

**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, 2022

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____
Commission File Number: 001-38067

Verona Pharma plc

(Exact name of Registrant as specified in its Charter)

United Kingdom

98-1489389

(State or other jurisdiction of incorporation or organization)

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

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

Not Applicable

(Address of principal executive offices)

(Zip Code)

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 3, 2022, the registrant had 487,633,374 ordinary shares, nominal value £0.05 per share, outstanding, which if all held in ADS form, would be represented by 60,954,172 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>2022</u>	<u>December 31,</u> <u>2021</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 111,510	\$ 148,380
Prepaid expenses	4,731	4,037
Tax and tax incentive receivable	20,185	15,583
Other current assets	2,206	2,063
Total current assets	<u>138,632</u>	<u>170,063</u>
Non-current assets:		
Furniture and equipment, net	91	80
Goodwill	545	545
Equity interest	15,000	15,000
Right-of-use assets	588	899
Total non-current assets	<u>16,224</u>	<u>16,524</u>
Total assets	<u>\$ 154,856</u>	<u>\$ 186,587</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 9,364	\$ 10,044
Accrued expenses	28,603	22,256
Operating lease liability	464	648
Taxes payable	311	147
Other current liabilities	121	327
Total current liabilities	<u>38,863</u>	<u>33,422</u>
Non-current liabilities:		
Term loan	4,981	4,874
Operating lease liability	132	286
Total non-current liabilities	<u>5,113</u>	<u>5,160</u>
Total liabilities	<u>43,976</u>	<u>38,582</u>
Commitments and contingencies		
Shareholders' equity:		
Ordinary £0.05 par value shares; 494,058,246 and 489,177,550 issued, and 485,298,326 and 480,082,966 outstanding, at June 30, 2022 and December 31, 2021, respectively	32,182	31,855
Additional paid-in capital	390,543	385,070
Ordinary shares held in treasury	(591)	(603)
Accumulated other comprehensive loss	(4,601)	(4,601)
Accumulated deficit	(306,653)	(263,716)
Total shareholders' equity	<u>110,880</u>	<u>148,005</u>
Total liabilities and shareholders' equity	<u>\$ 154,856</u>	<u>\$ 186,587</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,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 14,982	\$ 20,563	\$ 32,607	\$ 34,137
Selling, general and administrative	5,526	7,985	12,966	17,267
Total operating expenses	20,508	28,548	45,573	51,404
Operating loss	(20,508)	(28,548)	(45,573)	(51,404)
Other income/(expense)				
Research and development tax credit	5,409	3,836	6,711	5,906
Interest income	165	3	180	7
Interest expense	(91)	(85)	(175)	(169)
Fair value movement on warrants	—	2,711	—	2,204
Foreign exchange (loss)/gain	(2,662)	40	(3,585)	203
Total other income, net	2,821	6,505	3,131	8,151
Loss before income taxes	(17,687)	(22,043)	(42,442)	(43,253)
Income tax expense	(79)	(25)	(161)	(105)
Net loss	\$ (17,766)	\$ (22,068)	\$ (42,603)	\$ (43,358)
Loss per ordinary share - basic and diluted	\$ (0.04)	\$ (0.05)	\$ (0.09)	\$ (0.09)
Weighted-average shares outstanding - basic and diluted	484,777,837	470,786,767	483,226,039	469,036,978

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

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

	Ordinary shares		Additional paid-in capital	Ordinary shares held in treasury	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity
	Number	Amount					
Balance at December 31, 2021	489,177,550	\$ 31,855	\$385,070	\$ (603)	\$ (4,601)	\$ (263,716)	\$ 148,005
Net loss	—	—	—	—	—	(24,837)	(24,837)
Issuance of common shares under at-the-market sales agreement	80,696	5	62	—	—	—	67
Restricted share units vested	—	—	—	186	—	(186)	—
Issuance of ordinary shares to treasury	4,800,000	322	—	(322)	—	—	—
Common shares withheld for taxes on vested stock awards	—	—	(793)	—	—	—	(793)
Equity settled share-based compensation reclassified as cash-settled	—	—	118	—	—	—	118
Share-based compensation	—	—	3,747	—	—	—	3,747
Balance at March 31, 2022	<u>494,058,246</u>	<u>\$ 32,182</u>	<u>\$388,204</u>	<u>\$ (739)</u>	<u>\$ (4,601)</u>	<u>\$ (288,739)</u>	<u>\$ 126,307</u>
Net loss	—	—	—	—	—	(17,766)	(17,766)
Restricted share units vested	—	—	—	148	—	(148)	—
Common shares withheld for taxes on vested stock awards	—	—	(689)	—	—	—	(689)
Equity settled share-based compensation reclassified as cash-settled	—	—	(25)	—	—	—	(25)
Share-based compensation	—	—	3,053	—	—	—	3,053
Balance at June 30, 2022	<u>494,058,246</u>	<u>\$ 32,182</u>	<u>\$390,543</u>	<u>\$ (591)</u>	<u>\$ (4,601)</u>	<u>\$ (306,653)</u>	<u>\$ 110,880</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	Ordinary shares held in treasury	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' equity
	Number	Amount					
Balance at December 31, 2020	488,304,446	\$ 31,794	\$366,411	\$ (1,700)	\$ (4,601)	\$ (207,050)	\$ 184,854
Net loss	—	—	—	—	—	(21,290)	(21,290)
Restricted share units vested	—	—	—	30	—	(30)	—
Share-based compensation	—	—	8,850	—	—	—	8,850
Balance at March 31, 2021	<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)
Issuance of common shares under at-the-market sales agreement	434,704	30	353	—	—	—	383
Restricted share units vested	—	—	—	827	—	(827)	—
Common shares withheld for taxes on vested stock awards	—	—	(3,782)	—	—	—	(3,782)
Share-based compensation	—	—	7,450	—	—	—	7,450
Balance at June 30, 2021	<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 Cash Flows
(unaudited)
(in thousands)

