

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): May 9, 2024

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

United Kingdom  
(State or other jurisdiction  
of incorporation)

001-38067  
(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 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 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 1.01. Entry into a Material Definitive Agreement.

### *Credit Agreement and Guaranty*

On May 9, 2024 (the “Effective Date”), Verona Pharma, Inc. (the “Borrower”), a wholly-owned subsidiary of Verona Pharma plc (the “Company”), entered into a term loan facility of up to \$400.0 million (the “Term Loan”), consisting of a term loan advance in an aggregate amount of \$55.0 million to be funded on the Effective Date (the “Tranche A Term Loan”), a term loan advance to be borrowed within eight business days after the occurrence of certain terms and conditions in an aggregate amount of \$70.0 million (the “Tranche B Term Loan”), a term loan advance available subject to certain terms and conditions in an aggregate amount of \$75.0 million (the “Tranche C Term Loan”), a term loan advance available subject to certain terms and conditions in an aggregate amount of \$100.0 million (the “Tranche D Term Loan”) and a term loan advance available in the sole discretion of the lenders and subject to certain terms and conditions in an aggregate amount of up to \$100.0 million (the “Tranche E Term Loan”), with Oaktree Fund Administration, LLC, a Delaware limited liability company, as administrative agent (in such capacity, the “Agent”), and certain funds managed by each of Oaktree Capital Management, L.P. (“Oaktree”) and OCM Life Sciences Portfolio LP (“OMERS”) party thereto (collectively, the “Lenders”). The proceeds of the Term Loan will be used for general corporate and working capital purposes, and a portion of the proceeds of the Tranche A Term Loan will be used by the Borrower on the Effective Date to repay in full the existing outstanding indebtedness owed by the Borrower and the Company to certain funds managed by Oxford Finance LLC, (“Oxford”) and Hercules Capital, Inc. (“Hercules”), under that certain Loan and Security Agreement, dated as of December 27, 2023, by and among the Borrower, the Company, Oxford, as collateral agent and the lenders from time to time party thereto (the “Prior Loan Agreement”).

The Term Loan is governed by a credit agreement and guaranty, dated as of the Effective Date, by and among the Borrower, the Company, the Agent and the Lenders (the “Credit Agreement”). The Tranche B Term Loan will, subject to customary terms and conditions, be borrowed by the Borrower within eight business days after the date the Borrower receives approval from the United States Food and Drug Administration for its New Drug Application for ensifentrine; provided such approval is received prior to September 30, 2024. The Tranche C Term Loan will be available, subject to customary terms and conditions (including the prior borrowing of the Tranche A Term Loan and the Tranche B Term Loan), during the period commencing on the first Business Day following the date the Agent receives certification of the Company’s achievement of a specified net sales milestone and ending on December 31, 2025. The Tranche D Term Loan will be available, subject to customary terms and conditions (including the prior borrowing of the Tranche A Term Loan, the Tranche B Term Loan and the Tranche C Term Loan), during the period commencing on the first business day following the date the Agent receives certification of the Company’s achievement of a specified net sales milestone and ending on June 30, 2026. The Tranche E Term Loan will be available at the Lenders’ sole and absolute discretion.

The Term Loan will mature on May 9, 2029. Each advance under the Credit Agreement accrues interest at a per annum rate equal to 11.00%. The Term Loan provides for interest-only payments on a quarterly basis until maturity. Upon repayment (whether at maturity, upon acceleration or by prepayment or otherwise), the Borrower shall pay an exit fee to the Lenders in the amount of 2.50% of the aggregate principal amount of the Term Loans to be repaid (the “Exit Fee”). The Borrower may prepay the Term Loan in full or in part provided that the Borrower (i) provides at least two (2) business days’ prior written notice to the Agent, (ii) pays on the date of such prepayment (A) all outstanding principal to be prepaid plus accrued and unpaid interest, (B) a prepayment fee of 7.00% of the Term Loans so prepaid if paid on or before the first anniversary of the Effective Date; 5.00% of the Term Loans so prepaid if paid after the first anniversary of the Effective Date and on or before the second anniversary of the Effective Date; 2.00% of the Term Loans so prepaid if paid after the second anniversary of the Effective Date and on or before the third anniversary of the Effective Date or 1.00% of the Term Loans so prepaid if paid after the third anniversary of the Effective Date and on or before the fourth anniversary of the Effective Date, (C) the Exit Fee and (D) all other sums, if any, that shall become due and payable under the Credit Agreement, including interest at the default rate with respect to any past due amounts. Amounts outstanding during an event of default are due upon the Majority Lenders’ (as defined in the Credit Agreement) demand (except during a payment or bankruptcy event of default, whereupon such default interest is automatically imposed) and shall accrue interest at an additional rate of 2.00% per annum, which interest shall be payable on demand in cash and (iii) any partial prepayment of the Term Loans shall be an aggregate amount at least equal to \$5.0 million in a denomination that is a whole number multiple of \$1.0 million in excess thereof.

