

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 9, 2022

Verona Pharma plc
(Exact name of registrant as specified in its charter)

United Kingdom
(State or other jurisdiction
of incorporation)

001-39067
(Commission
File Number)

98-1489389
(IRS Employer
Identification No.)

3 More London Riverside
London SE1 2RE
United Kingdom
(Address of principal executive offices) (Zip Code)

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Conditions.

On August 9, 2022, Verona Pharma plc (the “Company”) announced its financial results for the quarter ended June 30, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the “Current Report”).

The information contained in this Item 2.02 of this Current Report (including Exhibit 99.1 attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

On August 9, 2022, the Company posted a slide presentation regarding top-line data from the Phase 3 ENHANCE-2 clinical trial in the “Events & Presentations” portion of its website at www.veronapharma.com. A copy of the slide presentation is furnished as Exhibit 99.2 to this Current Report.

The information contained in this Item 7.01 of this Current Report (including Exhibit 99.2 attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibits 99.2.

Item 8.01. Other Events.

On August 9, 2022, the Company announced the following top-line results from the Phase 3 ENHANCE-2 clinical trial evaluating nebulized ensifentrine for the maintenance treatment of chronic obstructive pulmonary disease (“COPD”):

- **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, 15% of all subjects received inhaled corticosteroids (“ICS”) with concomitant LAMA or LABA.
 - **Primary endpoint met (FEV₁* AUC 0-12 hr):**
 - Placebo corrected, 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, supporting 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 in the placebo group over time.
- **Favorable safety results:**
 - 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

These data, along with results from the Company’s ongoing Phase 3 ENHANCE-1 clinical trial, which is on track to be reported around the end of 2022, are expected to support the submission of a New Drug Application to the U.S. Food and Drug Administration (the “FDA”) in the first half of 2023.

In 2020, there were approximately 6 million patients on maintenance treatment for COPD in the United States, with approximately 5 million patients receiving two or more therapies or alternative therapies. Of those patients, approximately 40% remain symptomatic, resulting in more than 1 million patients that the Company believes has the potential to be treated with ensifentrine. As of December 2021, 35 payers covered more than 200 million lives, or 85% of all lives covered, for nebulizers, with the majority of claims for nebulizers in the United States reimbursed through Medicare Part B. If ensifentrine is approved, the Company plans to target the approximately 12,000 pulmonologists in the United States and expects that it will need approximately 100 sales representatives.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following Exhibits 99.1 and 99.2 relating to Items 2.02 and 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release of Verona Pharma plc issued on August 9, 2022.
99.2	ENHANCE-2 Data Slide Presentation of Verona Pharma plc.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the development of ensifentrine and the progress and timing of clinical trials and data, the timing of data from the Company’s clinical trials, the Company’s ability to submit a New Drug Application to the FDA and the timing for such an application, the potential number of patients that could be treated with ensifentrine, and the Company’s expectations regarding the commercialization resources needed for ensifentrine, if approved. These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company’s actual results, performance or achievements to be materially different from its expectations expressed or implied by the forward-looking statements, including without limitation: general business, financial and accounting risks; the

Company's need for additional funding to complete development and commercialization of ensifentrine, which may not be available and which may force the Company to delay, reduce or eliminate development or commercialization efforts; the reliance of the Company's business on the success of ensifentrine, its only product candidate under development; economic, political, regulatory and other risks involved with international operations; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; serious adverse, undesirable or unacceptable side effects associated with ensifentrine, which could adversely affect the Company's ability to develop or commercialize ensifentrine; potential delays in enrolling patients, which could adversely affect the Company's research and development efforts and the completion of its clinical trials; the Company's ability to obtain approval for and commercialize ensifentrine in multiple major pharmaceutical markets; material differences between the Company's "top-line" data and final data; the Company's reliance on third parties, including clinical research organizations, clinical investigators, manufacturers and suppliers, and the risks related to these parties' ability to successfully develop and commercialize ensifentrine; changes in the Company's tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments could affect profitability, and audits by tax authorities could result in additional tax payments for prior periods; the Company's vulnerability to natural disasters, global economic factors and other unexpected events, including health epidemics or pandemics like the COVID-19 pandemic, which has and may continue to adversely impact the Company's business, and Russia's invasion of Ukraine; and the other important factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2021 and as any such factors may be updated from time to time in its other filings with the SEC. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report.