	Six months ended June 30,	
	2022	2021
Operating activities:		
Net loss:	\$ (42,603)	\$ (43,358)
<i>Adjustments to reconcile net income to net cash used in operating activities:</i>		
Foreign exchange loss/(gain)	3,256	(186)
Amortization of debt issue costs	44	69
Accretion of redemption premium on debt	63	63
Fair value movement on warrants	—	(2,204)
Share-based compensation	6,801	16,300
Depreciation and amortization	328	305
<i>Changes in operating assets and liabilities:</i>		
Accounts receivable	—	(25,002)
Equity interest receivable	—	(15,000)
Prepaid expenses	(694)	(5,279)
Tax incentive receivable	(6,461)	(5,848)
Other current assets	(143)	(600)
Right-of-use asset	—	(4,823)
Accounts payable	(680)	(144)
Accrued expenses	6,347	6,325
Lease liabilities	(338)	393
Taxes payable	164	—
Deferred revenue	—	40,051
Other current liabilities	(113)	182
Net cash used in operating activities	(34,029)	(38,756)
Cash flows from investing activities:		
Purchases of furniture and equipment	(29)	—
Net cash used in investing activities	(29)	—
Cash flows from financing activities:		
Payments of withholding taxes from share-based awards	(1,482)	(3,782)
Proceeds from at-the-market sales agreement	67	383
Net cash used in financing activities	(1,415)	(3,399)
Effect of exchange rate changes on cash and cash equivalents		
Net change in cash and cash equivalents	(36,870)	(41,951)
Cash and cash equivalents at beginning of the period	148,380	187,986
Cash and cash equivalents at end of the period	\$ 111,510	\$ 146,035
Supplemental disclosure of cash flow information:		
Income taxes paid	\$ 1	\$ —
Interest paid	\$ 115	\$ 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 non-operating, wholly-owned subsidiary, was dissolved in June 2021. The address of the registered office is 1 Central Square, Cardiff, CF10 1FS, United Kingdom.

The Company is a clinical-stage biopharmaceutical group focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical needs. The Company’s American Depositary Shares (“ADSs”) are listed on the Nasdaq Global Market (“Nasdaq”) and trade under the symbol “VRNA”.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception, and has an accumulated deficit of \$306.7 million as of June 30, 2022. The Company expects to incur additional losses and negative cash flows from operations until its products potentially gain regulatory approval and reach commercial profitability, if at all.

The Company expects that its cash and cash equivalents as of June 30, 2022, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance.

In March, 2021, the Company entered into an open market sale agreement with respect to an at-the-market offering program (the “ATM Program”) under which the Company may issue and sell its ordinary shares in the form of ADSs, with an aggregate offering price of up to \$100.0 million.

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

The Company’s commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if ever. Additionally we may enter into out-licensing transactions from time to time but there can be no assurance that the company can secure such transactions in the future. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives including to further advance clinical and regulatory activities, to fund prelaunch and launch related costs and to create an effective sales and marketing organization to commercialize ensifentrine. 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 capital on acceptable terms, or at all.

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

Note 2 - Basis of presentation and summary of significant accounting policies

Basis of presentation and consolidation

The unaudited condensed consolidated financial statements include the accounts of Verona Pharma plc and its wholly-owned subsidiary Verona Pharma, Inc. All inter-company balances and transactions have been eliminated.

The accompanying unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q have been prepared in conformity with accounting principles generally accepted in the U.S. (“U.S. GAAP”).