---

The Term Loan is secured by a lien on substantially all of the assets of the Borrower and the Company, including intellectual property, subject to customary exclusions and exceptions.

The Credit Agreement contains customary representations and warranties, covenants and events of default, including two financial covenants: (i) commencing on the Effective Date, the Borrower is required to maintain certain levels of cash, and, after the Account Control Agreement Completion Date (as defined in the Credit Agreement) subject to control agreements in favor of the Agent, and (ii) commencing on the fiscal quarter of Company ending on September 30, 2025, the Borrower and the Company are required to maintain quarterly trailing twelve-month net sales from the sale of ensifentrine in the United States; provided that such revenue covenant will be waived at any time (x) the Borrower and the Company's unrestricted cash balance subject to control agreements in favor of the Agent on the last business day of the applicable fiscal quarter is equal to or greater than the product of 1.25 multiplied by the aggregate principal amount of outstanding Term Loans on such date or (y) the average daily closing price of the Company's American Depositary Shares for each of the thirty (30) trading days preceding the last trading day of such fiscal quarter multiplied by the total number of issued and outstanding American Depositary Shares of the Company is at least \$1.0 billion. The Credit Agreement also contains other customary provisions, such as expense reimbursement, as well as indemnification rights for the benefit of the Agent and the Lenders.

In connection with the entry into the Credit Agreement, on the Effective Date, the Borrowers will repay in full all outstanding indebtedness and terminated all commitments under the Prior Loan Agreement, the material terms of which have been disclosed previously. The aggregate principal amount of the loan outstanding under the Prior Loan Agreement will be \$50.0 million at the time of repayment. Oxford's and Hercules' security interests in the Borrower and the Company's assets under the Prior Loan Agreement were terminated in connection with the discharge of the indebtedness thereunder. The Borrower and the Company did not incur any penalties, but did incur a prepayment fee and a final payment fee, as a result of the foregoing.

#### *Revenue Interest Purchase and Sale Agreement*

On May 9, 2024, the Company and Verona Pharma, Inc. (collectively the "Sellers") entered into a revenue interest purchase and sale agreement (the "RIPSA") with Oaktree Fund Administration, LLC, a Delaware limited liability company, as administrative agent and certain funds managed by each of Oaktree and OMERS (collectively, the "Purchasers"). Under the terms of the RIPSA, in exchange for each of the Purchaser's payment to the Sellers of a purchase price of \$100 million, in the aggregate, upon approval of ensifentrine by the FDA by a specified date and subject to certain labeling conditions (the "Tranche A Purchase Price"), the Sellers agreed to a true sale of assigned interests to the Purchasers, including a right for the Purchasers to receive 6.50% on the global net sales of ensifentrine by the Sellers (the "Royalty Interest Payments"), 6.5% on certain proceeds the Sellers receive from licensees engaged during the term of the RIPSA in the U.S. (the "U.S. Payments") and 5% on certain proceeds the Sellers receive from licensees engaged during the term of the RIPSA outside of the U.S. (the "Ex-U.S. Payments"). The Sellers would begin payment of the Royalty Interest Payments, the U.S. Payments and Ex-U.S. Payments in the first fiscal quarter after receipt of the Tranche A Purchase Price. The Sellers will also have a right to receive an additional funding tranche equal to \$150 million (the "Tranche B Purchase Price") upon achievement of a specified net sales milestone in any trailing six-month period after receipt of the Tranche A Purchase Price and subject to certain terms and conditions. The Royalty Interest Payments, the U.S. Payments and Ex-U.S. Payments will cease upon reaching a multiple of 1.75 times the amounts actually funded by the Purchasers. The RIPSA includes a buy-out option, which provides us with the right to settle all outstanding liabilities at any time by paying a buy-out amount under various terms and conditions. The Purchasers have the right to terminate the RIPSA under certain conditions, including our insolvency, and our divestment of ensifentrine, in which case we must pay the Purchasers up to 1.75 times the amounts actually funded by the Purchasers as of such default determination date. Pursuant to a security agreement signed in connection with the RIPSA, the Sellers granted to the Purchasers a security interest in certain assets to secure obligations under the RIPSA.

---

**Item 1.02. Termination of a Material Definitive Agreement.**

The information set forth above in Item 1.01 of this Current Report on Form 8-K regarding the repayment and termination of the Prior Loan Agreement is incorporated into this Item 1.02 by reference.

**Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.**

To the extent required, the information set forth in Item 1.01 above is incorporated herein by reference.

**Item 7.01. Regulation FD Disclosure**

On May 9, 2024, the Company issued a press release announcing the Credit Agreement and RIPSAs described above. A copy of the press release is attached as Exhibit 99.1 and incorporated herein by reference.