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 hereunto duly authorized.

VERONA PHARMA PLC

Date: August 9, 2022

By: /s/ David Zaccardelli, Pharm. D.
Name: David Zaccardelli, Pharm. D.
Title: President and Chief Executive Officer



Verona Pharma Reports Second Quarter 2022 Financial Results and Provides Corporate Update

Ensifentrine met primary and secondary endpoints of evaluating lung function in Phase 3 ENHANCE-2 trial for COPD

Top-line Phase 3 ENHANCE-1 data expected around the end of 2022

Conference call today at 8:30 a.m. EDT / 1:30 p.m. BST

LONDON and RALEIGH, N.C., August 9, 2022 – Verona Pharma plc (Nasdaq: VRNA) (“Verona Pharma” or the “Company”), a clinical-stage biopharmaceutical company focused on respiratory diseases, announces its financial results for the three months ended June 30, 2022, and provides a corporate update.

In a separate press release issued earlier today, Verona Pharma announced positive top-line results from its Phase 3 ENHANCE-2 (“Ensifentrine as a Novel inHAled Nebulized COPD thErapy”) trial evaluating nebulized ensifentrine for the maintenance treatment of chronic obstructive pulmonary disease (“COPD”). The ENHANCE-2 trial has 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.

David Zaccardelli, Pharm. D., President and Chief Executive Officer, said: “We are very pleased by the successful outcome of our ENHANCE-2 study and remain committed to bringing ensifentrine to COPD patients as quickly as possible. These data, along with results from our ongoing Phase 3 trial, ENHANCE-1, which are on track to be reported around the end of 2022, if similarly positive, are expected to support the submission of a New Drug Application to the US Food and Drug Administration in the first half of 2023. We want to thank all the patients and investigators for their participation in the trial to advance ensifentrine as a potential new therapy for the treatment of COPD.”

Program Updates and Key Milestones

Based on current models of study progression, the Company’s near-term milestones include:

- Reporting top-line data from ENHANCE-1 around the end of 2022.
- Conditional upon positive results, the Company expects to submit a New Drug Application (“NDA”) to the US Food and Drug Administration (“FDA”) in the first half of 2023 for inhaled ensifentrine for the maintenance treatment of COPD.

With the recent sanctions and other government restrictions resulting from the Russia-Ukraine conflict and the COVID-19 pandemic continuing to impact a number of clinical trial activities, the Company continues to closely monitor these timelines.

Second Quarter and Recent Highlights

Clinical

- In August 2022, the Company reported positive top-line Phase 3 data from ENHANCE-2. The trial successfully met its primary endpoint and secondary endpoints evaluating lung function. Ensifentrine also significantly reduced the rate and risk of COPD exacerbations. Ensifentrine was well tolerated with safety results similar to placebo.
- In May 2022, the Company 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 is published on the ATS website and in the peer reviewed publication, *American Journal of Respiratory and Critical Care Medicine*.

- In June 2022, the Company completed enrollment in ENHANCE-1 with more than 800 subjects randomized.

Second Quarter 2022 Financial Results

- **Cash position:** Cash and cash equivalents at June 30, 2022, were \$111.5 million (March 31, 2022: \$132.8 million). The Company believes cash and cash equivalents at June 30, 2022, expected cash receipts from the U.K. tax credit program and funding expected to become available under the \$30.0 million debt facility, will enable Verona Pharma to fund planned operating expenses and capital expenditure requirements through at least the end of 2023.
- **R&D Expenses:** Research and development (“R&D”) expenses were \$15.0 million for the second quarter ended June 30, 2022 (Q2 2021: \$20.6 million). The decrease of \$5.6 million was primarily due to a \$4.2 million decrease in clinical trial and other development costs as we progressed to the later stages of our Phase 3 ENHANCE program and a \$1.9 million decrease in share-based compensation.
- **SG&A Expenses:** Selling general and administrative expenses (“SG&A”) were \$5.5 million for the second quarter ended June 30, 2022 (Q2 2021: \$8.0 million). The decrease of \$2.5 million was primarily due to a decrease in share-based compensation.
- **Net loss:** Net loss was \$17.8 million for the second quarter ended June 30, 2022 (Q2 2021: net loss \$22.1 million).