The unaudited condensed consolidated financial statements presented in this Quarterly Report should be read in conjunction with the consolidated financial statements and accompanying notes included in the Company’s Annual Report on Form 10-K filed with the SEC on March 3, 2022 (the “2021 Form 10-K”). The Consolidated Balance Sheet as of December 31, 2021, was derived from audited consolidated financial statements included in the 2021 Form 10-K but does not include all disclosures required by U.S. GAAP for complete financial statements. The Company’s significant accounting policies are described in Note 2 to those consolidated financial statements.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from these interim financial statements. The unaudited condensed consolidated financial statements reflect all adjustments which in the opinion of management are necessary for a fair statement of results of operations, comprehensive income, financial condition, cash flows and shareholders' equity for the periods presented. Except as otherwise disclosed, all such adjustments are of a normal recurring nature. Operating results for the interim periods are not necessarily indicative of the results that may be expected for the full year.

Segment reporting

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

Use of estimates

The preparation of interim unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these unaudited condensed consolidated financial statements include, but are not limited to, the accrual and prepayment of research and development expenses, the fair value of share-based compensation, the fair value of warrants, research and development tax credit and the carrying value of the equity interest in Nuance Pharma (as defined below). Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from the Company’s estimates.

Recently adopted accounting standards and recent accounting standards not yet adopted

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

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

Note 3 - Tax and tax incentive receivables

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

	June 30, 2022	December 31, 2021
Research and development tax credit receivable - U.K.	\$ 20,185	\$ 15,583
Total tax receivable	\$ 20,185	\$ 15,583

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

Effective for accounting periods starting after April 1, 2021, new rules were introduced whereby the amount of SME R&D tax credit that a business can receive in any one year will be capped at £20,000 plus three times the company's total Pay As You Earn ("PAYE") and National Insurance contributions ("NIC") liability, unless an exception applies. That exception requires the Company to a) be creating, taking steps to create or managing intellectual property, as well as b) having qualifying research and development expenditures in respect of related parties which does not exceed 15% of the total claimed. In July, 2022, the Company received a response to its' clearance application from HMRC agreeing to a) above and based upon analysis performed by the Company, it does not believe related party expenditures will exceed 15% of the total claim for 2022. Therefore, the Company has not applied the cap in determining the tax credit receivable.

Note 4 - Accrued expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Clinical trial and other development costs	\$ 26,364	\$ 21,336
Professional fees and general corporate costs	1,093	919
People related costs	1,146	1
Total accrued expenses	\$ 28,603	\$ 22,256

Note 5 - 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, 2022, the Company had \$5.0 million principal outstanding under the Term Loan.

The Term Loan is governed by a loan and security agreement, dated as of November 19, 2020, between the Borrowers and Silicon Valley Bank ("SVB"), as amended (the "Loan Agreement"). The Term B Loan will be available, subject to customary terms and conditions, only during the period commencing upon the achievement of a specific clinical milestone relating to ensifentrine through and including September 30, 2022. The Term C Loan will be available, subject to customary terms and conditions, only during the period commencing upon the achievement of an additional specific clinical milestone relating to ensifentrine through and including June 30, 2023.

The Term Loan will mature on November 1, 2024. Each advance under the Term Loan accrues interest at a floating per annum rate equal to the greater of (a) the sum of the prime rate reported in The Wall Street Journal plus 1.00% and (b) four and one-quarter of one percent (4.25%). The Term Loan provides for interest-only payments on a monthly basis until the payment date immediately preceding December 1, 2023. Thereafter, amortization payments will be payable monthly in equal installments of principal plus monthly payments of accrued interest. Upon repayment (whether at maturity, upon acceleration or by prepayment or otherwise), the Borrowers shall make a final payment to SVB in the amount of 10% of the aggregate Term Loans advanced (the "Final Payment"). The Borrowers may prepay the Term Loan in full but not in part provided that the Borrowers (i) provide ten days' prior written notice to SVB, (ii) pays on the date of such prepayment (A) all outstanding principal plus accrued and

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

unpaid interest, (B) a prepayment fee of \$450,000 plus 3.0% of the Term C Loans advanced if paid on or before the first anniversary of the closing date; \$300,000 plus 2.00% of the Term C Loans advanced if paid after the first anniversary of the closing date and on or before the second anniversary of the closing date; and \$150,000 plus 1.00% of the Term C Loans advanced if paid thereafter and prior to maturity, (C) the Final Payment and (D) all other sums, if any, that shall become due and payable with respect to the Term Loan Advances, including interest at the Default Rate with respect to any past due amounts. Amounts outstanding during an event of default are payable upon SVB's demand and shall accrue interest at an additional rate of 3.0% per annum.