The information contained under Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1), 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, or the Exchange Act except as may be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

**Exhibit**

**No. Description**

[99.1\\*](#) [Press Release, dated May 9, 2024.](#)

104 Cover Page Interactive Data File (embedded within the inline XBRL document).

\* Furnished herewith.

**Forward-Looking Statements**

This Current Report on Form 8-K contains forward-looking statements. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the debt facility providing non-dilutive capital and further financial flexibility to support Verona Pharma’s continued growth, including the planned commercial launch of ensifentrine, statements regarding the future availability of future draws under the debt facility, the timing of repayment and termination of the Prior Loan Agreement, the ability of Verona Pharma to reach certain net sales milestones, the potential for ensifentrine to be the first therapy for the treatment of respiratory diseases to combine bronchodilator and non-steroidal anti-inflammatory benefits in one compound, the potential for ensifentrine to be the first novel inhaled mechanism for the maintenance treatment of chronic obstructive pulmonary disease in more than 20 years, and the potential of ensifentrine in the treatment of cystic fibrosis, non-cystic fibrosis bronchiectasis, asthma and other respiratory diseases, as well as the potential of the DPI and pMDI formulations of ensifentrine.

---

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; 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, 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, 2023, as updated in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 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 Current Report on Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Current Report on Form 8-K. 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 Current Report on Form 8-K.

---

**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: May 9, 2024

By: /s/ David Zaccardelli, Pharm. D.

Name: David Zaccardelli, Pharm. D.

Title: President and Chief Executive Officer

---



**Verona Pharma Announces \$650 Million Strategic Financing  
with Oaktree and OMERS**

*Non-dilutive funding will support planned US commercial launch  
and expansion of ensifentrine's clinical activities*

*Cash runway extended beyond 2026*

**LONDON and RALEIGH, N.C., May 9, 2024** – Verona Pharma plc (Nasdaq: VRNA) (“Verona Pharma”), announces it and its wholly-owned subsidiary, Verona Pharma, Inc. (“VPI” and together with Verona Pharma, the “Company”), have entered into strategic financing agreements providing access to up to \$650 million from funds managed by Oaktree Capital Management, L.P. (“Oaktree”) and OMERS Life Sciences (“OMERS”).

The agreements provide non-dilutive capital and additional financial flexibility ahead of Verona Pharma’s planned US launch of ensifentrine and will support the Company’s continued growth. Ensisfentrine is currently under review by the US Food and Drug Administration (“FDA”), and, if approved, is expected to be the first novel inhaled mechanism for the maintenance treatment of chronic obstructive pulmonary disease in more than 20 years.

The strategic financing was led by Oaktree and is comprised of the following:

- **Debt facility:** Up to \$400 million in term loans available in five separate tranches via a term loan facility (“debt facility”).
- **Revenue interest purchase and sale agreement (“RIPSA”):** Up to \$250 million in funding from the sale of a redeemable interest in future ensifentrine-related revenue, which is capped at 1.75x of the amount funded.

The debt facility replaces the existing facility of up to \$400 million with funds managed by Oxford Finance LLC and Hercules Capital, Inc. (NYSE: HTGC).

Under the terms of the debt facility, VPI is drawing \$55 million at closing, and may draw, subject to certain conditions, an additional \$70 million upon FDA approval of ensifentrine, \$175 million in two separate tranches upon achievement of certain net sales milestones and, subject to the approval of the Lenders, \$100 million to support strategic initiatives. VPI will pay only interest on the outstanding loans under the five-year debt facility on a quarterly basis with all amounts outstanding due at maturity. Approximately \$52 million of the loans drawn at closing will be used to repay in full the existing facility, including to pay fees and associated costs thereunder.

Under the terms of the RIPSA, VPI will receive \$100 million upon FDA approval of ensifentrine and will be eligible to draw an additional \$150 million upon the achievement of certain net sales milestones. The revenue interest financing rate is 5% and 6.5% of certain proceeds the Company receives from licensees that the Company may engage during the term of the RIPSA outside of the US and in the US, respectively, and 6.5% of global net sales of ensifentrine by the Company. The total revenue interest financing payable by the Company to Oaktree and OMERS is capped at 1.75x of the amount actually funded, with the ability to redeem the RIPSA at lower multiples within the first three years from funding.

---

“As we finalize preparations for the potential US approval and commercial launch of ensifentrine, we are pleased to be working with Oaktree and OMERS who are aligned with our view of ensifentrine’s importance to the COPD community and its commercial opportunity. This strategic agreement, with access to up to \$650 million, allows us to further strengthen our cash position and improve our financial flexibility,” said David Zaccardelli, Pharm. D., President and Chief Executive Officer of Verona Pharma. “These funds, together with our existing cash of \$255 million, are expected to support the Company through commercialization and growth beyond 2026.”