Conference Call and Webcast Information

Verona Pharma will host an investment community webcast and conference call at 8:30 a.m. EDT / 1:30 p.m. BST on Tuesday, August 9, 2022, to discuss the ENHANCE-2 results, its second quarter financial results and the corporate update.

To participate, please dial one of the following numbers and reference conference ID 2165062:

- Link to ENHANCE-2 and second quarter 2022 results call
<https://www.veronapharma.com/media/verona-pharma-announces-ensifentrine-meets-primary-endpoint>
- +1-888-317-6003 for callers in the United States
- +1-412-317-6061 for international callers

A live webcast will be available on the Events and Presentations link on the Investors page of the Company’s website, www.veronapharma.com, and the audio replay will be available for 90 days. An electronic copy of the second quarter 2022 results press release will also be made available today on the Company’s website.

For further information please contact:

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Kimberly Minarovich / Michael Barron	
Optimum Strategic Communications (International Media and European Investor Enquiries)	Tel: +44 (0)203 882 9621 verona@optimumcomms.com
Mary Clark / Rebecca Noonan / Zoe Bolt	

About Verona Pharma

Verona Pharma is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of respiratory diseases with significant unmet medical needs. If successfully developed and approved, Verona Pharma's product candidate, ensifentrine, has the potential to be the first therapy for the treatment of respiratory diseases that combines bronchodilator and anti-inflammatory activities in one compound. The Company is evaluating nebulized ensifentrine in its Phase 3 clinical program ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") for COPD maintenance treatment. Ensifentrine met the primary endpoint in ENHANCE-2 demonstrating a statistically significant and clinically meaningful improvement in lung function. In addition, ensifentrine significantly reduced the rate of COPD exacerbations. Two additional formulations of ensifentrine are in Phase 2 development for the treatment of COPD: dry powder inhaler ("DPI") and pressurized metered-dose inhaler ("pMDI"). Ensifentrine has potential applications in cystic fibrosis, asthma and other respiratory diseases. For more information, please visit www.veronapharma.com.

COVID-19 Impact

Verona Pharma continues to monitor the impact of the COVID-19 pandemic on its 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 the Company 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, the Company continues to follow guidance from the FDA and other health regulatory authorities regarding the conduct of clinical trials during the COVID-19 pandemic in an effort 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 the Company is closely monitoring this situation and will provide an update if it becomes aware of any meaningful disruption caused by the pandemic to the supply of ensifentrine and drug-related products, equipment and services for its clinical trials.

Russia-Ukraine Conflict

Verona Pharma is 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, the Company's 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 the Company's clinical trials are being conducted, its clinical trial activities in those countries may also be impacted. The Company is closely monitoring the Russia-Ukraine conflict and will provide an update if it becomes

aware of any meaningful disruption to the cost and timelines of our Phase 3 program or its plans to submit an NDA for ensifentrine.

Forward-Looking Statements

This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding our operational review, outlook and financial review, the development of ensifentrine and the progress and timing of clinical trials and data, the goals and design of clinical trials, the assumptions underlying the Company's models on clinical trial recruitment and progress, including the potential impact of the COVID-19 pandemic and the Russia-Ukraine conflict on such progress and on our business and operations and the Company's future financial results, the timing of submission of an NDA for ensifentrine, the potential for ensifentrine to be the first therapy for the treatment of respiratory diseases to combine bronchodilator and anti-inflammatory effects in one compound, the potential of ensifentrine in the treatment of COPD, cystic fibrosis, asthma and other respiratory diseases, as well as the potential of the DPI and pMDI formulations of ensifentrine, the funding we expect to become available under the \$30.0 million debt financing facility and from cash receipts from U.K. tax credits, and the sufficiency of cash and cash equivalents.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from our expectations expressed or implied by the forward-looking statements, including, but not limited to, the following: our limited operating history; our need for additional funding to complete development and commercialization of ensifentrine, which may not be available and which may force us to delay, reduce or eliminate our development or commercialization efforts; the reliance of our business on the success of ensifentrine, our only product candidate under development; economic, political, regulatory and other risks involved with international operations; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; serious adverse, undesirable or unacceptable side effects associated with ensifentrine, which could adversely affect our ability to develop or commercialize ensifentrine; potential delays in enrolling subjects, which could adversely affect our research and development efforts and the completion of our clinical trials; we may not be successful in developing ensifentrine for multiple indications; our ability to obtain approval for and commercialize ensifentrine in multiple major pharmaceutical markets; misconduct or other improper activities by our employees, consultants, principal investigators, third-party service providers and licensees; our inability to realize the anticipated benefits under licenses granted by us to third parties to develop and commercialize ensifentrine, our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel; material differences between our "top-line" data and final data; our reliance on third parties, including clinical research organizations, clinical investigators, manufacturers and suppliers, and the risks related to these parties' ability to successfully develop and commercialize ensifentrine; lawsuits related to patents covering ensifentrine and the potential for our patents to be found invalid or unenforceable; lawsuits related to our licensing of patents and know-how with third parties for the development and commercialization of ensifentrine; changes in our tax rates, unavailability of certain tax credits or reliefs or exposure to additional tax liabilities or assessments could affect our profitability, and audits by tax authorities could result in additional tax payments for prior periods; and our vulnerability to natural disasters, global economic factors, geo-political actions and unexpected events, including health epidemics or pandemics like the COVID-19 pandemic, and conflicts such as the Russia-Ukraine conflict, which has and may continue to adversely impact our business. These and other important factors under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Verona Pharma plc
Consolidated Financial Summary
(unaudited)