The Term Loan is secured by a lien on substantially all of the assets of the Borrowers, other than the equity interests of Verona U.S. and other than intellectual property, provided that such lien on substantially all assets includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. The Borrowers have also granted SVB a negative pledge with respect to its intellectual property.

The Loan Agreement contains customary covenants and representations, including but not limited to financial reporting obligations and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries. The Loan Agreement also contains other customary provisions, such as expense reimbursement, non-disclosure obligations as well as indemnification rights for the benefit of SVB. The Loan Agreement includes a minimum cash covenant triggered when Borrowers' consolidated cash and cash equivalents drop below \$45.0 million at any time after the earliest to occur of any of the following: (i) the release of negative data from ENHANCE-2 and/or ENHANCE-1, which in the reasonable business discretion Borrowers' senior management, would be considered insufficient to support submission of an NDA to the FDA, (ii) the FDA issues a complete response letter with respect to an NDA submitted for ensifentrine, or (iii) failure to achieve a specific regulatory milestone relating to ensifentrine by June 30, 2023 (extendable to March 31, 2024 upon the Borrowers receiving a specified amount of new cash proceeds after September 8, 2020 from the sale of equity securities in one or more public financings or other bona fide equity financings, subordinated debt and/or upfront/milestone payments from one or more collaboration agreements not prohibited in the Loan Agreement). Upon such trigger, Borrowers must cash collateralize an amount equal to the outstanding obligations to SVB plus the amount of any prepayment penalty and Final Payment which would be due in the event the Loan Agreement were prepaid in full with respect to the Term Loans advanced as of such time.

As of June 30, 2022, the carrying value of the Term Loan was approximately \$5.0 million, of which all was due in more than 12 months. The debt balance has been categorized within Level 3 of the fair value hierarchy. The carrying amount of the debt approximates its fair value based on prevailing interest rates as of the balance sheet date.

Note 6 - Equity interest

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

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

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

Note 7 - Significant agreements

Ligand agreement

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

Ligand assigned to the Company all of its rights to certain patents and patent applications relating to ensifentrine and related compounds (the “Ligand Patents”) and an exclusive, worldwide, royalty-bearing license under certain Ligand know-how to develop, manufacture and commercialize products (the “Ligand Licensed Products”) developed using Ligand Patents, Ligand know-how and the physical stock of certain compounds.

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

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

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

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

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

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

Nuance agreement

The Company entered into a collaboration and license agreement (the “Nuance Agreement”) with Nuance Pharma Limited (“Nuance Pharma”) effective June 9, 2021 (the “Effective Date”) under which the Company granted Nuance Pharma the exclusive rights to develop and commercialize ensifentrine in Greater China (China, Taiwan, Hong Kong and Macau). In return, the Company received an unconditional right to consideration aggregating \$40.0 million consisting of \$25.0 million in cash and an equity interest, valued at \$15.0 million as of the Effective Date, in Nuance Biotech, the parent company of Nuance Pharma. The Company is eligible to receive future milestone payments of up to \$179.0 million triggered upon achievement of certain clinical, regulatory, and commercial milestones, as well as tiered double-digit royalties as a percentage of net sales of the products in Greater China.

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

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

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

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

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

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

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

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

Note 8 - Share-based compensation

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

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Research and development	\$ 1,330	\$ 3,234	\$ 2,869	\$ 6,666
Selling, general and administrative	1,723	4,217	3,932	9,634
Total	\$ 3,053	\$ 7,451	\$ 6,801	\$ 16,300

Share options

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

	2022	
	Number of share options outstanding	Weighted average exercise price
Balance as of December 31, 2021	12,695,200	\$ 1.38
Granted	608,000	0.62
Balance as of March 31, 2022	13,303,200	\$ 1.34
Granted	1,760,000	0.51
Balance as of June 30, 2022	15,063,200	\$ 1.24

Restricted stock units activity

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

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

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

Note 9 - Net loss per share

Net loss per share is calculated on an ordinary share basis. The Company's ADSs that are listed on the Nasdaq Global Market each represent eight ordinary shares. The following table shows the computation of basic and diluted net loss per share for the three and six months ended June 30, 2022 and 2021 (net loss in thousands, loss per share in dollars):

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Numerator:				
Net loss	\$ (17,766)	\$ (22,068)	\$ (42,603)	\$ (43,358)
Denominator:				
Weighted-average shares outstanding - basic and diluted	<u>484,777,837</u>	<u>470,786,767</u>	<u>483,226,039</u>	<u>469,036,978</u>
Net loss per share - basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.05)</u>	<u>\$ (0.09)</u>	<u>\$ (0.09)</u>

During the three and six months ended June 30, 2022 and 2021, outstanding share options, RSUs and warrants over 46,183,144 and 75,713,291 ordinary shares, respectively, were not included in the computation of diluted earnings per ordinary share, because to do so would be antidilutive.

