen (15)

days following circulation. No chairperson of the JSC shall have any greater authority than any other representative of such committee.

Section III.04 Meetings. The JSC shall hold an initial meeting within thirty (30) days after its formation or as otherwise agreed by the Parties. Thereafter, unless the Parties otherwise agree, the JSC shall meet in person or by video or teleconference at least once each calendar quarter. Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in JSC meetings.

Section III.05 JSC Decision Making. All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote, and shall be set forth in minutes approved by both Parties. If the JSC is unable to reach agreement on any matter within ten (10) Business Days after a matter is referred to it or first considered by it, such matter shall be referred to the Executive Officers for resolution in accordance with Section 3.06 (Executive Officers; Disputes).

Section III.06 Executive Officers; Disputes. Each Party shall ensure that an executive officer is designated for such Party at all times during the Term for dispute resolution purposes (each such individual, such Party's "Executive Officer"), and shall promptly notify the other Party of its initial, or any change in its, Executive Officer. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties shall refer such dispute to the Executive Officers, who shall attempt in good faith to resolve such dispute.

Section III.07 Final Decision-Making Authority. If the Parties are unable to resolve a given dispute within the purview of the JSC within fifteen (15) Business Days after referring such dispute to the Executive Officers pursuant to Section 3.06 (Executive Officers; Disputes), then, subject to Section 3.08 (Limitations on Decision-Making):

(a) Verona shall have the deciding vote on all matters related to (i) the Development and Commercialization of Licensed Product outside the Territory; [***].

(b) Nuance shall have the deciding vote on all matters directly related to the Development and Commercialization of Licensed Product in the Field in the Territory, excluding [***].

(c) Any decision made by an Executive Officer in accordance with this Section 3.07 (Final Decision-Making Authority) shall be deemed to be a decision of the JSC.

Section III.08 Limitations on Decision-Making.

(a) The JSC shall not have any authority other than that expressly set forth in Section 3.02 and matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement or other subsequent agreements between the Parties, are outside the jurisdiction and authority of the JSC. Specifically, the JSC shall have no authority in the following matters:

(i) the imposition of any requirements on the other Party to undertake obligations beyond those for which it is responsible, or to forgo any of its rights, under this Agreement;

(ii) the imposition of any requirements that the other Party takes or declines to take any action that would result in a violation of any Law or any agreement with any Third Party or the infringement of intellectual property rights of any Third Party;

(iii) the resolution of any dispute involving the breach or alleged breach of this Agreement;

(iv) the determination of whether either Party exerts Commercially Reasonable Efforts under this Agreement;

(v) any decision that is expressly stated to require the approval of the JSC or the mutual agreement (or similar language) of the Parties or the approval of the other Party;

(vi) any matters that would excuse a Party from any of its obligations under this Agreement; or

(vii) modifying the terms of this Agreement or taking any action to expand or narrow the responsibilities of the JSC.

(b) The decision-making Party shall make its decision in good faith, subject to the terms and conditions of this Agreement.

(c) In no event may the decision-making Party unilaterally determine that it has fulfilled any obligations hereunder or that the non-deciding Party has breached any obligations hereunder.

(d) In no event may Nuance unilaterally determine that the events required for the payment of milestone payments have not occurred.

(e) In no event may Verona unilaterally determine that the events required for the payment of milestone payments have occurred.

(f) For clarity, approval by the JSC shall not be understood to mean approval by a Party.

Section III.9 Scope of Governance. Notwithstanding the creation of the JSC or anything to the contrary in this Article III (Governance), each Party shall retain the rights, powers and discretion granted to it under this Agreement, and the JSC shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. It is understood and agreed that issues to be formally decided by the JSC are only those specific issues that are expressly provided in this Agreement to be decided by such committee.

Section III.10 Alliance Managers. Each of the Parties shall appoint a single individual to manage Development and Commercialization obligations between the Parties under this Agreement (each, an “Alliance Manager”). The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers may attend any JSC meetings. Each Alliance Manager shall be a non-voting participant in such Committee and Subcommittee meetings, unless s/he is also appointed a member of the JSC; *provided, however*, that an Alliance Manager may bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement. Each Party may change its designated Alliance Manager at any time upon written notice to the other Party, provided that the Executive Officer of each Party will consult with the Executive Officer of the other Party regarding the individual selected as the replacement prior to that individual being appointed. If a Party reasonably believes that the Alliance Manager of the other Party is underperforming with respect to his/her obligations under this Agreement, it will have the right to notify the other Party and such other Party shall reasonably review and remedy such issue. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Party’s Alliance Manager and any substitute for an Alliance Manager shall be bound by obligations of confidentiality and non-use applicable to the other Party’s Confidential Information that are at least as stringent as those set forth in Article XII (Confidentiality). Each Alliance Manager will also: (a) plan and coordinate cooperative efforts and internal and external communications; and (b) facilitate the governance activities hereunder and the fulfillment of action items resulting from JSC meetings.

Article IV.

DEVELOPMENT

Section IV.01 Development in the Field in the Territory; Diligence. Nuance shall use Commercially Reasonable Efforts (directly or through its Affiliates or sublicensees) to Develop Licensed Product in the Territory, at its sole costs and expenses. Within three (3) months after the completion of the Technology Sharing pursuant to Section 2.02(a), Nuance shall present a Development Plan to the JSC to be reviewed and approved by the JSC under Section 3.02(a). The Development Plan shall include, among other things, the nebulizer devices to be used with the Licensed Product in the Territory, and shall be focused on efficiently obtaining Regulatory Approval in the Territory, while taking into consideration potential impacts on Development, Regulatory Approval or Commercialization of the Licensed Products outside the Territory. Nuance shall comply with all applicable Laws in connection with its activities to Develop and seek Regulatory Approval for the Licensed Product under this Agreement and shall ensure such compliance by its Affiliates and sublicensees.

Section IV.02 Development Plan Updates. At least two (2) weeks in advance of the first meeting of the JSC in each calendar year, Nuance shall provide Verona with a written update of the Development Plan, including any amendments thereof. Any updates or amendment of the Development Plan shall be submitted to and approved by the JSC under Section 3.02(a).

Section IV.03 Development Report. Until the later of First Commercial Sale or completion of all Development Activities in the Territory, Nuance shall deliver to Verona an annual development update no later than the anniversary date of this Agreement, which report shall include a reasonably detailed summary of Development activities conducted in such reporting period and the results thereof, and the amount spent on Development activities conducted in such reporting period, in each case at a level of detail reasonably requested by Verona and sufficient to enable Verona to determine Nuance's compliance with its obligations to use Commercially Reasonable Efforts to Develop Licensed Product in the Territory.

Section IV.04 Records; Audits. Nuance shall maintain appropriate records in either tangible or electronic form of all significant Development activities, in each case in accordance with its usual documentation and record retention practices. Such records shall be in reasonably sufficient detail to properly reflect, in a good scientific manner, all significant work done, and the results of studies and trials undertaken and, further, shall be at a level of detail appropriate for patent and regulatory purposes. Upon Verona's reasonable request, Nuance shall, and shall cause its Affiliates and sublicensees, to provide to Verona copies of such records related to the Development of the Licensed Product in the Territory, to the extent available and Controlled by Nuance and its Affiliates. Upon reasonable notification, Verona shall be entitled to conduct an audit, [***], of any Nuance Entity's records of its Development activities for the Licensed Product in the Territory.

Article V.

REGULATORY

Section V.01 Regulatory Filings.

(a) Nuance shall have the responsibility and the right to prepare, obtain, and maintain all Regulatory Filings and Regulatory Approvals, and to conduct communications with the Regulatory Authorities in the Territory, for the Development or Commercialization of Licensed Products in the Field in the Territory undertaken by any Nuance Entity.

(b) All Nuance Regulatory Documents (including all Regulatory Approvals therein) shall be owned by, and shall be the sole property of, Nuance or its designated Nuance Entity. All Regulatory Filings and Regulatory Approvals in the Field in the Territory shall be at Nuance's sole expense. Nuance will lead and have control over preparing and submitting all regulatory filings related to Licensed Products for the Field in the Territory, including all applications for Regulatory Approval; provided, however, that it shall provide Verona the ability to review all such filings and submissions prior to submission and shall take in good faith consideration Verona's comments on such submission. Nuance shall provide all Regulatory Documents to Verona in English and bear the costs of any such translation.