	Three months ended June 30,	
	2022	2021
	(\$000's)	(\$000's)
Operating expenses		
Research and development	\$ 14,982	\$ 20,563
Selling, general and administrative	5,526	7,985
Total operating expenses	20,508	28,548
Operating loss	(20,508)	(28,548)
Other income/(expense)		
Benefit from R&D tax credit	5,409	3,836
Interest income	165	3
Interest expense	(91)	(85)
Fair value movement on warrants	-	2,711
Foreign exchange (loss) / gain	(2,662)	40
Total other income, net	2,821	6,505
Loss before income taxes	(17,687)	(22,043)
Income tax expense	(79)	(25)
Net loss	\$ (17,766)	\$ (22,068)
Weighted-average shares outstanding – basic and diluted	484,777,837	470,786,767
Loss per ordinary share – basic and diluted	\$ (0.04)	\$ (0.05)
	June 30 2022	March 31 2022
Cash and cash equivalents	\$ 111,510	\$ 132,764
Total assets	\$ 154,856	\$ 169,315
Equity	\$ 110,880	\$ 126,307



ENHANCE-2 Phase 3 data

August 2022

Nasdaq: VRNA | www.veronapharma.com



Forward-looking statements

This presentation contains “forward-looking” statements that are based on the beliefs and assumptions and on information currently available to management of Verona Pharma plc (together with its consolidated subsidiaries, the “Company”). All statements other than statements of historical fact contained in this presentation are forward-looking statements. Forward-looking statements include information concerning the initiation, timing, progress and results of clinical trials of the Company’s product candidate, the timing or likelihood of regulatory filings and approvals for of its product candidate, and estimates regarding the Company’s expenses, future revenues and future capital requirements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other comparable terminology.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors include those under “Risk Factors” in the Company’s annual report on Form 10-K for the year ended December 31, 2021, and current reports on Form 8-K and our other filings with the Securities and Exchange Commission (the “SEC”). Forward-looking statements represent the Company’s beliefs and assumptions only as of the date of this presentation. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this presentation, or to conform any of the forward-looking statements to actual results or to changes in its expectations.

This presentation also contains estimates, projections and other information concerning the Company’s business and the markets for the Company’s product candidate, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, the Company obtained this industry, business, market and other data from reports, research surveys, clinical trials studies and similar data prepared by market research firms and other third parties, from industry, medical and general publications, and from government data and similar sources.

Agenda

On Today's Call:



- **Welcome and ENHANCE-2 Data Overview**
David Zaccardelli, PharmD, CEO



- **Financial Review**
Mark Hahn, CFO

- **Q&A**

- **Closing Remarks**
David Zaccardelli, PharmD, CEO

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Joining for Q&A:



Key Opinion
Leader

- **Antonio Anzueto, MD**
*Professor of Medicine and Section,
Chief of Pulmonary at South Texas
Veterans Healthcare System*



- **Kathy Rickard, MD**
CMO



- **Chris Martin**
SVP of Commercial

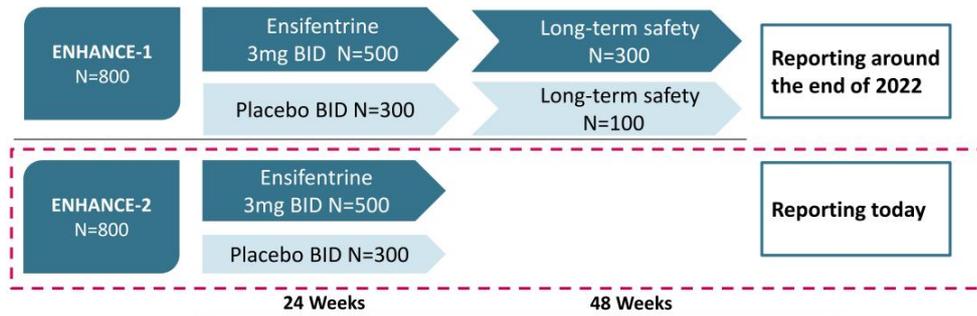


- **Tara Rheault, PhD**
SVP of R&D

Pivotal Phase 3 program

Two efficacy and safety studies: ENHANCE-1 and ENHANCE-2

Ensifentrine as a Novel inHAled Nebulized COPD thErapy in moderate to severe COPD



Patient population:

- LAMA or LABA background allowed (approx. 50% of trial population) and ICS (up to approx. 20% of population)
- 30-70% predicted FEV₁
- Symptomatic (mMRC ≥ 2)

Additional information:

- Long-term safety in ENHANCE-1
- Sites in North America, EU and Asia

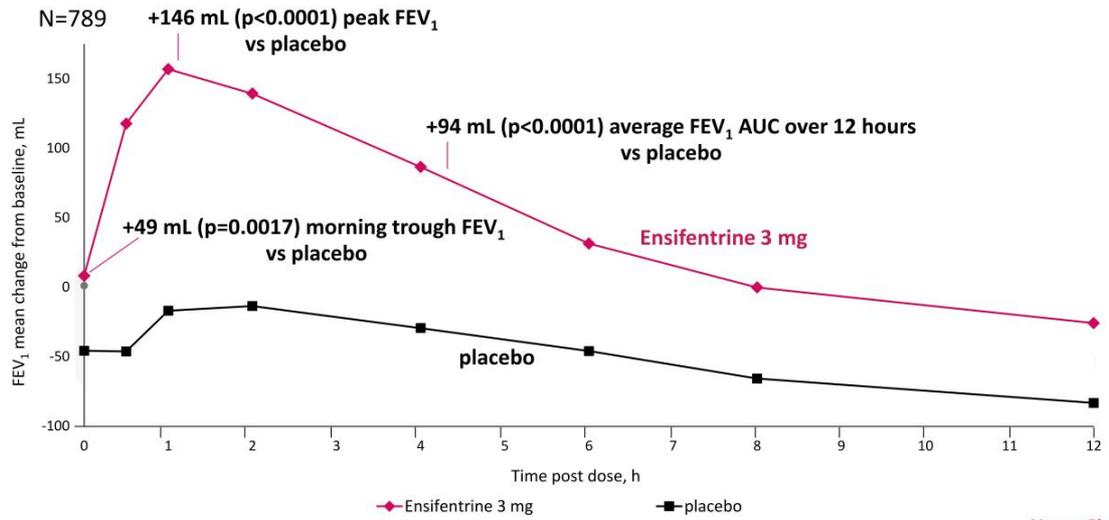
ENHANCE-2 baseline characteristics

Demographics and baseline characteristics well balanced between groups

<i>Parameter</i>	<i>Ensifentrine n=499</i>	<i>Placebo n=291</i>	<i>Total n=790</i>
Age, mean (SD)	65.0 (7.4)	65.3 (7.3)	65.1 (7.4)
Gender, % Male, n (%)	245 (49.1)	138 (47.4)	383 (48.5)
Moderate / Severe COPD, n (%)	266 (53.3) / 231 (46.3)	143 (49.1) / 148 (50.9)	409 (51.8) / 379 (48.0)
Mild/Very Severe COPD, n (%)	1 (0.2)/ 1 (0.2)	0/0	1 (0.1)/ 1 (0.1)
% Predicted FEV ₁ mean, (SD)	50.8 (10.7)	50.4 (10.7)	50.6 (10.7)
% with Chronic Bronchitis, n (%)	322 (64.5)	190 (65.3)	512 (64.8)
% Current Smokers, n (%)	276 (55.3)	160 (54.9)	436 (55.2)
Background Meds: Yes, n (%)	264 (52.9)	150 (51.5)	414 (52.4)
LAMA	157 (31.5)	80 (27.5)	237 (30.0)
LAMA/ICS	1 (0.2)	0	1 (0.1)
LABA	34 (6.8)	23 (7.9)	57 (7.2)
LABA/ICS	72 (14.4)	47 (16.2)	119 (15.0)
E-RS Baseline, mean (SD)	13.3 (6.7)	13.3 (6.2)	-
SGRQ Baseline, mean (SD)	50.6 (17.4)	51.2 (16.4)	-

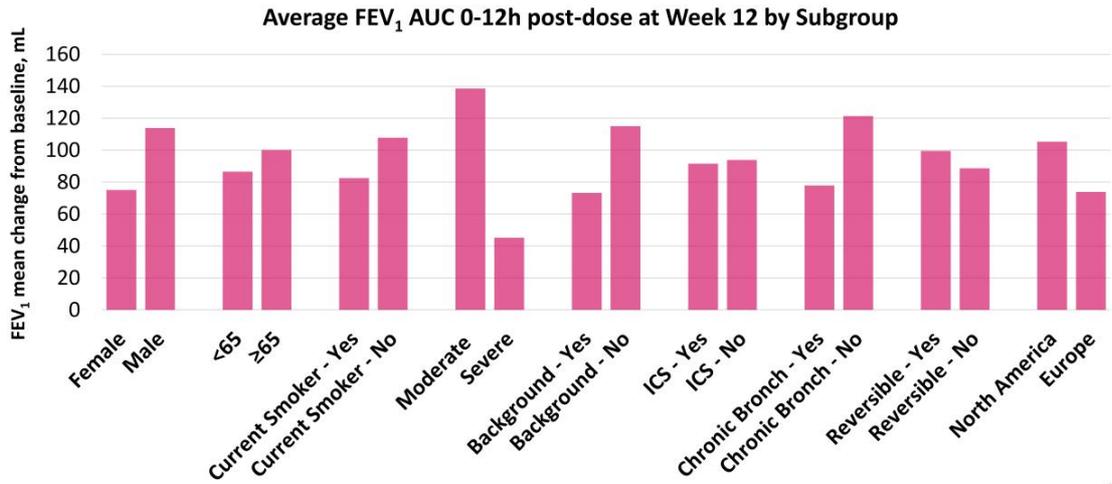
Primary endpoint met in Phase 3 ENHANCE-2

Significant and clinically meaningful improvements in lung function at Week 12



Enfentrine improves lung function in all subgroups

Statistically significant improvements versus placebo in all subgroups (All $p < 0.05$)



Ensifentrine reduces exacerbation rate

42% reduction in rate of moderate or severe COPD exacerbation vs placebo

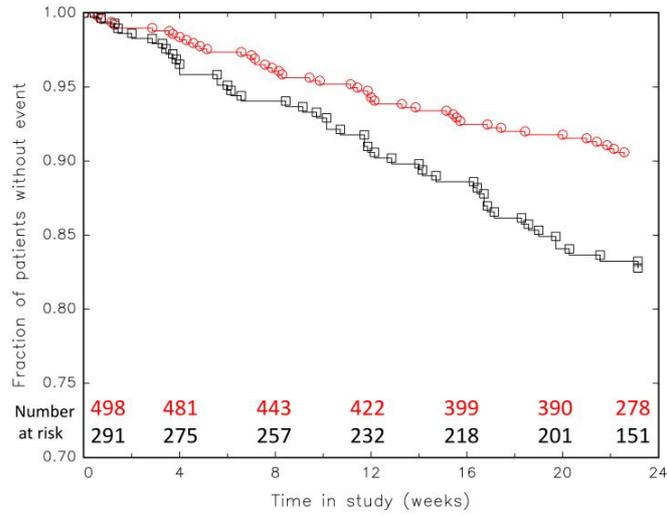
Treatment	Annualized Event Rate LS mean, (95% CI)	Rate Ratio (95% CI)	Exacerbation Rate Reduction	p-value
Ensifentrine 3 mg (n = 498)	0.24 (0.18, 0.33)	0.58 (0.39, 0.88)	42%	0.0109
Placebo (n = 291)	0.42 (0.31, 0.57)	--	--	