Note 10 - Commitments and contingencies

Management is currently negotiating a matter with a supplier that has an estimated exposure of approximately \$1.3 million. Management does not currently consider it probable that a payment will be made and therefore no accrual is recorded at June 30, 2022. This matter is expected to be resolved within the next 12 months.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and related notes as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission on March 3, 2022 (the “2021 Form 10-K”).

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

All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including without limitation statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, the development of ensifentrine or any other product candidates, including statements regarding the expected initiation, timing, progress and availability of data from our clinical trials and potential regulatory approvals, research and development costs, timing and likelihood of success, potential collaborations, our estimates regarding expenses, future revenues, capital requirements, debt service obligations and our need for additional financing, the funding we expect to become available from cash receipts from U.K. tax credits, and 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 2021 Form 10-K under the heading “Risk Factors”. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events.

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

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical need. Our product candidate, ensifentrine, is an investigational, potential first-in-class, inhaled, dual inhibitor of the enzymes phosphodiesterase 3 and 4 (“PDE3” and “PDE4”), which is designed to act as both a bronchodilator and an anti-inflammatory agent.

In the third quarter of 2020, we commenced our Phase 3 ENHANCE (“Ensifentrine as a Novel inHAled Nebulized COPD thErapy”) trials evaluating nebulized ensifentrine for the maintenance treatment of COPD. In August 2022, we announced positive top-line results from the ENHANCE-2 trial. ENHANCE-2 successfully met its primary endpoint, as well as secondary endpoints demonstrating improvements in lung function, and significantly reduced the rate and risk of COPD exacerbations. Ensifentrine was well tolerated with safety results similar to placebo.

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

We have incurred recurring losses and negative cash flows from operations since inception, and have an accumulated deficit of \$306.7 million as of June 30, 2022. We expect to incur additional losses and negative cash flows from operations until our product candidates potentially gain regulatory approval and reach commercial profitability, if at all.

We anticipate significant expenses in connection with our ongoing activities, as we:

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

We believe that our cash and cash equivalents as of June 30, 2022, expected cash receipts from U.K. tax credits and funding expected to become available under the \$30.0 million term loan secured in November 2020, will enable us to fund our planned operating expenses and capital expenditure requirements through at least the end of 2023. The Term Loan advances are contingent upon achievement of certain clinical development milestones and other specified conditions. See “Indebtedness” for additional information.

Clinical development update

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

Highlights

- **Study population (n=789):**
 - Subject demographics and disease characteristics were well balanced between treatment groups.
 - Approximately 52% of subjects received background COPD therapy, either a long-acting muscarinic antagonist (“LAMA”) or a long-acting beta-agonist (“LABA”). Additionally, approximately 15% of all subjects also received inhaled corticosteroids (“ICS”) with concomitant LAMA or LABA.
- **Primary endpoint met (FEV₁* AUC 0-12 hr):**
 - Placebo corrected, the change from baseline in average FEV₁ area under the curve 0-12 hours post dose at week 12 was 94 mL (p<0.0001) for ensifentrine.
 - Statistically significant and clinically meaningful improvements with ensifentrine demonstrated across all subgroups including gender, age, smoking status, COPD severity, background medication, ICS use, chronic bronchitis, FEV₁ reversibility, and geographic region.
- **Secondary endpoints of lung function met:**
 - Placebo corrected, increase in peak FEV₁ of 146 mL (p<0.0001) 0-4 hours post dose at week 12.
 - Placebo corrected, increase in morning trough FEV₁ of 49 mL (p=0.0017) at week 12, confirming twice daily dosing regimen.
- **Exacerbation rate reduced:**
 - Subjects receiving ensifentrine demonstrated a 42% reduction in the rate of moderate to severe COPD exacerbations over 24 weeks compared to those receiving placebo (p=0.0109).
 - Treatment with ensifentrine significantly decreased the risk of a moderate/severe exacerbation as measured by time to first exacerbation when compared with placebo by 42% (p=0.0088).
- **COPD symptoms and Quality of Life (“QOL”):**
 - Daily symptoms and QOL as measured by E-RS** Total Score and SGRQ** Total Score in the ensifentrine group improved from baseline to greater than the minimal clinically important difference (“MCID”) of -2 units and -4 units, respectively, at week 24. Improvements in these measures were seen as early as 6 weeks and showed continued improvement at 12 and 24 weeks, numerically exceeding placebo at each measurement. Statistical significance was not achieved due to improvements observed in the placebo group over time.
- **Favorable safety profile:**
 - Ensifentrine was well tolerated with safety results similar to placebo, including occurrence of pneumonia, gastrointestinal and cardiovascular adverse events.