(c) Verona shall, in support of Nuance's preparation and filing of any IND or Drug Approval Application with respect to any Licensed Product in the Field in the Territory, to the extent required and upon Nuance's written request, provide Nuance access to a complete electronic copy of and a right of reference to (i) all Regulatory Documents Controlled by any

Verona Entity (including those generated by any of Verona's sublicensees that are Controlled by Verona) that are related to any Licensed Product in the Field, and (ii) any other information that is Controlled by Verona and is requested by Regulatory Authorities in the Territory in connection with Nuance's Regulatory Filings, in each case ((i) through (ii)) to the extent permitted by applicable Law.

(d) Nuance shall provide Verona with copies of all relevant Regulatory Documents to the extent making claims relating to the Licensed Product that are not previously publicly available or previously approved by Verona at least ten (10) Business Days prior to submission for review and comment by Verona, and Nuance shall consider in good faith any comments received from Verona. In addition, Nuance shall notify Verona of material correspondences received from any Regulatory Authority related to any Licensed Product as soon as reasonably practical after receipt.

(e) Throughout the Term, upon Verona's request, Nuance shall make available to Verona copies of Nuance Regulatory Documents, clinical and preclinical data, and efficacy, safety and pharmacovigilance data, in each case that pertain to Licensed Product and are Controlled by the Nuance Entity (collectively, the "Nuance Product Data"), to the extent such Nuance Product Data are reasonably necessary for any Verona Entity or its (sub)licensees to Develop, Manufacture or Commercialize Licensed Product in the Field outside the Territory. Nuance hereby grants to the Verona Entity and its (sub)licensees a perpetual right to access, use and reference the Nuance Product Data and Nuance Regulatory Documents in any Regulatory Filing made by Verona (or its Affiliates or (sub)licensees as the case may be) pertaining to Licensed Product for the Development, Manufacture or Commercialization of Licensed Product in the Field outside the Territory.

Article VI.

COMMERCIALIZATION

Section VI.01 General; Diligence. Nuance (itself or through any of the Nuance Entities) shall have the sole right to Commercialize (including booking sales, interactions with Governmental Authorities to have Licensed Products listed on the central or provincial reimbursement list, warehousing, commercial distribution, order processing, invoicing and collection) the Licensed Products in the Field in the Territory at its sole expense. Nuance shall use Commercially Reasonable Efforts (directly or through a sublicensee) to Commercialize Licensed Product in the Territory after obtaining Regulatory Approval for such Licensed Product. Nuance shall mark all Licensed Products with the relevant patent numbers together with a statement that the Licensed Products are manufactured and/or sold under license.

Section VI.02 Promotional Materials. Each Party shall, if permitted, share with the other Party on a regular basis the Licensed Product promotional materials it (or, in the case of Verona, any Verona Entity or any of their respective sublicensees; or, in the case of Nuance, any Nuance Entity) used with respect to Licensed Product, and the other Party shall have the right to review and comment on such materials, which comments shall be considered in good faith by the Party

promulgating such materials. Notwithstanding the foregoing, Nuance shall have final decision rights related to promotional materials it shall use in the Territory.

Section VI.03 Commercialization Reports. At least two (2) weeks in advance of each meeting of the JSC, for any meeting of the JSC following the First Commercial Sale of any Licensed Product in the Field in the Territory, Nuance shall provide the JSC with a high level written report that summarizes Commercialization activities performed during the prior twelve (12) month period and anticipated to be performed within the subsequent twelve (12) month period with respect to each Licensed Product in each Jurisdiction in the Territory, and the amount spent on Commercialization activities conducted during the prior twelve (12) month period, in each case at a level of detail reasonably requested by Verona and sufficient to enable Verona to determine Nuance's compliance with its obligations to use Commercially Reasonable Efforts to Commercialize Licensed Product in the Territory.

Section I.04 Trademarks.

(a) Trademark Development. Verona shall notify Nuance when it has commenced global development of trademark(s) applicable to the Licensed Product. Verona shall provide Nuance with an opportunity to review and comment on the development of trademarks suitable for the Territory. Trademarks approved for use with the Licensed Product by Verona shall be deemed Verona Marks.

(b) Trademark License. Verona hereby grants to Nuance, for the Term, an exclusive authorized use license to the Verona Marks in the Field in the Territory in association with the Licensed Product. All use of the Verona Marks by Nuance, including goodwill, and rights to sue for past infringement, will inure to the benefit of Verona.

(c) Ownership. Nuance acknowledges that the Verona Marks are owned by Verona. The Verona Marks shall be and remain the sole and exclusive property of Verona. Nuance shall not contest the ownership of the Verona Marks or the validity of any registration relating thereto. Nuance agrees, at the request of Verona, to execute any and all proper documents appropriate to assist Verona in obtaining and maintaining Verona's rights in and to the Verona Marks.

(d) Use of Marks. Licensed Product distributed by Nuance under this Agreement shall bear the Verona Marks together with a notice that the Verona Marks are used under authorized license from Verona, subject to the approval of such labeling by appropriate Governmental Authorities. Nuance shall submit to Verona, for prior approval, which shall not be unreasonably withheld, a representative sample of any marketing, promotional or other materials to be used by Nuance, bearing the Verona Marks. Verona will communicate to Nuance its approval or disapproval within fifteen (15) Business Days of receipt of such sample. Upon Verona's request, Nuance will immediately cease use of any unapproved trademarks. In the event Verona modifies or changes any Verona Marks, Nuance will use Commercially Reasonable Efforts to promptly institute such modifications or changes as requested by Verona.

(e) No Similar Mark. Nuance will not, without Verona's prior written consent, register or use in connection with any product or service, any trademark that is confusingly similar to the Verona Marks, as determined by the Verona.

(f) In the event that Nuance cannot use the Verona Marks in the Territory, then Nuance shall select and submit to Verona local trademarks for use in the Territory, and obtain Verona's approval before using such trademarks, not to be unreasonably withheld, conditioned, or delayed, provided that any such trademark shall be owned by Nuance.

Section I.05 No Diversion. Each Party hereby covenants and agrees that, during the Term of the Agreement, it shall not, and shall ensure that its Affiliates and sublicensees will not, directly or indirectly, promote, market, distribute, import, sell or have sold the Licensed Products, including via internet or mail order, in the other Party's territory. With respect to any country in the other Party's territory, a Party shall not, and shall ensure that its Affiliates and their respective sublicensees will not: (a) establish or maintain any branch, warehouse or distribution facility for Licensed Products in such countries, (b) knowingly engage in any advertising or promotional activities relating to Licensed Products that are directed primarily to customers or other purchaser or users of Licensed Products located in such countries, (c) actively solicit orders for Licensed Products from any prospective purchaser located in such countries, or (d) knowingly sell or distribute Licensed Products to any person in such Party's territory who intends to sell or has in the past sold Licensed Products in such countries. If either Party receives any order for any Licensed Product from a prospective purchaser reasonably believed to be located in a country in the other Party's territory, such Party shall immediately refer that order to the other Party and such Party shall not accept any such orders. Each Party shall not deliver or tender (or cause to be delivered or tendered) Licensed Products into a country in the other Party's territory. Each Party shall not, and shall ensure that its Affiliates and their respective sublicensees will not, knowingly restrict or impede in any manner the other Party's exercise of its retained exclusive rights in the other Party's territory.

Article VII.

MANUFACTURE AND SUPPLY

Section VII.01 Manufacture and Supply of Licensed Products. Throughout the Term, each Nuance Entity shall have Verona supply to such Nuance Entity all quantities of Licensed Product that such Nuance Entity needs for the Development or Commercialization of Licensed Product in the Field in the Territory. In connection therewith, at a Nuance Entity's written request ("Supply Request"), but in no event later than one hundred and eighty (180) days following the Effective Date of this Agreement, Nuance and Verona will negotiate in good faith and enter into a supply agreement for clinical and/or commercial supply of Licensed Product and a related quality agreement (collectively with the aforementioned supply agreement between Nuance and Verona, the "Supply Agreement"). The Supply Agreement will be consistent with the terms set forth in this Section 7.01 (Manufacture and Supply of Licensed Products). From and after the execution of the Supply Agreement, and subject to the terms of such Supply Agreement, Verona will use Commercially Reasonable Efforts, either itself or through Third

Parties, to supply to the applicable Nuance Entity Licensed Product in quantities that are requested by Nuance for the conduct of Development and Commercialization of Licensed Product in the Field and in the Territory. The purchasing Nuance Entity shall pay Verona the Supply Price for any Licensed Product supplied by Verona pursuant to this Section 7.01 (Manufacture and Supply of Licensed Products). Nuance shall be responsible for, and shall pay directly for, all import-related requirements, expenses or taxes related to importing Licensed Product into the Territory. In addition, if Verona will be required to engage in any product development work specifically needed in order to supply Licensed Product to Nuance for Development or Commercialization by Nuance in the Territory, Nuance shall agree in advance to reimburse Verona for the costs of all such work.