Exacerbation is defined as a **worsening of symptoms** requiring:

- Minimum of 3 days of treatment with oral/systemic steroids and/or antibiotics **OR** hospitalization

Ensifentrine significantly delays time to first exacerbation

42% reduction in risk of a COPD exacerbation



	Ensifentrine vs. Placebo (N = 789)
Hazard Ratio (95% CI)	0.58 (0.38, 0.87)
Risk Reduction	42%
P-value	0.0088



Ensifentrine showed improvement in symptoms and QOL

Progressive improvement in placebo impacted statistical significance

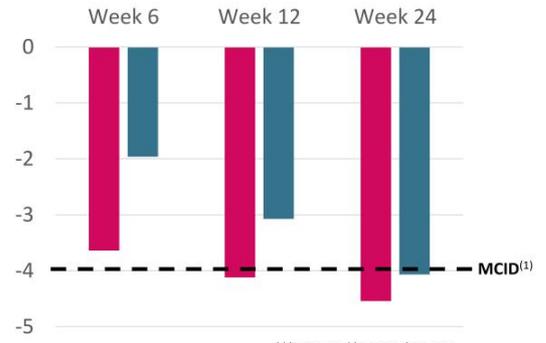
Symptoms

E-RS Total Score by Week (units)



Health-related Quality of Life

SGRQ Total Score by Week (units)



■ Ensifentrine
■ Placebo

***p ≤ 0.001 **p ≤ 0.01 *p ≤ 0.05
(1) Minimal clinically important difference

Adverse events similar to placebo

Few events greater than 1% and greater than placebo

<i>Event</i>		<i>Ensifentrine 3 mg (n = 498)</i>	<i>Placebo (n = 291)</i>
Subjects with at least one TEAE, n (%)		176 (35.3)	103 (35.4)
Any TEAE ≥1% and greater than placebo	Worsening of COPD, n (%)	11 (2.2)	5 (1.7)
	Nasopharyngitis, n (%)	9 (1.8)	3 (1.0)
	Diarrhea, n (%)	8 (1.6)	2 (0.7)
	Sinusitis, n (%)	6 (1.2)	0 (0)
	Hypertension, n (%)	5 (1.0)	1 (0.3)

- Cardiovascular: 11 (2.2%) on ensifentrine; 13 (4.5%) on placebo
- Gastrointestinal Disorders: 26 (5.2%) on ensifentrine; 15 (5.2%) on placebo
- Pneumonia: 3 (0.6%) on ensifentrine; 5 (1.7%) on placebo

ENHANCE-2 top-line summary

Ensifentrine improves lung function and reduces the rate of exacerbation

Endpoint	Top-line Measurement	Data
Primary endpoint (at Week 12)	Average FEV ₁ AUC (0-12 hours) post dose	+94 mL (p<0.0001) vs placebo
Secondary endpoints (Lung function at Week 12) (Symptoms / QOL at Week 24)	Peak FEV ₁	+146 mL (p<0.0001) vs placebo
	Morning Trough FEV ₁	+49 mL (p=0.0017) vs placebo
	Symptoms (E-RS Total Score) Quality of Life (SGRQ Total Score)	Change from baseline -2.1 Change from baseline -4.5 Not statistically significant
Exacerbations (over 24 Weeks)	Exacerbation rate	42% reduction in exacerbation rate (p=0.0109)
	Time to first moderate / severe COPD exacerbation	42% reduction in risk of exacerbation (p=0.0088)
Safety	Incidence of adverse events	Incidence similar to placebo including occurrence of pneumonia, GI and CV events



Financial Update

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Q2 2022 financial results (\$ thousands)

Cash runway through at least 2023*

Statements of Operations	Q2 2022	Q2 2021
Research and development	14,982	20,563
Selling, general and administrative	5,526	7,985
Total operating expenses	\$20,508	\$28,548
Operating loss	(20,508)	(28,548)
R&D tax credit	5,409	3,836
Net loss	\$(17,766)	\$(22,068)
Balance Sheet		
Cash and cash equivalents	\$111,510	\$132,764
Total assets	\$154,856	\$169,315
Total shareholders' equity	\$110,880	\$126,307



Q&A

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