*FEV₁: Forced Expiratory Volume in one second, a standard measure of lung function

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

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

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

The two randomized, double-blind placebo-controlled studies (ENHANCE-1 and ENHANCE-2) evaluate the efficacy and safety of nebulized ensifentrine in subjects with COPD as monotherapy and added onto a single bronchodilator, either a LAMA or a LABA, compared to placebo, and up to approximately 20% of subjects may receive ICS. The two study designs replicate measurements of efficacy and safety data over 24 weeks and ENHANCE-1 also evaluates longer-term safety over 48 weeks. The primary endpoint of both studies is

improvement in lung function, as measured by FEV₁ area under curve (“AUC”) 0-12 hours post dose at week 12. Key secondary endpoints comprise measurements of COPD symptoms and health-related quality of life measures, including SGRQ and E-RS.

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

In May 2022, we presented a successful thorough QT analysis demonstrating ensifentrine had no clinically relevant effect on the QT interval or cardiac conduction at the American Thoracic Society International Conference (“ATS”) 2022. The abstract was published on the ATS website and in the peer reviewed publication, *American Journal of Respiratory and Critical Care Medicine*.

In June 2022, we hosted an investor event where leading pulmonologists discussed the COPD treatment landscape, including unmet needs, and the treatment paradigm.

COVID-19 impact

We continue to monitor the potential impact of the COVID-19 pandemic on our operations and clinical trials, in particular the timelines and costs of its Phase 3 clinical program ENHANCE. The pandemic and government and other measures in response continue to impact a number of clinical trial activities and management will provide an update if it becomes aware of any meaningful disruption caused by the pandemic to its clinical trials.

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

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

Russia-Ukraine Conflict

We are conducting ENHANCE-1 at a number of clinical trial sites in Russia and Europe (but not including Ukraine). The sanctions and other restrictions imposed by the U.S. and other countries as a result of the current conflict between Russia and Ukraine are impacting, and may continue to impact, our outsourced clinical research vendor’s ability to pay the clinical trial sites and investigators in Russia and may impact the vendor’s ability to supply ensifentrine and equipment to the sites and validate their trial data. If the conflict extends into other countries in Europe where our clinical trials are being conducted, our clinical trial activities in those countries may also be impacted. Management is closely monitoring the Russia-Ukraine conflict and will provide an update if we become aware of any meaningful disruption to the cost and timelines of our Phase 3 program or our plans to submit an NDA for ensifentrine.

Significant agreements

Ligand agreement

In 2006 we acquired Rhinopharma and assumed contingent liabilities owed to Ligand UK Development Limited (“Ligand”) (formerly Vernalis Development Limited). We refer to the assignment and license agreement as the Ligand Agreement.

Ligand assigned to us all of its rights to certain patents and patent applications relating to ensifentrine and related compounds (the “Ligand Patents”) and an exclusive, worldwide, royalty-bearing license under certain Ligand know-how to develop, manufacture and commercialize products (the “Ligand Licensed Products”) developed using Ligand Patents, Ligand know-how and the physical stock of certain compounds.

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

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

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

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

Nuance agreement

We entered into a collaboration and license agreement (the “Nuance Agreement”) with Nuance Pharma Limited (“Nuance Pharma”) effective June 9, 2021 (the “Effective Date”) under which we granted Nuance Pharma the exclusive rights to develop and commercialize ensifentrine in Greater China (China, Taiwan, Hong Kong and Macau). In return, we received an unconditional right to consideration aggregating \$40.0 million consisting of \$25.0 million in cash and an equity interest valued at \$15.0 million as of the Effective Date in Nuance Biotech, the parent company of Nuance Pharma. We are eligible to receive future milestone payments of up to \$179.0 million, triggered upon achievement of certain clinical, regulatory, and commercial milestones as well as tiered double-digit royalties on net sales in Greater China.

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

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

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

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

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

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

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

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

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

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

Warrants

On July 29, 2016, as part of a private placement we issued warrants to investors. The warrant holders could subscribe for an ordinary share at a per share exercise price of £1.7238. They could also opt for a cashless exercise of their warrants whereby they could choose to exchange the warrants held for a reduced number of warrants exercisable at nil consideration.

If, after a transaction, should the warrants be exercisable for unlisted securities, the warrant holders were able to demand a cash payment instead of the delivery of the underlying securities. Accordingly, they were accounted for as a liability under ASC 480 "Distinguishing Liabilities from Equity" and recorded at fair value using the Black-Scholes valuation methodology, on recognition and at each reporting date. The warrants were exercisable by the holders until May 2, 2022. None of the warrants were exercised prior to their expiration.