Article VIII.

PAYMENTS

Section VIII.01 Upfront Payment.

(a) Within [***] following the Effective Date and following Nuance's receipt of invoice from Verona for such upfront payment, Nuance shall pay Verona a one-time, non-creditable upfront payment of Twenty Five Million Dollars (\$25,000,000), by wire transfer, net of any withholding or other taxes imposed by any Governmental Authority in the Territory, which, for clarity, will be the responsibility of Nuance.

(b) Within [***] following the Effective Date, Nuance shall grant Verona [***] Series D Preferred Shares in Nuance Biotech, a company duly established under the laws of the Cayman Islands, net of any withholding or other taxes imposed by any Governmental Authority in the Territory, which, for clarity, will be the responsibility of Nuance. The Parties hereby acknowledge and agree that, the value of such shares equals to Fifteen Million Dollars (\$15,000,000) in Nuance Biotech based on the post-money valuation of its last round of financing.

Section VIII.02 Development Milestone Payments.

(a) Nuance shall make the one-time milestone payments to Verona set forth in the table below no later than thirty (30) days after the earliest date on which the corresponding milestone event has been achieved by any Nuance Entity with respect to the first Licensed Product to achieve such milestone event, subject to receipt of invoice issued by Verona.

Milestone Event	Milestone Payment
(i) Earlier of [***] or [***]	[\$***]
(ii) [***]	[\$***]

(b) The milestone payments set forth in rows (i) through (ii) above shall be payable only once, upon the first achievement of such milestone event by the first Licensed Product to achieve such event. In the event milestone (ii) is achieved without the achievement of milestone

(i), then the milestone payment associated with milestone (i) shall become due and payable at the same time that the milestone (ii) payment is due. In the event that the First Commercial Sale of the Licensed Product in the Field in the Territory occurs without the achievement of either milestone (i) or milestone (ii), then the milestone payments associated with milestone (i) and milestone (ii) shall become due and payable at the time the First Commercial Sale of the Licensed Product in the Field in the Territory occurs.

(c) Upon achievement by any Nuance Entity of any of the milestone events listed above, Nuance shall promptly (but in no event more than seven (7) Business Days after such achievement) notify Verona of such achievement.

Section VIII.03 Sales Milestone Payments. Nuance shall, subject to receipt of the invoice issued by Verona, pay to Verona the following amounts after the first achievement of aggregate Net Sales of all Licensed Products in the Territory in a calendar year that meet or exceed the minimum annual Net Sales thresholds set forth below, which payment shall be made no later than [***]after the end of the calendar quarter in which the applicable threshold(s) is(are) met or exceeded:

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each milestone payment in this Section 8.03 (Sales Milestone Payments) shall be payable only once upon the first achievement of such milestone in a given calendar year and no amounts shall be due for subsequent or repeated achievements of such milestone in subsequent calendar years. For clarity, the Net Sales of all Licensed Products in a calendar year shall be aggregated for purposes of determining whether any milestone in the table above has been met. If more than one of the milestones set forth in the table above are first achieved in a single calendar year, then Nuance shall pay to Verona in such calendar year all of the payments corresponding to all of the milestones achieved in such calendar year under this Section 8.03 (Sales Milestone Payments). Upon achievement by any Nuance Entity of any of the Annual Net Sales milestone events listed above, Nuance shall promptly (but in no event more than [***]after such achievement) notify Verona of such achievement.

Section VIII.04 Royalties.

(a) Subject to the remainder of this Section 8.04 (Royalties), Nuance shall pay Verona the following royalties on aggregate Net Sales of all Licensed Products, at an incremental royalty rate determined by aggregate annual Net Sales of all Licensed Products in all Jurisdictions in each calendar year during the Royalty Term:

Portion of Annual Net Sales of all Licensed Products	Royalty Rate
Less than or equal to \$[***]	[***]%
Greater than \$[***] but less than or equal to \$[***]	[***]%
Greater than \$[***] but less than or equal to \$[***]	[***]%
Greater than \$[***]	[***]%

(b) Running royalties paid by Nuance under this Section 8.04 (Royalties) shall be paid on a Licensed Product-by-Licensed Product and Jurisdiction-by-Jurisdiction basis until the latest of (i) the expiration of the last-to-expire Valid Claim in the Verona Patent Rights that Covers such Licensed Product, (ii) expiration of marketing or regulatory exclusivity with respect to such Licensed Product in such Jurisdiction, or (iii) ten (10) years from the First Commercial Sale of such Licensed Product in the Field in such Jurisdiction (each, a “Royalty Term”). For clarity, Nuance shall pay Verona royalties under this Section 8.04 (Royalties) for the transfer of Licensed Product in connection with any named patient sales, whether before or after the First Commercial Sales of Licensed Product in the Field in the Territory. Following the expiration of the Royalty Term with respect to a particular Licensed Product in the Field in a Jurisdiction (but not following an earlier termination of this Agreement), the licenses granted by Verona to Nuance pursuant to Section 2.01(a) with respect to such Licensed Product in the Field in such Jurisdiction shall be perpetual, irrevocable, fully-paid and royalty-free, but Net Sales of such Licensed Product shall continue to be included in the aggregate Net Sales calculation for the purposes of Section 8.03 (Sales Milestones Payments).

(c) Notwithstanding the provisions of Section 8.04(a), on a Jurisdiction-by-Jurisdiction and calendar quarter-by-calendar quarter basis, during any period in which there is at least one Generic Product for sale in such Jurisdiction, Nuance shall pay royalty rates for sales of such Licensed Product in such Jurisdiction at fifty percent (50%) of the applicable royalty rate determined in accordance with Section 8.04(a).

Section VIII.05 Royalty Payments and Reports.

(a) On a Licensed Product-by-Licensed Product and Jurisdiction-by-Jurisdiction basis, until the expiration of the Royalty Term with respect to such Licensed Product in such Jurisdiction, Nuance agrees to provide [***] written reports to Verona within [***] after the end of each [***], covering all Net Sales of such Licensed Product in such Jurisdiction by any Nuance Entity, each such written report including for the period in question (i) the number of Licensed Products which have been sold by a Nuance Entity; (ii) the number of Licensed Products which have been produced by a Nuance Entity but not yet sold; (iii) the gross invoiced amount for Licensed Products which have been sold by a Nuance Entity; (iv) the deductions taken by a Nuance Entity in accordance with Section 1.33 (Net Sales) to reach the Net Sales; (v) the Net Sales of each Licensed Product sold by a Nuance Entity; and (vi) the amounts of royalties due and payable and the amount of any tax deductible or due to be deducted from those figures, and in each case of (i) through (vi), reasonably detailed supporting documentation.

(b) Nuance shall make the royalty payments due hereunder within [***].

Section VIII.6Recordkeeping; Audit. Each Nuance Entity shall keep accurate records of Licensed Products that are made, used or sold under this Agreement, in accordance with the Accounting Standards consistently applied, for a period of at least three (3) years after the end of the calendar year to which the records relate, setting forth the sales of Licensed Products in sufficient detail to enable royalties and other amounts payable to Verona hereunder to be determined. Each Nuance Entity further agrees to permit its books and records to be examined, no more than once during any calendar year unless required to investigate specific issues, by an independent accounting firm selected by Verona and reasonably acceptable to Nuance, to verify any reports and payments delivered under this Agreement during the [***] most recently-ended calendar years, upon reasonable notice (which shall be no less than [***] prior notice) and during regular business hours and subject to a reasonable confidentiality agreement. The Parties shall reconcile any underpayment or overpayment and make the corresponding required payments together with any accrued interest pursuant to Section 8.11 (Late Payments) within [***] after the accounting firm delivers the results of any audit. Such examination is to be made at the expense of Verona, except in the event that the results of the audit reveal an underpayment by Nuance of [***] or more during the period being audited, in which case reasonable audit fees for such examination shall be paid by Nuance.

Section VIII.7Currency Conversion. Wherever it is necessary to convert currencies for Net Sales invoiced in a currency other than the Dollar, such conversion shall be made into Dollars at the conversion rate existing in the United States (as reported in the *Wall Street Journal*) on the last Business Day of the applicable calendar quarter or, if such rate is unavailable, a substitute therefor reasonably selected by Verona. All payments due to Verona under this Agreement shall be made without deduction of exchange, collection or other charges. Once the amount of Net Sales paid to Verona in respect of a particular calendar quarter has been converted into Dollars, such amount of Dollars shall be used for the purpose of calculating the total amount of Net Sales during the calendar year that includes such calendar quarter.

Section VIII.8Methods of Payment. All payments due to Verona under this Agreement shall be made by Nuance in U.S. Dollars by wire transfer to a bank account of Verona.

Section VIII.9Taxes. The upfront payments, milestone payments, royalties and other amounts payable by Nuance to Verona pursuant to this Agreement (each, a “Payment”) will be paid free and clear of any and all taxes, except for any withholding taxes required by applicable Law. Except as provided in this Section 8.09 (Taxes), Verona will be solely responsible for paying any and all taxes (other than withholding taxes required by applicable Law to be deducted from Payments and remitted by Nuance) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Nuance will deduct or withhold from the Payments any taxes that it is required by applicable Law to deduct or withhold. If Verona is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Nuance or the appropriate governmental authority (with the assistance of Nuance to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Nuance of its

obligation to withhold such tax and Nuance will apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that Nuance has received evidence, in a form reasonably satisfactory to Nuance, of Verona's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) prior to the time that the Payments are due. If, in accordance with the foregoing, Nuance deducts or withholds any amount, the payment by Nuance (in respect of which such deduction or withholding of tax is required to be made) shall be increased by the amount necessary to ensure that Verona receives an amount equal to the same amount that it would have received had no amounts been deducted or withheld. Any payment to be made under this Agreement shall be exclusive of any value added tax(es).

Section VIII.10 Invoices. Verona acknowledges that, other than royalty payments, Nuance requires invoices for all payments due under this Agreement, which invoices may be delivered by email to: [***] (which email address may be changed by Nuance from time to time upon written notice to Verona), with a hard copy confirmed by mailing to:

Nuance (Shanghai) Pharma Co Ltd

Address: Room 639, East Tower, Shanghai Centre, No.1376 West Nanjing Road, Shanghai 200040, PRC

Attention: [***]

(which addresses may be changed by Nuance from time to time upon written notice to Verona).

Section VIII.11 Late Payments. If Verona does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to Verona from the due date until the date of payment at the prime rate, as reported by The Wall Street Journal from time to time, plus five percent (5%) per annum or the maximum applicable legal rate, if less. The interest payment shall be due from the day the original payment was due until the day that the payment was received by Verona; provided, that, with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

Article IX.

INTELLECTUAL PROPERTY

Section IX.01 Ownership.

- (a) Ownership of the Verona Technology shall remain vested at all times in Verona.
- (b) Ownership of the Nuance Technology shall remain vested at all times in Nuance.
- (c) Notwithstanding anything to the contrary in this Agreement, Inventions that constitute Improvements shall be solely owned by Verona, provided that such Improvement shall

be Verona Technology and shall be licensed to Nuance pursuant to **Section 2.01(a)**. Nuance hereby assigns to Verona all its rights, title, and interest in and to Improvements. Verona will, at its expense, have sole control of filing and prosecuting applications for, and maintenance and enforcement of, Patent Rights for Improvements. Nuance shall, at Verona's expense, use reasonable efforts to assist Verona to obtain, maintain and enforce Patent Rights and other intellectual property protection for Improvements.

(d) Subject to Section 9.01(c), each Party shall own all Inventions that are made solely by it and its Affiliates or sublicensees during the performance of activities under this Agreement other than Improvements. The Parties shall jointly own all Inventions that are made jointly by or on behalf of both Parties or their Affiliates or (sub)licensees other than Improvements ("Joint Inventions"). Patents Rights claiming the Joint Inventions are "Joint Patent Rights." Each Party owns an undivided half interest in the Joint Inventions, and neither Party shall be entitled to practice, license, assign (its respective interest only) or otherwise exploit the Joint Inventions and Joint Patent Rights in any Jurisdiction or in the Territory without the prior written consent from the other Party.

(e) Inventorship shall be determined according to United States patent Laws.

Section IX.02 Prosecution of Patent Rights

(a) Verona has the sole right, at its discretion and using counsel it selects, to prepare, file, prosecute and maintain all Verona Patent Rights and all Joint Patent Rights in Verona's name. Verona will: (i) instruct such patent counsel to provide Nuance with copies of all filings and formal correspondences relating to such Patent Rights and (ii) keep Nuance advised of the status of actual and prospective patent filings related to a License Product in the Territory. Verona will give Nuance the opportunity to provide and will reasonably consider comments on the preparation, filing, prosecution and maintenance of the Verona Patent Rights and Joint Patent Rights. Each Party will treat any consultation regarding the preparation, filing, prosecution and maintenance of such Patent Rights, along with any information disclosed by each Party in connection therewith (including any information concerning patent expenses), as Confidential Information.

(b) In preparing, filing, prosecuting and maintaining any Patent Rights, in no event shall either Party take any position that is contrary to or detrimental to the scope or enforceability of any Patent Rights belonging to the other Party within the scope of this Agreement.

Section IX.03 Enforcement and Defense

(a) If either Party becomes aware of any Third Party activity, including any Development activity (whether or not an exemption from infringement liability for such Development activity is available under applicable Law), that infringes (or that is directed to a product that would infringe), misappropriates (or that is directed to a product that would misappropriate), or otherwise violates (or that is directed to a product that would violate) any Verona Technology, Nuance Technology or Joint Inventions, then the Party becoming aware of

such activity shall give prompt written notice to the other Party regarding such alleged infringement, misappropriation or violation (collectively, "Infringement Activity").

(b) Verona shall have the sole right, but not the obligation, to control and attempt to resolve any Infringement Activity related to the Verona Technology or Joint Inventions by commercially appropriate steps [***], including the filing of an infringement or misappropriation suit using counsel of its own choice. Verona shall (i) keep Nuance reasonably informed regarding such infringement or misappropriation suit (including by providing Nuance with drafts of each filing within a reasonable period before the deadline for such filing and promptly providing Nuance with copies of all final filings and correspondence), (ii) consult with Nuance on such infringement or misappropriation suit, and (iii) consider in good faith all comments from Nuance regarding such infringement or misappropriation suit and incorporate all reasonable comments or suggested changes proposed by Nuance, except any comments or suggested changes that would reasonably be expected to have a negative impact on Verona's intellectual property rights outside the Territory. [***].

(c) Any amounts recovered by Verona as a result of an action relating to Verona Technology pursuant to Section 9.03(b), whether by settlement or judgment, after reimbursement or deduction of costs and expenses incurred by each Party in connection with such infringement or misappropriation suit shall be [***]. Any amounts recovered by Verona as a result of an action relating to any Joint Technology shall be [***].

(d) In any event, at the request and expense of the Party bringing an infringement or misappropriation action under Section 9.03(b), the other Party shall provide reasonable assistance in any such action (including entering into a common interest agreement if reasonably deemed necessary by any Party) and be joined as a party to the suit if necessary for the initiating or defending Party to bring or continue such suit. Neither Party may settle any action or proceeding brought under Section 9.03(b), or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party's interest in any Verona Technology, Nuance Technology or Joint Inventions without the written consent of such other Party. Each Party shall always have the right to be represented by counsel of its own selection and its own expense in any suit or other action instituted by the other Party pursuant to Section 9.03(b).

Section IX.04 Defense of Third Party Infringement and Misappropriation Claims.

(a) If a Third Party asserts that a Patent Right or other right controlled by it in the Territory is infringed or misappropriated by a Party's activities under this Agreement or a Party becomes aware of a Patent Right or other right that might form the basis for such a claim, the Party first obtaining knowledge of such a claim or such potential claim shall immediately provide the other Party with notice thereof and the related facts in reasonable detail. The Parties shall discuss what commercially appropriate steps, if any, to take to avoid infringement or misappropriation of said Third Party Patent Right or other right controlled by such Third Party in the Territory.

(b) If a Third Party asserts that a Patent Right or other right controlled by it in the Territory is infringed or misappropriated by a Party's activities under this Agreement, then such Party shall have the right, but not the obligation, to defend against such assertion and, at such Party's request and expense, the other Party will provide reasonable assistance in defending against such Third Party assertion. Such Party shall keep the other Party reasonably informed regarding such assertion and such defense.

Section IX.05 Patent Term Extensions. Verona shall have the sole right to select the appropriate Verona Patent Rights or Joint Patent Rights for filing to obtain any available patent term extensions, including supplementary protection certificates and any other extensions that are now available or become available in the future, based on Regulatory Approvals for Licensed Products in the Field in the Territory. Nuance shall reasonably cooperate with Verona in gaining any such patent term extensions, including by signing all necessary papers.

Article X.

ADVERSE DRUG EVENTS AND REPORTS

Section X.01 Complaints. Verona shall be responsible for maintaining the global safety database for the Licensed Product. Nuance shall be responsible for the collection and timely transfer of drug safety information to Verona with respect to the Licensed Product in the Territory. Without limiting the generality of the foregoing, Each Party shall maintain a record of all non-medical and medical product-related complaints it receives with respect to any Licensed Product. Each Party shall notify the other Party of any such complaint received by it in sufficient detail and in accordance with the timeframes and procedures for reporting established by the Parties within the Safety Data Exchange Agreement and the quality agreement, and in any event in sufficient time to allow each Verona Entity and their respective sublicensees (with regards to Verona Entity's sublicensees, solely to the extent such sublicensees are subject to similar obligations under this Section 10.01 (Complaints)) and each Nuance Entity to comply with any and all regulatory requirements imposed upon it, including in accordance with International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") guidelines. The Party that holds the applicable Regulatory Filing(s) in a particular country or jurisdiction shall investigate and respond to all such complaints in such country or jurisdiction with respect to any Licensed Product as soon as reasonably practicable. All such responses shall be made in accordance with the procedures established pursuant to ICH, FDA, EMA, NMPA and other applicable guidelines. The Party responsible for responding to such complaint shall promptly provide the other Party a copy of any such response.

Section X.02 Adverse Drug Events. Within ninety (90) days of the Effective Date, both Parties shall develop and agree to the worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product, such as safety data sharing and exchange, and adverse events reporting, in the Safety Data Exchange Agreement. Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning adverse events or any other important safety information, and product quality and product complaints involving adverse events, sufficient to permit each Party, its Affiliates, or

Sublicensees to comply with its legal obligations. The Parties shall promptly update the Safety Agreement if required by changes in Applicable Law. Each Party shall comply with its respective obligations under the Safety Agreement and shall cause its Affiliates and Sublicensees to comply with such obligations.

Article XI.

REPRESENTATIONS, WARRANTIES, AND COVENANTS

Section XI.01 Mutual Representations and Warranties. Each of Nuance and Verona hereby represents and warrants to the other Party as of the Effective Date that:

- (a) it is a corporation or entity duly organized and validly existing under the Laws of the state, municipality, province, administrative division or other jurisdiction of its incorporation or formation;
- (b) the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action;
- (c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and such performance does not conflict with or constitute a breach of any of its agreements with any Third Party;
- (d) it has the right to grant the rights and licenses described in this Agreement;
- (e) it has not made any commitment to any Third Party in conflict with the rights granted by it hereunder;
- (f) to its knowledge, no consent, approval or agreement of any person or Governmental Authority is required to be obtained in connection with the execution and delivery of this Agreement; and
- (g) it has not been debarred by the FDA, is not the subject of a conviction described in Section 306 of the FD&C Act, and is not subject to any similar sanction of any other Governmental Authority outside of the U.S., and neither it nor any of its Affiliates has used, in any capacity, any person or entity who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction inside or outside of the U.S.

Section XI.02 Mutual Covenants. Each of Nuance and Verona hereby covenants to the other Party that:

- (a) it will not engage, in any capacity in connection with this Agreement or any ancillary agreement, any person or entity who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any similar sanction inside or outside of the U.S., and such Party shall inform the other Party in writing promptly if such Party or any person or entity engaged by such Party who is performing services

under this Agreement, or any ancillary agreement, is debarred or is the subject of a conviction described in Section 306 of the FD&C Act or any similar sanction inside or outside of the U.S., or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to any such debarment or conviction of a Party, any of its Affiliates or any such person or entity performing services hereunder or thereunder;

(b) during the Term, it will not make any commitment to any Third Party in conflict with the rights granted by it hereunder; and

(c) it will comply with all applicable Laws in performing its activities hereunder.

Section XI.03 Additional Verona Warranties. Verona hereby represents and warrants to Nuance as of the Effective Date that:

(a) to Verona's knowledge, Exhibit A contains a list of all Patent Rights that are Controlled by Verona as of the Effective Date and necessary or reasonably useful for the Development or Commercialization of any Licensed Product in the Field in the Territory in accordance with this Agreement;

(b) all of the issued Patent Rights on Exhibit A are in full force and effect, and, to Verona's knowledge, are not invalid or unenforceable, in whole or in part;

(c) to Verona's knowledge, Verona is unaware of any challenge in the Territory to the validity or enforceability of any of the Verona Patent Rights listed in Exhibit A;

(d) to Verona's knowledge, no Third Party is infringing or misappropriating any Verona Technology in the Field in the Territory in derogation of the rights granted to Nuance in this Agreement;

(e) Verona and its Affiliates have not, prior to the Effective Date, assigned, licensed, transferred, conveyed or otherwise encumbered their right, title and interest in any Verona Technology in the Field within the Territory; and

(f) neither Verona nor any of its Affiliates has received any written notification from a Third Party that the research, development, manufacture, use, sale or import of Licensed Products in the Field in the Territory would infringe or misappropriate the Patent Rights or Know-How owned or controlled by such Third Party.

Section XI.04 Anti-Corruption.

(a) Anti-Corruption Provisions. Each Party represents and warrants to the other Party that such Party has not, directly or indirectly, offered, promised, paid, authorized or given, and each Party agrees that such Party will not, in the future, offer, promise, pay, authorize or give, money or anything of value, directly or indirectly, to any Government Official (as defined below) or Other Covered Party (as defined below) for the purpose, pertaining to this Agreement, of: (i) influencing any act or decision of such Government Official or Other Covered Party; (ii) inducing such Government Official or Other Covered Party to do or omit to do an act in violation

of a lawful duty; (iii) securing any improper advantage; or (iv) inducing such Government Official or Other Covered Party to influence the act or decision of a Governmental Authority, in order to obtain or retain business, or direct business to, any person or entity, in any way related to this Agreement.

For purposes of this Agreement: (A) “Government Official” means any official, officer, employee or representative of: (1) any Governmental Authority; (2) any public international organization or any department or agency thereof; or (3) any company or other entity owned or controlled by any Governmental Authority; and (B) “Other Covered Party” means any political party or party official, or any candidate for political office.

(b) Anti-Corruption Compliance.

(i) In performing under this Agreement, each Party, on behalf of itself, its respective Affiliates and (in the case of Verona) other Verona Entities and (in the case of Nuance) other Nuance Entities, agrees to comply with all applicable anti-corruption Laws, including the Foreign Corrupt Practices Act of 1977, as amended from time to time (“FCPA”) and all anti-corruption Laws of the Territory.

(ii) Each Party represents and warrants to the other Party that such Party is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly or indirectly, from this Agreement.

(iii) No Party, nor any Affiliate of any Party (and (in the case of Verona) no other Verona Entity and (in the case of Nuance) no other Nuance Entity), shall give, offer, promise or pay any political contribution or charitable donation at the request of any Government Official or Other Covered Party that is in any way related to this Agreement or any related activity.

(iv) Nuance Entities shall in all cases, refrain from engaging in any activities or conduct which would cause any Verona Entity to be in violation of the FCPA and any applicable anti-bribery Laws. To the extent allowed by Law, if any Nuance Entity proposes to provide any information, data or documentation to any governmental or regulatory authority in respect of the Licensed Product that relates to or may result in a violation of the FCPA or any applicable anti-bribery Law, it shall first obtain the prior written approval of Verona, which will not be unreasonably withheld, or shall provide such information, data or documentation in accordance with Verona’s written instructions.

(v) Nuance agrees that should it learn or have reason to know of: (i) any payment, offer, or agreement to make a payment to a foreign official or political party for the purpose of obtaining or retaining business or securing any improper advantage for Verona under this Agreement or otherwise, or (ii) any other development during the Term that in any way makes inaccurate or incomplete the representations, warranties and certifications of Nuance hereunder given or made as of the date hereof or at any time during the Term, relating to the

FCPA, Nuance will immediately advise Verona in writing of such knowledge or suspicion and the entire basis known to Nuance therefor.

(vi) Notwithstanding any other provisions contained in this Agreement, Nuance agrees that full disclosure of information relating to a possible violation of the FCPA or the existence and terms of this Agreement, including the compensation provisions hereof, may be made at any time and for any reason to the U.S. government and its agencies, and to whomsoever Verona determines has a legitimate need to know.

(vii) In the event that a Party violates the FCPA, any anti-corruption Law of the Territory or any other applicable anti-corruption Law, or breaches any provision in this Section 11.04 (Anti-Corruption), the other Party shall have the right to terminate this Agreement pursuant to Section 14.03 (Termination for Breach).

Section XI.05 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY VERONA TO NUANCE HEREIN ARE PROVIDED “AS IS” AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

Section XI.06 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, EXEMPLARY, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER. THE FOREGOING SHALL NOT LIMIT (a) ANY INDEMNIFICATION OBLIGATIONS HEREUNDER OR (b) REMEDIES AVAILABLE TO EITHER PARTY WITH RESPECT TO A BREACH OF Article XII (CONFIDENTIALITY), OR (c) DAMAGES IN INSTANCES OF INTENTIONAL MISCONDUCT OR FRAUD COMMITTED BY THE OTHER PARTY.

Article XII.

CONFIDENTIALITY

Section XII.01 Generally. During the Term and for a period of seven (7) years thereafter, each Party (a) shall maintain in confidence all Confidential Information of the other Party or any of such Party’s Affiliates; (b) shall not use such Confidential Information for any purpose except to fulfill its obligations or exercise its rights (for the avoidance of doubt, including, with respect to Verona, the right to Commercialize the Licensed Products outside of the Field or Territory (and inside of the Field and Territory after any termination of this Agreement) and to Develop and Manufacture the Licensed Products in accordance with this

Agreement) under this Agreement; and (c) shall not disclose such Confidential Information to anyone other than those of its Affiliates, directors, investors, prospective investors, lenders, prospective lenders, acquirers, prospective acquirers, licensees, prospective licensees, sublicensees, prospective sublicensees, employees, consultants, financial or legal advisors, or other agents or contractors (collectively, “Representatives”) who are bound by written obligations of nondisclosure and non-use no less stringent than those set forth in this Article XII (Confidentiality) and to whom such disclosure, under this Agreement, is necessary in connection with the fulfillment of such Party’s obligations or exercise of such Party’s rights under this Agreement or in connection with *bona fide* financing or acquisition activities. Each Party shall (i) ensure that such Party’s Representatives who receive any of the other Party’s (or any of such Party’s Affiliates’) Confidential Information comply with the obligations set forth in this Article XII (Confidentiality) and (ii) be responsible for any breach of these obligations by any of its Representatives who receive any of the other Party’s (or any of such Party’s Affiliates’) Confidential Information. Each Party shall notify the other Party promptly on discovery of any unauthorized use or disclosure of the other’s (or any of its Affiliates’) Confidential Information.

Section XII.02 Exceptions. The obligations of confidentiality, non-disclosure, and non-use set forth in Section 12.01 (Generally) shall not apply to, and “Confidential Information” shall exclude, any information to the extent the receiving Party (the “Recipient”) can demonstrate that such information: (a) was in the public domain or publicly available at the time of disclosure to the Recipient or any of its Affiliates by the disclosing Party or any of its Affiliates pursuant to this Agreement or the Confidentiality Agreement, or thereafter entered the public domain or became publicly available, in each case other than as a result of any action of the Recipient, or any of its Representatives, in breach of this Agreement or the Confidentiality Agreement; (b) was rightfully known by the Recipient or any of its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient or any of its Affiliates by the disclosing Party or any of its Affiliates pursuant to this Agreement or the Confidentiality Agreement; (c) was received by the Recipient or any of its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality to the disclosing Party or any of its Affiliates; or (d) was independently developed by or for the Recipient or any of its Affiliates without reference to or reliance on the Confidential Information of the other Party or any of its Affiliates (as demonstrated by written records).

Section XII.03 Permitted Disclosures. Notwithstanding any other provision of this Agreement, Recipient’s (or its Affiliates’) disclosure of the other Party’s (or any of such Party’s Affiliates’) Confidential Information shall not be prohibited if such disclosure: (a) is in response to a valid order of a court or other Governmental Authority, including the rules and regulations promulgated by the Securities and Exchange Commission (or similar foreign authority) or any other Governmental Authority; (b) is otherwise required by applicable Law or rules of a nationally or internationally recognized securities exchange or Nasdaq or (c) is to patent offices in order to seek or obtain Patent Rights or to Regulatory Authorities in order to seek or obtain approval to conduct clinical trials or to gain Regulatory Approval with respect to the Licensed Products as contemplated by this Agreement; *provided* that such disclosure may be made only to the extent reasonably necessary to seek or obtain such Patent Rights or Regulatory Approvals, and the Recipient (or its applicable Affiliate(s)) shall use Commercially Reasonable

Efforts to obtain confidential treatment of such information. If a Recipient is required to disclose Confidential Information pursuant to Section 12.03(a) or Section 12.03(b), prior to any disclosure the Recipient shall, to the extent legally permitted and practicable, provide the disclosing Party with prior written notice of such disclosure in order to permit the disclosing Party to seek a protective order or other confidential treatment of such disclosing Party's Confidential Information.

Section XII.04 Publicity. The Parties will issue a joint press release in connection with this Agreement. The Parties recognize that each Party may from time to time desire to issue press releases and make other public statements or public disclosures in respect of this Agreement, including the Development or Commercialization of Licensed Products in the Territory (each, a "Public Statement"). If Nuance desires to make a Public Statement, it shall provide Verona a copy of such Public Statement at least [***] Business Days prior to the date it desires to make such public disclosure. Nuance shall not issue a Public Statement without Verona's prior written approval, which advance approval shall not be unreasonably withheld, conditioned or delayed. Verona shall provide to Nuance a preliminary draft of any Public Statement that it intends to make on a global basis with respect to Development of Licensed Products at least [***] Business Days in advance of such public disclosure and shall provide a final draft of such Public Statement at least [***] in advance of such public disclosure; *provided* that, [***]. Once any public statement or public disclosure has been approved in accordance with this Section 12.04 (Publicity), then the applicable Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding anything to the contrary in this Section 12.04 (Publicity), nothing in this Section 12.04 (Publicity) shall be deemed to limit either Party's rights under Section 12.03 (Permitted Disclosures) or either Party's ability to issue press releases or make other public statements or public disclosures required by applicable Law or rules of a nationally or internationally recognized securities exchange or Nasdaq.

Section XII.05 Publications. Verona acknowledges Nuance's interest in publishing certain key results of Nuance's Development and Commercialization of Licensed Products in the Field in the Territory. Nuance recognizes the mutual interest in obtaining valid patent protection and Verona's interest in protecting its proprietary information. Consequently, except for disclosures permitted pursuant to Section 12.02 (Exceptions), Section 12.03 (Permitted Disclosures) or Section 12.04 (Publicity), if Nuance wishes to make a publication or public presentation with respect to its Development or Commercialization of Licensed Products in the Field in the Territory, Nuance shall deliver to Verona a copy of the proposed written publication or presentation at least [***] prior to submission for publication or presentation. Verona shall have the right (a) to require modifications to the publication or presentation for patent or any other business reasons, and Nuance will remove all of Verona's Confidential Information if requested by Verona, and (b) to require a reasonable delay in publication or presentation in order to protect patentable information. If Verona requests a delay, then Nuance shall delay submission or presentation for a period of [***] (or such shorter period as may be mutually agreed by the Parties) to enable Verona to file patent applications protecting Verona's rights in such information.

Section XII.06 Injunctive Relief. Each Party acknowledges and agrees that there may be no adequate remedy at law for any breach of its obligations under this Article XII (Confidentiality), that any such breach may result in irreparable harm to the other Party and, therefore, that upon any such breach or any threat thereof, such other Party may seek appropriate equitable relief in addition to whatever remedies it might have at law, without the necessity of showing actual damages.

Article XIII.

INDEMNIFICATION

Section XIII.01 Indemnification by Verona. Verona shall indemnify, hold harmless and defend any Nuance Entity, and their respective directors, officers, and employees (the “Nuance Indemnitees”) from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses, costs, damages, deficiencies, obligations or losses (including reasonable attorneys’ fees, court costs, witness fees, damages, judgments, fines and amounts paid in settlement) (“Losses”) to the extent that such Losses arise out of (a) any breach of this Agreement by Verona, (b) the Development, Manufacture or Commercialization of any Licensed Product by or on behalf of any Verona Entity or their sublicensees or (c) the negligence or willful misconduct of any Verona Indemnitee. Notwithstanding the foregoing, Verona shall not have any obligation to indemnify the Nuance Indemnitees to the extent that the applicable Losses arise out of the negligence or willful misconduct of any Nuance Indemnitee or any breach of this Agreement by Nuance.

Section XIII.02 Indemnification by Nuance. Nuance shall indemnify, hold harmless and defend any Verona Entity and any of their sublicensees, and their respective directors, officers, and employees (the “Verona Indemnitees”) from and against any and all Losses, to the extent that such Losses arise out of (a) any breach of this Agreement by Nuance, (b) the Development or Commercialization of any Licensed Product by or on behalf of any Nuance Entity or their sublicensees or (c) the negligence or willful misconduct of any Nuance Indemnitee. Notwithstanding the foregoing, Nuance shall not have any obligation to indemnify the Verona Indemnitees to the extent that the applicable Losses arise out of the negligence or willful misconduct of any Verona Indemnitee or any breach of this Agreement by Verona.

Section XIII.03 Procedure. In the event of a claim by a Third Party against a Nuance Indemnitee or Verona Indemnitee entitled to indemnification under this Agreement (“Indemnified Party”), the Indemnified Party shall promptly notify the Party obligated to provide such indemnification (“Indemnifying Party”) in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party. The Indemnified Party may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party’s written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto and does not

impose any obligations on the Indemnified Party, unless the Indemnified Party otherwise agrees in writing. No Indemnified Party may settle any claim for which it is being indemnified under this Agreement without the Indemnifying Party's prior written consent.

Section XIII.04 Insurance. Each Party will have and maintain, at its sole cost and expense, adequate liability insurance (including product liability insurance, clinical trial insurance employers liability, statutory Workers Compensation and contractual liability) to protect against potential liabilities and risk arising out of activities to be performed under this Agreement and any agreement related hereto and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the pharmaceutical industry generally for the activities to be conducted by such Party under this Agreement. Without limiting the generality of the foregoing, such coverage shall include (a) product liability, clinical trial and general liability coverage in an amount no less than [***] per occurrence for personal injury and [***] per occurrence for property damage. Such insurance policy shall provide product liability coverage and broad form contractual liability coverage for indemnification obligations under this Agreement. Each Party shall provide a copy of such insurance policy to the other Party upon reasonable request. Each Party shall provide the other Party with written notice at least [***] prior to any cancellation, non-renewal or material change in such insurance. This Section 13.04 (Insurance) shall survive expiration or termination of this Agreement and last until [***] after the last sale of any Licensed Product in the Field in the Territory by any Nuance Entity.

Article XIV.

TERM AND TERMINATION

Section XIV.01 Term. The term of this Agreement shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article XIV (Term and Termination), will expire upon the expiration of the last-to-expire Royalty Term (the "Term"). Notwithstanding the foregoing, the Parties shall negotiate in good faith for renewal of the Term at least [***] days prior to the expected expiration of the initial Royalty Term. Any extension of the Term shall be agreed by the Parties in writing.

Section XIV.02 Termination at Will by Nuance. At any time, Nuance may terminate this Agreement for any or no reason upon giving ninety (90) days' notice to Verona. Should Nuance exercise such termination right, it will not be entitled to a refund of any amounts previously paid to Verona.

Section XIV.03 Termination for Breach. Subject to the terms and conditions of this Section 14.03 (Termination for Breach), a Party (the "Non-Breaching Party") shall have the right, in addition to any other rights and remedies available to such Party at law or in equity, to terminate this Agreement in the event the other Party (the "Breaching Party") is in material breach of its obligations under this Agreement. The Non-Breaching Party shall first provide written notice to the Breaching Party, which notice shall identify with particularity the alleged breach (the "Breach Notice"). With respect to material breaches of any payment provision hereunder, the Breaching Party shall have a period of [***] after such Breach Notice is provided

to cure such breach. With respect to all other breaches, the Breaching Party shall have a period of [***] after such Breach Notice is provided to cure such breach. If such breach is not cured within the applicable period set forth above, the Non-Breaching Party may, at its election, terminate this Agreement upon written notice to the Breaching Party. The waiver by either Party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach.

Section XIV.04 Termination for Bankruptcy and Rights in Bankruptcy.

(a) To the extent permitted under applicable Law, if, at any time during the Term, an Event of Bankruptcy (as defined below) relating to either Party (the “Bankrupt Party”) occurs, the other Party (the “Other Party”) shall have, in addition to all other legal and equitable rights and remedies available to such Party, the option to terminate this Agreement upon sixty (60) days written notice to the Bankrupt Party. It is agreed and understood that, if the Other Party does not elect to terminate this Agreement upon the occurrence of an Event of Bankruptcy, except as may otherwise be agreed with the trustee or receiver appointed to manage the affairs of the Bankrupt Party, the Other Party shall continue to perform all the obligations required of it under this Agreement as if the Event of Bankruptcy had not occurred, and the Bankrupt Party shall not have the right to terminate any license granted herein. The term “Event of Bankruptcy” means: (a) filing in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Bankrupt Party or of its assets or (b) being served with an involuntary petition against the Bankrupt Party, filed in any insolvency proceeding, where such petition is not dismissed within sixty (60) days after the filing thereof.

(b) All rights and licenses granted under or pursuant to this Agreement by Nuance and Verona are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as sublicensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party’s possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party’s written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

Section I.05 Termination for Patent Challenge. Except to the extent the following is unenforceable under the laws of a particular Jurisdiction, this Agreement shall terminate

automatically in its entirety immediately if any Nuance Entity, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any of the Verona Patent Rights.

Section I.06 Effect of Termination.

(a) All license grants in this Agreement from Verona to Nuance shall terminate, but the license granted from Nuance to Verona shall survive;

(b) Nuance shall assign and transfer to Verona all Regulatory Approvals, Regulatory Documents, and Trademarks pertaining to (with respect to Trademarks, only those specific to) the Licensed Product in the Territory;

(c) Nuance shall conduct an orderly wind down of its activities for the Licensed Product or, at Verona's request, transfer such activities to Verona or its designee;

(d) At Verona's request, Nuance shall, to the extent possible, assign to Verona or its designee any Third Party agreements it entered into in connection with the Development or Commercialization of the Licensed Product, and Nuance shall remain responsible for any outstanding amounts owing to such Third Party up to the date of the assignment of such Third Party agreement to Verona; for any Third Party agreement that cannot be assigned to Verona or its designee, Nuance shall use Commercially Reasonable Efforts to help facilitate Verona's discussion and negotiation with such Third Party for a direct agreement between Verona and such Third Party;

(e) Nuance shall transfer to Verona all Know-How (including technical, clinical and commercial Know-How, and including for clarity Verona Product Data) Developed by Nuance in the Territory with respect to the Licensed Product, and shall return, or at Verona's option destroy any Verona Know-How that is in a tangible or electronic form; provided, however, that nothing in this Agreement shall require the alteration, modification, deletion or destruction of computer backup tapes made in the ordinary course of business; Notwithstanding the foregoing, legal counsel to the recipient shall be permitted to retain in its files one copy of all Confidential Information to evidence the scope of and to enforce the Party's obligation of confidentiality under this Section.

(f) Nuance shall remain responsible for all non-cancellable Third Party obligations with respect to the Licensed Product;

(g) Nuance shall have the right to dispose of any stocks of Licensed Products for a period of [***] from the date of termination that may be in its possession or in the process of being manufactured provided that Nuance pays to Verona any applicable milestone payments or royalties under Article VIII (Payments) on such sales.

Section I.07 Survival; Accrued Rights. The following articles and sections of this Agreement shall survive expiration or early termination for any reason: Article I (Definitions), Article VIII (Payments) (solely to the extent any payments became payable prior to the effective

date of such expiration or termination), Section 9.01 (Ownership), Section 11.06 (Limitation of Liability), Article XII (Confidentiality), Article XIII (Indemnification), Section 14.06 (Effect of Termination), Section 14.07 (Survival; Accrued Rights), Article XV (Dispute Resolution; Governing Law), Section 16.01 (Assignment) (solely with respect to the last sentence in clause (a) and the entirety of clause (b)) and Article XVII (Miscellaneous). In any event, expiration or termination of this Agreement shall not relieve either Party of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

Article XV.

DISPUTE RESOLUTION; GOVERNING LAW

Section XV.01 Arbitration. Subject to Section 15.01(d), any disputes, claims or controversies in connection with this Agreement, including any questions regarding its formation, existence, validity, enforceability, performance, interpretation, breach or termination, that are not resolved in accordance with Article III (Governance) and are not subject to a Party's final decision-making authority in accordance with Article III (Governance) shall be referred to and finally resolved by binding arbitration under the International Chamber of Commerce Rules of Arbitration (the "Rules"), which rules are deemed to be incorporated by reference into this Section 15.01 (Arbitration), in the manner described below; provided that, prior to commencing of arbitration or other legal proceedings with respect to any disputes, claims or controversies in connection with this Agreement, the CEOs of both Parties shall discuss in good faith such disputes, claims or controversies for at least [***].

(a) Arbitration Request. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "Arbitration Request") to the other Party of such intention and the issues for resolution. Any such dispute that is not to be resolved in accordance with Section 15.01(d) shall be resolved in accordance with Section 15.01(c); and any such dispute that relates to validity or enforceability of a Patent Right shall be resolved in accordance with Section 15.01(d).

(b) Additional Issues. Within [***] after the receipt of an Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

(c) General Arbitration Procedure for Disputes. The seat of arbitration will be in New York, New York, unless another venue is agreed upon by Parties, and it will be conducted in the English language. The arbitrators may not decide based on equity. Unless agreed by the Parties to choose a single common arbitrator, the arbitration will be conducted by three arbitrators, one appointed by each Party, according to the Rules. The two arbitrators appointed by the Parties will by mutual agreement appoint the third arbitrator, who will preside over the arbitration. Any dispute or omission regarding the appointment of the arbitrators by the Parties, as well as the choice of the third arbitrator, will be resolved by the International Chamber of Commerce ("ICC"). The arbitral award shall be final, definitive and binding on the Parties and

their successors. The Parties reserve the right to apply to a competent judicial court to obtain urgent remedies to protect rights before establishment of the arbitration panel, without such recourse being considered as a waiver of arbitration. [***]. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, Confidential Information, Know-How, intellectual property rights or any other proprietary right or otherwise to avoid irreparable harm. If the issues in dispute involve scientific or technical matters, any arbitrators chosen hereunder shall have educational training or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology and pharmaceuticals. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The Parties intend that each award rendered by an Arbitrator hereunder shall be entitled to recognition and enforcement under the United Nations Convention on the Recognition and Enforcement of Arbitral Awards (New York, 1958).

(d) **Intellectual Property Disputes.** Unless otherwise agreed by the Parties, a dispute between the Parties relating to the validity or enforceability of any Patent Right shall not be subject to arbitration and shall be submitted to a court or patent office of competent jurisdiction in the relevant country or jurisdiction in which such patent was issued or, if not issued, in which the underlying patent application was filed.

Section XV.02 **Choice of Law.** This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties hereunder, shall be construed under and governed by the Laws of England and Wales, exclusive of its conflicts of laws principles.

Section XV.03 **Language.** This Agreement has been prepared in the English language and the English language shall control its interpretation. All consents, notices, reports and other written documents to be delivered or provided by a Party under this Agreement shall be in the English language, and, in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation shall control.

Article XVI.

ASSIGNMENT AND ACQUISITIONS

Section XVI.01 **Assignment.**

(a) Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by either Party (and, for these purposes, a merger, sale of assets, operation of law or other transaction shall be deemed an assignment) without the prior written consent of the other Party. Notwithstanding the foregoing, Verona may, without the other Nuance's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to (i) an Affiliate of Verona or (ii) a Third Party that acquires, by or otherwise in connection with, a license, merger, sale of assets or otherwise, all or substantially all of the business of Verona to

which the subject matter of this Agreement relates; *provided* that the assignee agrees in writing to assume all of Verona's obligations under this Agreement. The assigning Party will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned. Notwithstanding the foregoing or anything herein to the contrary, Verona may sell, assign, convey, pledge, grant a security interest in, encumber, allocate or otherwise transfer or distribute any of its economic interests (e.g, rights to receive any payments, revenues, or other economic value) and any ancillary rights or remedies under this Agreement, including without limitation pursuant to any royalty monetization transaction, royalty buyout, revenue participation, royalty or revenue purchase, synthetic royalty assignment or any similar structure or transfer transaction. Nuance agrees to enter into any documentation or make any filings reasonably requested by Verona in order to effectuate any transaction permitted under this Section, including an agreement to pay directly to any counterparty to any of the foregoing transactions or to establish an escrow or similar account for the benefit of such parties. Nuance further agrees that Verona may disclose to any counterparty of such transaction any royalty payments and reports and any other information relating to the royalties or other economic interests transferred as part of such transaction permitted under this Section.

(b) The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this Section 16.01 (Assignment) will be null and void *ab initio*.

Article XVII.

MISCELLANEOUS

Section XVII.1 Force Majeure. If either Party shall be delayed, interrupted in or prevented from the performance of any obligation hereunder by reason of force majeure, which may include any act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, government action, strike or labor differences, in each case outside of such Party's reasonable control, such Party shall not be liable to the other therefor, and the time for performance of such obligation shall be extended for a period equal to the duration of the force majeure which occasioned the delay, interruption or prevention. The Party invoking the force majeure rights of this Section 17.01 (Force Majeure) must notify the other Party by courier or overnight dispatch (*e.g.*, Federal Express) within a period of [***] of both the first and last day of the force majeure unless the force majeure renders such notification impossible, in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds [***], the other Party may terminate this Agreement immediately upon written notice to the Party invoking the force majeure rights of this Section 17.01 (Force Majeure).

Section XVII.2 Entire Agreement. This Agreement, together with the Exhibits and Schedules attached hereto, constitutes the entire agreement between Verona or any of its Affiliates, on the one hand, and Nuance or any of its Affiliates, on the other hand, with respect to the subject matter hereof, supersedes all prior agreements, understandings and writings between Verona or any of its Affiliates, on the one hand, and Nuance or any of its Affiliates, on the other hand relating to such subject matter, including the Confidentiality Agreement and the agreement

dated June 9, 2021 entered into between Nuance Shanghai and Verona (and Verona, Nuance and Nuance Shanghai hereby agree that such agreement dated June 9, 2021 shall have no effect and shall be deemed null and void ab initio), and shall not be modified, amended or (subject to Article XIV (Term and Termination)) terminated, except by another agreement in writing executed by the Parties.

Section XVII.3 Severability. If, under applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision of this Agreement (such invalid or unenforceable provision, a “Severed Clause”), it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use their reasonable efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.

Section XVII.4 Notices. Any notice required or permitted to be given under this Agreement shall be in writing and shall be mailed by internationally recognized express delivery service, or sent by facsimile or email and confirmed by mailing, as follows (or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith):

If to Verona:

Verona Pharma plc
3 More London Riverside
London, SE1 2RE, United Kingdom
Attn: David Zaccardelli

With a copy to (which shall not constitute notice for purposes of this Agreement):

Latham & Watkins, LLP
1271 Avenue of the Americas
New York, NY 10020
Attn: [***]

If to Nuance:

Nuance Pharma Limited
Room 639, East Tower, Shanghai Centre,
No.1376 West Nanjing Road,
Shanghai 200040, PRC
Attn: [***]

Any such notice shall be deemed to have been given (a) when delivered if personally delivered, (b) on receipt if sent by overnight courier or (c) on receipt if sent by mail.

Section XVII.5 Agency. Neither Party is, nor will be deemed to be a partner, employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

Section XVII.6 No Waiver. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof, by the other Party, shall not constitute a waiver of such Party's rights to the enforcement of any of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party shall not operate or be construed as a waiver of any subsequent breach or default by the other Party.

Section XVII.7 Cumulative Remedies. Except as may be expressly set forth herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law or in equity.

Section XVII.8 No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than (a) to the extent provided in Section 13.01 (Indemnification by Verona), the Nuance Indemnitees and (b) to the extent provided in Section 13.02 (Indemnification by Nuance), the Verona Indemnitees.

Section XVII.9 Performance by Affiliates. Subject to Section 8.08 (Methods of Payment), either Party may use one or more of its Affiliates to perform its obligations and duties hereunder; *provided* that such Party so notifies the other Party in writing and *provided, further*, that such Party shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

Section XVII.10 Counterparts. This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Effective Date.

VERONA PHARMA PLC

By: /s/ David Zaccardelli
Name: David Zaccardelli
Title: CEO & President
Date: 7/14/2021

NUANCE PHARMA LIMITED

By: /s/ [***]
Name: [***]
Title: [***]
[***]
Date: 7/15/2021

NUANCE (SHANGHAI) PHARMA CO LTD

By: /s/ [***]
Name: [***]
Title: [***]
Date: 7/15/2021

1 Schedule 2.05

[***]

EXHIBIT A

VERONA PATENT RIGHTS – SECTION 11.03

[***]

EXHIBIT B

TECHNOLOGY SHARING – SECTION 2.02

[***]

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: August 5, 2021

By:

/s/ David Zaccardelli, Pharm.D.

David Zaccardelli, Pharm.D.

Chief Executive Officer
(principal executive officer)

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: August 5, 2021

By:

/s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (*principal financial officer*)

**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 June 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: August 5, 2021

By:

/s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (*principal financial officer*)