“We believe ensifentrine’s impressive clinical data generated to date and unique mechanism of action position it well to become a paradigm-shifting advancement in the maintenance treatment of COPD, a condition with continued unmet need,” said Aman Kumar, Co-Portfolio Manager for Oaktree’s Life Sciences Lending platform. “This strategic investment in Verona Pharma underscores Oaktree’s commitment to provide flexible capital solutions to innovative life sciences companies that are working on bringing important therapies to patients and providers worldwide.”

Morgan Stanley & Co. LLC acted as sole structuring agent on the transaction. Latham & Watkins LLP served as legal counsel to Verona Pharma. Sullivan & Cromwell LLP served as legal counsel to Oaktree.

For further information please contact:

<b>Verona Pharma plc</b>	US Tel: +1-833-417-0262 UK Tel: +44 (0)203 283 4200
Victoria Stewart, Senior Director of Investor Relations and Communications	<a href="mailto:IR@veronapharma.com">IR@veronapharma.com</a>
<b>Argot Partners</b> US Investor Enquiries	Tel: +1-212-600-1902 <a href="mailto:verona@argotpartners.com">verona@argotpartners.com</a>
<b>Ten Bridge Communications</b> International / US Media Enquiries	Tel: +1-312-523-5016 <a href="mailto:tbcverona@tenbridgecommunications.com">tbcverona@tenbridgecommunications.com</a>
Leslie Humbel	

#### About Verona Pharma

Verona Pharma is a biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of chronic respiratory diseases with significant unmet medical needs. In the third quarter of 2023, the US Food and Drug Administration accepted for review the Company’s NDA for ensifentrine for the maintenance treatment of patients with COPD and assigned a PDUFA target action date of June 26, 2024. If approved, ensifentrine has the potential to become the first inhaled non-steroidal therapy for the treatment of respiratory diseases that combines bronchodilator and anti-inflammatory activities in one molecule. The Company has evaluated 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 both ENHANCE-1 and ENHANCE-2 trials demonstrating statistically significant and clinically meaningful improvements in lung function. In addition, ensifentrine substantially reduced the rate and risk of COPD exacerbations in pooled analysis from ENHANCE-1 and ENHANCE-2. Two additional formulations of ensifentrine have been evaluated in Phase 2 trials for the treatment of COPD: dry powder inhaler (“DPI”) and pressurized metered-dose inhaler (“pMDI”); and a fixed-dose combination formulation with ensifentrine and glycopyrrolate, a LAMA, is currently under development, also for the treatment of COPD. Ensifentrine also has potential applications in cystic fibrosis, non-cystic fibrosis bronchiectasis, asthma and other respiratory diseases. For more information, please visit [www.veronapharma.com](http://www.veronapharma.com).



## **About Oaktree**

Oaktree is a leader among global investment managers specializing in alternative investments, with \$192 billion in assets under management as of March 31, 2024. The firm emphasizes an opportunistic, value-oriented and risk-controlled approach to investments in credit, private equity, real assets and listed equities. The firm has over 1,200 employees and offices in 23 cities worldwide. For additional information, please visit Oaktree's website at <http://www.oaktreecapital.com/>.

## **About OMERS Life Sciences and OMERS**

OMERS Life Sciences provides royalty financings and other non-dilutive solutions to biopharma companies and academic institutions, supporting their efforts to address unmet medical needs and improve the quality of life of patients around the world.

OMERS is a jointly sponsored, defined benefit pension plan, with 1,000 participating employers ranging from large cities to local agencies, and over 600,000 active, deferred and retired members. Our members include union and non-union employees of municipalities, school boards, local boards, transit systems, electrical utilities, emergency services and children's aid societies across Ontario. OMERS teams work in Toronto, London, New York, Amsterdam, Luxembourg, Singapore, Sydney and other major cities across North America and Europe – serving members and employers, and originating and managing a diversified portfolio of high-quality investments in bonds, public and private credit, public and private equity, infrastructure and real estate.

## **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 the debt facility providing non-dilutive capital and further financial flexibility to support Verona Pharma's continued growth, including the planned commercial launch of ensifentrine, statements regarding the future availability of future draws under the debt facility, the timing of repayment and termination of the existing facility, the ability of Verona Pharma to reach certain net sales milestones, the potential for ensifentrine to be the first therapy for the treatment of respiratory diseases to combine bronchodilator and non-steroidal anti-inflammatory benefits in one compound, the potential for ensifentrine to be the first novel inhaled mechanism for the maintenance treatment of chronic obstructive pulmonary disease in more than 20 years, and the potential of ensifentrine in the treatment of cystic fibrosis, non-cystic fibrosis bronchiectasis, asthma and other respiratory diseases, as well as the potential of the DPI and pMDI formulations of ensifentrine.

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; 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, 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, 2023, as updated in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 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.

---