Loan and security agreement

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

Critical accounting estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. (“U.S. GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the recognition of revenue, the accrual and prepayment of research and development expenses, the fair value of share-based compensation, the carrying value of the equity interest in Nuance Pharma, research and development tax credit and the fair value of warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from our estimates. The accounting policies considered to be critical to the judgments and estimates used in the preparation of our financial statements are disclosed in the Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our 2021 Form 10-K. There have been no material changes to that information disclosed in our 2021 Form 10-K during the six months ended June 30, 2022.

Components of results of operations

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

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

Operating expenses

Research and development costs

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

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

Selling, general and administrative costs

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

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

Other income/(expense)

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

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

Effective January 1, 2022, this tax credit will be subject to a cap equal to a multiple of employment taxes the entity pays in the year in question. In July, 2022, we received a response to our clearance application from HMRC agreeing we meet certain conditions to qualify as an exception. Therefore, we have not applied the cap in determining the tax credit receivable.

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, 2022 and 2021

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

	Three months ended June 30,		Change
	2022	2021	
Operating expenses			
Research and development	14,982	20,563	(5,581)
Selling, general and administrative	5,526	7,985	(2,459)
Total operating expenses	<u>20,508</u>	<u>28,548</u>	<u>(8,040)</u>
Operating loss	(20,508)	(28,548)	8,040
Other income/(expense)			
Research and development tax credit	5,409	3,836	1,573
Interest income	165	3	162
Interest expense	(91)	(85)	(6)
Fair value movement on warrants	—	2,711	(2,711)
Foreign exchange (loss)/gain	(2,662)	40	(2,702)
Total other income, net	<u>2,821</u>	<u>6,505</u>	<u>(3,684)</u>
Loss before income taxes	(17,687)	(22,043)	4,356
Income tax expense	(79)	(25)	(54)
Net loss	<u>\$ (17,766)</u>	<u>\$ (22,068)</u>	<u>\$ 4,302</u>

Research and development costs were \$15.0 million for the three months ended June 30, 2022, compared to \$20.6 million for the three months ended June 30, 2021, a decrease of \$5.6 million. This decrease was primarily due to a \$4.2 million decrease in clinical trial and other development costs, as we progressed to later stages of our Phase 3 ENHANCE program and a \$1.9 million decrease in share-based compensation.

Selling, general and administrative costs

Selling, general and administrative costs were \$5.5 million for the three months ended June 30, 2022, compared to \$8.0 million for the three months ended June 30, 2021, a decrease of \$2.5 million, primarily due to a decrease in share-based compensation.

Other income/(expense)

The research and development tax credit for the three months ended June 30, 2022 was \$5.4 million compared to \$3.8 million for the three months ended June 30, 2021, an increase of \$1.6 million. Based upon feedback received from HMRC in July 2022, we concluded a cap on this credit is not applicable for Verona Pharma in 2022. Therefore we recognized the full credit for expenditures made in the second quarter and also recognized an increase in the credit for expenditures made in the first quarter, which had been recognized previously as if the cap applied.

We recorded no movements in the three months ended June 30, 2022, compared to income of \$2.7 million in the comparative period relating to the fair value movements of the warrants. The warrants expired in the three months ended June 30, 2022 and having previously no value in the three months ended March 31, 2022 no income was recorded. In the three months ended June 30, 2021, the reduction in liability was due to a decrease in the share price in that period and reduced volatility.

Net loss

Net loss was \$17.8 million for the three months ended June 30, 2022, compared to a net loss of \$22.1 million for the three months ended June 30, 2021, because of the factors outlined above.

Results of operations for the six months ended June 30, 2022 and 2021

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

	Six months ended June 30,		Change
	2022	2021	
Operating expenses			
Research and development	\$ 32,607	\$ 34,137	\$ (1,530)
Selling, general and administrative	12,966	17,267	(4,301)
Total operating expenses	<u>45,573</u>	<u>51,404</u>	<u>(5,831)</u>
Operating loss	(45,573)	(51,404)	5,831
Other income/(expense)			
Research and development tax credit	6,711	5,906	805
Interest income	180	7	173
Interest expense	(175)	(169)	(6)
Fair value movement on warrants	—	2,204	(2,204)
Foreign exchange (loss)/gain	(3,585)	203	(3,788)
Total other income, net	<u>3,131</u>	<u>8,151</u>	<u>(5,020)</u>
Loss before income taxes	(42,442)	(43,253)	811
Income tax expense	(161)	(105)	(56)
Net loss	<u>\$ (42,603)</u>	<u>\$ (43,358)</u>	<u>\$ 755</u>

Research and development costs

Research and development costs were \$32.6 million for the six months ended June 30, 2022, compared to \$34.1 million for the six months ended June 30, 2021, a decrease of \$1.5 million. This decrease was primarily due to a \$3.8 million decrease in share-based compensation charges, partially offset by a \$1.3 million increase in clinical trial and other development costs and a \$0.7 million increase in clinical trial site audit and NDA filing preparation costs.

Selling, general and administrative costs

Selling, general and administrative costs were \$13.0 million for the six months ended June 30, 2022 compared to \$17.3 million for the six months ended June 30, 2021, a decrease of \$4.3 million. This decrease was driven primarily by a \$5.7 million decrease in share-based compensation charges and a \$0.5 million decrease in professional fees, partially offset by a \$2.0 million charge related to the modification of the Ligand Agreement.

Other income/(expense)

The research and development tax credit for the six months ended June 30, 2022 was \$6.7 million compared to \$5.9 million for the six months ended June 30, 2021, an increase of \$0.8 million. This increase is attributable to higher qualifying research and development expenditures in the six months ended June 30, 2022, compared to the comparative 2021 period.

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

Net loss

Net loss was \$42.6 million for the six months ended June 30, 2022, compared to \$43.4 million for the six months ended June 30, 2021, because of the factors outlined above.

Cash flows

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

	Six months ended June 30,		
	2022	2021	Change
Cash and cash equivalents at beginning of the period	<u>\$ 148,380</u>	<u>\$ 187,986</u>	<u>\$ (39,606)</u>
Net cash used in operating activities	(34,029)	(38,756)	4,727
Net cash used in investing activities	(29)	—	(29)
Net cash used in financing activities	(1,415)	(3,399)	1,984
Effect of exchange rate changes on cash and cash equivalents	(1,397)	204	(1,601)
Cash and cash equivalents at end of the period	<u><u>\$ 111,510</u></u>	<u><u>\$ 146,035</u></u>	<u><u>\$ (34,525)</u></u>

Operating activities

Net cash used in operating activities was \$34.0 million in the six months ended June 30, 2022, compared to \$38.8 million during the six months ended June 30, 2021, a decrease of \$4.8 million. This decrease is predominantly due to timing of supplier payments.

Financing activities

Net cash used in financing activities was \$1.4 million in the six months ended June 30, 2022, compared to \$3.4 million in the six months ended June 30, 2021. This decrease is primarily due to lower payments of withholding taxes due on the net-settling of certain employees' RSU awards.

Liquidity and capital resources

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily through the issuances of our equity securities, including warrants, from borrowings under the Term Loan and upfront payments from the Nuance Agreement. See “Significant Agreements” and “Indebtedness” for additional information.

We have incurred recurring losses since inception, including net losses of \$42.6 million for the six months ended June 30, 2022, and \$55.6 million for the year ended December 31, 2021. As of June 30, 2022, we had an accumulated deficit of \$306.7 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 six months ended June 30, 2022, we sold 80,696 ordinary shares (equivalent to 10,087 ADSs) under the ATM Program, at an average price of approximately \$0.86 per share (equivalent to \$6.86 per ADS), raising aggregate net proceeds of approximately \$0.1 million after deducting issuance costs. As of June 30, 2022, \$99.2 million of ordinary shares, in the form of ADSs, remained available for sale under the ATM Program.

Indebtedness

In November 2020, we and Verona Pharma, Inc. entered into a term loan facility of up to \$30.0 million with Silicon Valley Bank, which we refer to as the Term Loan, consisting of term loan advances in an aggregate amount of \$5.0 million funded at closing, a term loan advance of an aggregate amount of \$10.0 million available subject to certain terms and conditions and the achievement of a specific clinical milestone, and a term loan advance of an aggregate amount of \$15.0 million contingent upon achievement of a specific clinical development milestone and other specified conditions. As of June 30, 2022, 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 2021 Form 10-K. There have been no material changes to that information disclosed in our 2021 Form 10-K during the six months ended June 30, 2022.

Funding requirements

We believe that our cash and cash equivalents as of June 30, 2022, expected cash receipts from U.K. tax credits and funding expected to become available under the Term Loan, will enable us to fund our planned operating expenses and capital expenditure requirements through at least the end of 2023. The Term Loan advances are contingent upon achievement of certain clinical development milestones and other specified conditions.

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

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

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds

through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

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

Recent accounting pronouncements

For a discussion of pending and recently adopted accounting pronouncements, see Note 2 to our consolidated financial statements included in the 2021 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended June 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors have not changed materially from those described in Part I, Item 1A of the 2021 Form 10-K under the heading “Risk Factors”.

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	
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	Inline XBRL Instance Document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*
*	Filed herewith.					
**	Furnished herewith.					

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VERONA PHARMA PLC

Date: August 9, 2022

By:

/s/ David Zaccardelli

David Zaccardelli, Pharm. D.

President and Chief
Executive Officer

Date: August 9, 2022

By:

/s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer