# 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, 2024**

**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<br>London SE1 2RE United Kingdom** | **Not Applicable** |
| **(Address of principal executive offices)** | **(Zip Code)** |

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

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

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

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

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☒ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☐ |
| | | Emerging growth company | ☐ |

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

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

As of August 2, 2024, the registrant had 649,881,246 ordinary shares, nominal value £0.05 per share, outstanding, which if all held in ADS form, would be represented by 81,235,156 American Depositary Shares, each representing eight (8) ordinary shares.

**SUMMARY RISK FACTORS**

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties when investing in our common shares. The principal risks and uncertainties affecting our business include the following:

- We have a limited operating history and have never generated any product revenue.
- We may need additional funding to complete development and commercialization of any future product candidates and to commercialize Ohtuvayre. If we are unable to raise capital when needed, or if a failure of any financial institution where we maintain our cash and cash equivalents prevents or delays us from accessing uninsured funds, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We depend solely on the success of ensifentrine, which was recently approved by the FDA as Ohtuvayre. If we are unable to commercialize Ohtuvayre, or successfully develop ensifentrine for other indications, our ability to generate revenue and our financial condition will be adversely affected.
- The terms of our credit facility place restrictions on our operating and financial flexibility, and our existing and any future indebtedness could adversely affect our ability to operate our business.
- The terms of the revenue interest purchase and sale agreement ("RIPSA") place restrictions on our operating and financial flexibility, and if we fail to comply with certain covenants in the RIPSA, our results of operations and financial condition may be harmed.
- Clinical drug development and regulatory approval involve a lengthy and expensive process, with uncertain outcomes.
- Our product and product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during product development or following approval, if any, we may need to abandon our development programs, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.
- We depend on enrollment of patients in our clinical trials. If we are unable to enroll patients in our clinical trials, or enrollment is slower than anticipated, our research and development efforts could be adversely affected.

- We may become exposed to costly and damaging liability claims, either when testing product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.
- The regulatory approval processes of the FDA, the EMA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for ensifentrine for the maintenance treatment of COPD in adult patients in jurisdictions outside the U.S. or for ensiftentrine for additional targeted indications and formulations, our business will be substantially harmed.
- We may never obtain approval or commercialize ensifentrine in other major markets outside of the U.S., which would limit our ability to realize its full market potential.
- Enacted and future legislation and regulation may increase the difficulty and cost for us to commercialize our products and may affect the prices we may set.
- We operate in a highly competitive and rapidly changing industry, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If our products, including Ohtuvayre, do not gain market acceptance or if we fail to accurately forecast demand or manage our inventories, our business will suffer because we might not be able to fund future operations.
- Our commercial capabilities and infrastructure, including sales, marketing, operations, distribution, and reimbursement infrastructure, may not be adequate to successfully commercialize Ohtuvayre.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our pre-clinical studies and clinical trials.
- The collaboration and license agreement with Nuance Pharma is important to our business. If Nuance Pharma is unable to develop and commercialize products containing ensifentrine in Greater China, if we or Nuance Pharma fail to adequately perform under the Nuance Agreement, or if we or Nuance Pharma terminate the Nuance Agreement, our business would be adversely affected.
- We rely on patents and other intellectual property rights to protect our products and product candidates, the enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.
- Our information technology systems, and those of our manufacturers, suppliers and other third parties that we use to perform services for us or otherwise collaborate with, may fail or suffer security breaches, which could distract our operations and cause delays in our research and development and commercialization activities, and may adversely affect our business, operations and financial performance.
- Our future growth and ability to compete depends on our ability to retain our key personnel and recruit additional qualified personnel.
- Certain of our shareholders, members of our board of directors, and senior management who own our ordinary shares (including ordinary shares represented by ADSs) may be able to exercise significant control over us.
- 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.
- The price of our ADSs may be volatile and may fluctuate due to factors beyond our control.
- Business interruptions could adversely affect our operations.

## PART I - FINANCIAL INFORMATION

**Item 1. Financial statements**

**Verona Pharma plc**
**Condensed Consolidated Balance Sheets**
**(unaudited)**
**(in thousands, except share and per share amounts)**

| | June 30, 2024 | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 404,599 | $ 271,772 |
| Prepaid expenses | 5,433 | 3,617 |
| Tax incentive receivable | 3,684 | 10,954 |
| Other current assets | 2,576 | 3,365 |
| **Total current assets** | 416,292 | 289,708 |
| | | |
| **Non-current assets:** | | |
| Furniture and equipment, net | 44 | 24 |
| Goodwill | 545 | 545 |
| Equity interest | 15,000 | 15,000 |
| Right-of-use assets | 2,242 | 2,847 |
| **Total non-current assets** | 17,831 | 18,416 |
| **Total assets** | $ 434,123 | $ 308,124 |
| | | |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 4,152 | $ 3,492 |
| Accrued expenses | 19,630 | 3,585 |
| License agreement obligations | 21,322 | — |
| Current operating lease liabilities | 1,031 | 1,180 |
| Taxes payable | 1,011 | — |
| Other current liabilities | 1,200 | 435 |
| **Total current liabilities** | 48,346 | 8,692 |
| | | |
| **Non-current liabilities:** | | |
| Term loan | 119,687 | 48,374 |
| Revenue interest purchase security agreement | 96,338 | — |
| Non-current operating lease liabilities | 1,478 | 1,775 |
| **Total non-current liabilities** | 217,503 | 50,149 |
| **Total liabilities** | 265,849 | 58,841 |
| | | |
| **Commitments and contingencies** | | |
| | | |
| **Shareholders' equity:** | | |
| Ordinary £0.05 par value shares; 667,659,630 and 667,659,630 issued, and 648,654,174 and 643,536,094 outstanding, at June 30, 2024 and December 31, 2023, respectively | 42,771 | 42,771 |
| Additional paid-in capital | 616,618 | 601,063 |
| Ordinary shares held in treasury | (1,203) | (1,517) |
| Accumulated other comprehensive loss | (4,601) | (4,601) |
| Accumulated deficit | (485,311) | (388,433) |
| **Total shareholders' equity** | 168,274 | 249,283 |
| **Total liabilities and shareholders' equity** | $ 434,123 | $ 308,124 |

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, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| **Operating expenses:** | | | | |
| Research and development | $ 19,388 | $ (2,474) | $ 26,152 | $ 10,136 |
| Selling, general and administrative | 49,035 | 12,439 | 69,469 | 22,028 |
| **Total operating expenses** | 68,423 | 9,965 | 95,621 | 32,164 |
| **Operating loss** | (68,423) | (9,965) | (95,621) | (32,164) |
| **Other income/(expense):** | | | | |
| Research and development tax credit | 847 | (1,934) | 1,432 | 379 |
| Loss on extinguishment of debt | (3,653) | — | (3,653) | — |
| Interest income | 3,140 | 3,402 | 6,518 | 6,079 |
| Interest expense | (1,757) | (740) | (3,343) | (1,033) |
| Foreign exchange gain/(loss) | 25 | 740 | (194) | 1,672 |
| **Total other (expense)/income, net** | (1,398) | 1,468 | 760 | 7,097 |
| **Loss before income taxes** | (69,821) | (8,497) | (94,861) | (25,067) |
| Income tax expense | (1,014) | (310) | (1,768) | (483) |
| **Net loss** | $ (70,835) | $ (8,807) | $ (96,629) | $ (25,550) |
| Loss per ordinary share - basic and diluted | $ (0.11) | $ (0.01) | $ (0.15) | $ (0.04) |
| | | | | |
| Weighted-average shares outstanding - basic and diluted | 648,217 | 634,469 | 646,959 | 627,996 |

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, 2023** | 667,659,630 | $ 42,771 | $ 601,063 | $ (1,517) | $ (4,601) | $ (388,433) | $ 249,283 |
| Net loss | — | — | — | — | — | (25,794) | (25,794) |
| Restricted share units vested | — | — | — | 170 | — | (170) | — |
| Share options exercised | — | — | 751 | 65 | — | — | 816 |
| Common shares withheld for taxes on vested stock awards | — | — | (3,338) | — | — | — | (3,338) |
| Equity settled share-based compensation reclassified as cash-settled | — | — | (237) | — | — | — | (237) |
| Share-based compensation | — | — | 4,258 | — | — | — | 4,258 |
| **Balance at March 31, 2024** | 667,659,630 | $ 42,771 | $ 602,497 | $ (1,282) | $ (4,601) | $ (414,397) | $ 224,988 |
| Net loss | — | — | — | — | — | (70,835) | (70,835) |
| Restricted share units vested | — | — | — | 79 | — | (79) | — |
| Common shares withheld for taxes on vested stock awards | — | — | (1,273) | — | — | — | (1,273) |
| Equity settled share-based compensation reclassified as cash-settled | — | — | (200) | — | — | — | (200) |
| Share-based compensation | — | — | 15,594 | — | — | — | 15,594 |
| **Balance at June 30, 2024** | 667,659,630 | $ 42,771 | $ 616,618 | $ (1,203) | $ (4,601) | $ (485,311) | $ 168,274 |

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

| | 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, 2022** | 631,338,246 | $ 40,526 | $ 529,187 | $ (1,549) | $ (4,601) | $ (333,097) | $ 230,466 |
| Net loss | — | — | — | — | — | (16,743) | (16,743) |
| Issuance of common shares under at-the-market sales agreement | 20,321,384 | 1,227 | 55,682 | — | — | — | 56,909 |
| Restricted share units vested | — | — | — | 270 | — | (270) | — |
| Share options exercised | — | — | 1,756 | 71 | — | — | 1,827 |
| Share-based compensation | — | — | 4,290 | — | — | — | 4,290 |
| **Balance at March 31, 2023** | 651,659,630 | $ 41,753 | $ 590,915 | $ (1,208) | $ (4,601) | $ (350,110) | $ 276,749 |
| Net loss | — | — | — | — | — | (8,807) | (8,807) |
| Restricted share units vested | — | — | — | 226 | — | (226) | — |
| Share options exercised | — | — | 70 | 7 | — | — | 77 |
| Share-based compensation | — | — | 5,074 | — | — | — | 5,074 |
| **Balance at June 30, 2023** | 651,659,630 | $ 41,753 | $ 596,059 | $ (975) | $ (4,601) | $ (359,143) | $ 273,093 |

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, | |
|---|---|---|
| | **2024** | **2023** |
| **Cash flows from operating activities:** | | |
| Net loss: | $ (96,629) | $ (25,550) |
| *Adjustments to reconcile net income to net cash used in operating activities:* | | |
| Foreign exchange loss/(gain) | 194 | (1,672) |
| Other non-cash items | 285 | 88 |
| Accretion of redemption premium on debt | 120 | 51 |
| Loss on extinguishment of debt | 3,653 | — |
| Share-based compensation | 19,852 | 9,364 |
| Depreciation | 533 | 314 |
| *Changes in operating assets and liabilities:* | | |
| Prepaid expenses | (1,816) | 1,605 |
| Tax incentive receivable | 7,201 | (380) |
| Other current assets | 35 | (2,016) |
| Accounts payable | 756 | (417) |
| Accrued expenses | 11,617 | (6,285) |
| License agreement obligations | 21,322 | — |
| Operating lease liabilities | (365) | (305) |
| Income taxes | 1,765 | (939) |
| Other current liabilities | 765 | (951) |
| Net cash used in operating activities | (30,712) | (27,093) |
| **Cash flows from investing activities:** | | |
| Purchases of furniture and equipment | (45) | — |
| Net cash used in investing activities | (45) | — |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of ordinary shares | — | 56,909 |
| Proceeds from Term Loans | 122,500 | 9,996 |
| Proceeds from RIPSA | 100,000 | — |
| Payment of debt issuance costs | (2,303) | — |
| Repayment of 2023 Term Loans | (52,256) | — |
| Payments of withholding taxes from share-based awards | (5,048) | — |
| Proceeds from exercise of share options | 816 | 1,904 |
| Net cash provided by financing activities | 163,709 | 68,809 |
| **Effect of exchange rate changes on cash and cash equivalents** | (125) | 1,184 |
| Net change in cash and cash equivalents | 132,827 | 42,900 |
| **Cash and cash equivalents at beginning of the period** | 271,772 | 227,827 |
| **Cash and cash equivalents at end of the period** | $ 404,599 | $ 270,727 |
| **Supplemental disclosure of cash flow information:** | | |
| Income taxes paid | $ — | $ 1,215 |
| Interest paid | $ 2,021 | $ 685 |

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

## Note 1 - Organization and description of business operations

Verona Pharma plc is incorporated and domiciled in the United Kingdom. Verona Pharma plc has one wholly-owned subsidiary, Verona Pharma, Inc., a Delaware corporation (together with Verona Pharma plc, the "Company"). The address of the registered office is 1 Central Square, Cardiff, CF10 1FS, United Kingdom.

The Company is a 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".

On June 26, 2024, the FDA approved Ohtuvayre (ensifentrine) for the maintenance treatment of chronic obstructive pulmonary disease ("COPD") in adult patients and the Company launched Ohtuvayre in the U.S. through an exclusive network of accredited specialty pharmacies in August 2024. Ohtuvayre is the Company's first commercial product and the first inhaled therapy with a novel mechanism of action available for the maintenance treatment of COPD in more than 20 years.

Ohtuvayre is a first-in-class selective dual inhibitor of the enzymes phosphodiesterase 3 and phosphodiesterase 4 that combines bronchodilator and non-steroidal anti-inflammatory effects in one molecule. Ohtuvayre is delivered directly to the lungs through a standard jet nebulizer without the need for high inspiratory flow rates or complex hand-breath coordination.

***Pipeline***

The Company is developing a fixed-dose combination formulation with ensifentrine and glycopyrrolate, a Long-Acting Muscarinic Antagonist ("LAMA"), for the maintenance treatment of patients with COPD via delivery in a nebulizer. The Company has filed patent applications in multiple jurisdictions including the U.S. In July 2024, the Company submitted an investigational new drug application ("IND") to the FDA to allow initiation of the clinical program. Subject to clearance of the IND, the Company intends to initiate a Phase 2 dose-ranging trial in the third quarter of 2024.

Additionally, based on the clinical results of ensifentrine observed in patients with COPD, including improvements in lung function and symptoms of cough and sputum, the Company believes ensifentrine could potentially be an effective treatment for non-cystic fibrosis bronchiectasis ("NCFBE"). The Company plans to commence a Phase 2 clinical trial to assess the efficacy and safety of nebulized ensifentrine in patients with NCFBE in the third quarter of 2024.

***Liquidity***

The Company has incurred recurring losses and negative cash flows from operations since inception, and has an accumulated deficit of $485.3 million as of June 30, 2024. The Company expects to incur additional losses and negative cash flows from operations until its products reach commercial profitability, if at all.

The Company expects that its cash and cash equivalents as of June 30, 2024 will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance.

Additionally, the Company 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, the Company may need to obtain substantial additional funds to achieve its business objectives including to further advance clinical and regulatory activities, to fund launch related costs and to create an effective sales and marketing organization to commercialize Ohtuvayre. Any such funding will need to be obtained through public or private financings, debt financing, collaboration or licensing arrangements or other arrangements. However, there is no guarantee the Company will be successful in securing additional capital on acceptable terms, or at all.

## 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") and 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 on February 29, 2024 (the "2023 Form 10-K"). The Consolidated Balance Sheet as of December 31, 2023, was derived from audited consolidated financial statements included in the 2023 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, the development and commercialization of ensifentrine.

*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, and the fair value of share-based compensation. 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, and actual results could differ from the Company's estimates.

*Inventories, including Pre-Launch Inventories*

Prior to obtaining regulatory approval for Ohtuvayre, the Company expensed costs relating to production of pre-launch inventory as research and development expense in its condensed consolidated statements of operations and comprehensive loss in the period incurred. Inventory acquired and the related costs after June 26, 2024, the date of the FDA's approval of Ohtuvayre, will be capitalized. Products used in clinical trials are expensed as research and development expense in the statement of operations and comprehensive loss.

The Company will value its inventories at the lower-of-actual cost or net realizable value. Due to the timing of the approval of Ohtuvayre, the Company did not capitalize any inventory costs in the three or six months ended June 30, 2024.

*Revenue Interest Purchase and Sale Agreement*

The revenue interest purchase and sale agreement (the "RIPSA") liability is eligible to be repaid based on royalties from net sales of Ohtuvayre (ensifentrine) and any other future products. Interest expense is accrued using the effective interest rate method over the estimated period the related liability will be paid. This requires the Company to estimate the total amount of future royalty payments to be generated from product sales over the life of the agreement. The Company imputes interest on the carrying value of the RIPSA and records interest expense using an imputed effective interest rate. The Company reassesses the expected royalty payments each reporting period and accounts for any changes through an adjustment to the effective interest rate on a prospective basis. The assumptions used in determining the expected repayment term of the debt and amortization period of the issuance costs require

that the Company make estimates that could impact the carrying value of the liability, as well as the periods over which associated issuance costs will be amortized. A significant increase or decrease in forecasted net sales could materially impact each of the liability balances, interest expense and the time periods for repayment.

*Recently issued accounting standards not yet adopted*

In December 2023, the FASB issued ASU No. 2023-09, Improvements to Income Tax Disclosures, which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The amendments in this ASU are effective for annual periods beginning on December 15, 2024, and should be applied on a prospective basis with the option to apply the standard retrospectively. Early adoption is permitted. This ASU will have no impact on the Company's Consolidated Balance Sheets or Consolidated Statements of Operations and Comprehensive Loss. The Company is currently evaluating the impact to its income tax disclosures.

In November 2023, the FASB issued ASU No. 2023-07, Improvements to Reportable Segment Disclosures, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, provide new segment disclosure requirements for entities with a single reportable segment, and contain other disclosure requirements. The purpose of the amendments is to enable investors to better understand an entity's overall performance and assess potential future cash flows. The amendments in this ASU are effective for annual periods beginning on December 15, 2023 and interim periods beginning on December 15, 2024 and should be applied on a retrospective basis for all periods presented. This ASU will have no impact on the Company's Consolidated Balance Sheets or Consolidated Statements of Operations and Comprehensive Loss. The Company is currently evaluating the impact to its segment disclosures.

**Note 3 - 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 equity interest is recorded at cost as the Company has elected to use the measurement alternative for equity investments without readily determinable fair values. The Company evaluates this investment for indicators of impairment quarterly. The Company did not identify events or changes in circumstances that may have a significant effect on the fair value of the investment during the six months ended June 30, 2024.

**Note 4 - Accrued expenses**

Accrued expenses consisted of the following (in thousands):

| | June 30, 2024 | December 31, 2023 |
|---|---|---|
| Clinical trial and other development costs | $ 5,959 | $ 752 |
| Professional fees and general corporate costs | 5,095 | 2,039 |
| People related costs | 3,964 | 794 |
| Debt issuance costs | 4,612 | — |
| **Total accrued expenses** | $ 19,630 | $ 3,585 |

**Note 5 - Ligand license agreement obligations**

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 assumed included a milestone payment on obtaining the first approval of any regulatory authority for the commercialization of a Ligand Licensed Product, low single digit royalties based on the future sales performance of all Ligand Licensed Products and a portion equal to a mid-twenty percent of any consideration received from any sub-licensees for the Ligand Patents and for Ligand know-how.

At the time of the acquisition the contingent liability was not recognized as part of the acquisition accounting as it was immaterial.

Due to the FDA approval of Ohtuvayre on June 26, 2024, the Company has recognized the following in the three and six months ended June 30, 2024:

- $6.3 million in research and development costs related to a milestone payment for first approval of any regulatory authority for the commercialization of ensifentrine; and
- $15.0 million related to a milestone payment for first commercial sale of ensifentrine. The Company has classified this as selling, general and administrative expense as it relates to the resolution of the 2021 dispute with Ligand.

The Company has recognized the milestone payment for first commercial sale of ensifentrine in the three and six months ended June 30, 2024 as it considers the payment of this milestone probable due to the approval of ensifentrine and the progress towards commercialization including the first sale in the third quarter of 2024.

**Note 6 - Debt**

**2023 Term Loan**

On December 27, 2023 (the "2023 Effective Date"), Verona Pharma, Inc. entered into a term loan facility of up to $400.0 million (the "2023 Term Loan" or "Loan Agreement"), consisting of a term loan advance in an aggregate amount of $50.0 million funded on the 2023 Effective Date (the "Term A Loan") and four additional term loan advances subject to certain terms and conditions. The 2023 Term Loan was repaid in full as of May 9, 2024. Verona Pharma, Inc. and the Company did not incur any penalties, but did incur a prepayment fee and final payment fee in the aggregate amount of $2.3 million.

**2024 Term Loans**

On May 9, 2024 (the "2024 Effective Date"), Verona Pharma, Inc. (the "Borrower") entered into a term loan facility of up to $400.0 million (the "2024 Term Loans" or "2024 Loan Agreement"), consisting of a term loan advance in an aggregate amount of $55.0 million funded on the 2024 Effective Date (the "Tranche A Term Loan") and four additional term loan advances subject to certain terms and conditions, as discussed below, in the amounts of $70.0 million (the "Tranche B Term Loan"), $75.0 million (the "Tranche C Term Loan"), $100.0 million (the "Tranche D Term Loan") and $100.0 million (the "Tranche E Term Loan") with each tranche issued subject to an original issue discount of 2.0%. The 2024 Loan Agreement was entered into 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 "2024 Lenders"). The net proceeds of the 2024 Term Loans will be used for general corporate and working capital purposes and a portion of the proceeds from the Tranche A Term Loan was used by the Borrower on the 2024 Effective Date to repay, in full, the existing outstanding indebtedness owed under the 2023 Term Loan.

The Tranche B Term Loan was available, subject to customary terms and conditions, during the period commencing on the date the Company received approval from the FDA for its new drug application for ensifentrine through and including the earliest of (i) the date that is 30 days immediately following the date the Company receives such approval and (ii) September 30, 2024. The Tranche C Term Loan will be available, subject to customary terms and conditions (including the prior borrowing of the Tranche B Term Loan), during the period commencing on the first business day following the achievement of a specified net sales milestone for ensifentrine 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 C Term Loan), during the period commencing on the first business day following the achievement of a specified net sales milestone for ensifentrine and ending on June 30, 2026. The Tranche E Term Loan will be available, subject to customary terms and conditions (including the prior borrowing of the Tranche D Term Loan) at the 2024 Lenders sole discretion and upon the Company's request.

The Company received $52.8 million in net proceeds at closing of the 2024 Loan Agreement and draw of the Tranche A Term Loan, which consisted of the Tranche A Term Loan face value of $55.0 million less the original issue discount of $1.1 million and lender and third-party fees related to the 2024 Loan Agreement and RIPSA, as defined and discussed below, of $1.1 million. $52.4 million of the net cash proceeds from the Tranche A Term Loan were used for the repayment in full of the existing outstanding indebtedness owed by the Company under the 2023 Term Loan of $52.3 million and interest amounts related to the 2023 Term Loan of $0.1 million.

On June 28, 2024, the Company received $68.6 million in net proceeds related to the Tranche B Term Loan, which was available upon FDA approval for Ohtuvayre. The amount received consisted of the Tranche B Term Loan face value of $70.0 million less the original issue discount of $1.4 million.

The 2024 Term Loans will mature on May 9, 2029 and each advance under the 2024 Loan Agreement accrues interest at a fixed per annum rate of 11.00%. The 2024 Loan Agreement 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 2024 Lenders in the amount of 2.50% of the aggregate principal amount of the 2024 Term Loans to be paid (the "Exit Fee"). The Borrower may prepay the 2024 Term Loans 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 2024 Term Loans so prepaid if paid on or before the first anniversary of the 2024 Effective Date; 5.00% of the 2024 Term Loans so prepaid if paid after the first anniversary of the 2024 Effective Date and on or before the second anniversary of the 2024 Effective Date; 2.00% of the 2024 Term Loans so prepaid

if paid after the second anniversary of the 2024 Effective Date and on or before the third anniversary of the 2024 Effective Date or 1.00% of the 2024 Term Loans so prepaid if paid after the third anniversary of the 2024 Effective Date and on or before the fourth anniversary of the 2024 Effective Date, (C) the Exit Fee and (D) all other sums, if any, that shall become due and payable under the 2024 Loan 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 2024 Loan 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 2024 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 2024 Term Loans are 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 2024 Loan Agreement contains customary representations and warranties, covenants and events of default, including two financial covenants: (i) commencing on the 2024 Effective Date, the Borrower is required to maintain certain levels of cash, and, after the Account Control Agreement Completion Date (as defined in the Loan 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 2024 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 2024 Loan Agreement also contains other customary provisions, such as expense reimbursement, as well as indemnification rights for the benefit of the Agent and the 2024 Lenders.

As of June 30, 2024, the effective interest rate was approximately 13% per annum and there was no material difference between the carrying value and the estimated fair value of the 2024 Term Loans.

**Revenue Interest Purchase and Sale Agreement**

On May 9, 2024, the Company and Verona Pharma, Inc. (collectively the "Sellers") entered into 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") 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 will begin payment of the Royalty Interest 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 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 the Sellers with the right to settle all outstanding liabilities at any time by paying a buy-out amount under various terms and conditions. As of any date of determination, the aggregate amount of payments received by the Purchasers under the RIPSA, divided by the amount funded as of such date (the "MOIC") equals 1.20x, if such date is on or before the one-year anniversary of the funding of the first tranche of the RIPSA, the MOIC equals 1.40x if such date is after the one-year anniversary of the Tranche A Funding Date and on or before the two-year anniversary of the Tranche A Funding Date, the MOIC equals 1.55x if such date is after the two-year anniversary of the Tranche A Funding Date and on or before the three-year anniversary of the Tranche A Funding Date, and the MOIC equals 1.75x if such date is after the three-year anniversary of the Tranche A Funding Date. The Purchasers have the right to terminate the RIPSA under certain conditions, including the Company's insolvency, and the Company's divestment of ensifentrine, in which case the Sellers 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.

On June 28, 2024, the Company received the Tranche A Purchase Price of $100.0 million.

As of June 30, 2024, the effective interest rate was approximately 20% per annum and there was no material difference between the carrying value and the estimated fair value of the RIPSA.

As of June 30, 2024, the Company had $4.6 million in accrued debt issuance costs related to the 2024 Term Loans and RIPSA which are considered non-cash financing activities for purposes of the Condensed Consolidated Statements of Cash Flows.

**Note 7 - 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, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development | $ 3,664 | $ 1,123 | $ 4,680 | $ 2,226 |
| Selling, general and administrative | 11,930 | 3,951 | 15,172 | 7,138 |
| **Total** | $ 15,594 | $ 5,074 | $ 19,852 | $ 9,364 |

The following tables show the activity of each type of share-based compensation and are presented in ordinary shares. The Company's ADSs that are listed on Nasdaq each represent eight ordinary shares.

*Share options activity*

| | Number of share options outstanding |
|---|---|
| **Balance as of December 31, 2023** | 24,689,624 |
| Granted | 2,432,000 |
| Forfeited | (64,000) |
| Exercised | (1,037,424) |
| **Balance as of March 31, 2024** | 26,020,200 |
| Granted | 7,924,000 |
| Forfeited | (72,000) |
| Expired | (160,000) |
| **Balance as of June 30, 2024** | 33,712,200 |

*Restricted stock units ("RSU") activity*

| | Number of RSUs outstanding |
|---|---|
| **Balance as of December 31, 2023** | 19,502,624 |
| Forfeited | (1,752) |
| Vested | (4,357,208) |
| **Balance as of March 31, 2024** | 15,143,664 |
| Vested | (2,045,384) |
| **Balance as of June 30, 2024** | 13,098,280 |

*Performance restricted stock units ("PRSU") activity*

PRSUs will begin to vest upon achievement of certain performance conditions and are subject to continued service. The fair value of PRSUs will be recognized over the remaining service period using the graded-vesting method once the performance conditions are determined to be probable of occurring. As of June 30, 2024, the performance conditions were assessed by the Company and considered probable of being met under the applicable accounting framework, and accordingly the Company recognized $9.9 million in share-based compensation expense related to the PRSUs in the three and six months ended June 30, 2024. The total compensation cost not yet recognized as of June 30, 2024 related to PRSUs was $7.9 million, which will be recognized over a weighted-average period of approximately one year.

A summary of the Company's PRSU activity for the period ended June 30, 2024 is as follows:

| | Number of PRSUs outstanding |
|---|---|
| **Balance as of December 31, 2023** | 10,730,144 |
| Forfeited | (5,248) |
| **Balance as of March 31, 2024** | 10,724,896 |
| **Balance as of June 30, 2024** | 10,724,896 |

**Note 8 - Net loss per share**

Net loss per share is calculated on an ordinary share basis. The Company's ADSs that are listed on Nasdaq 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, 2024 and 2023 (in thousands except per share amounts):

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Numerator: | | | | |
| Net loss | $ (70,835) | $ (8,807) | $ (96,629) | $ (25,550) |
| Denominator: | | | | |
| Weighted-average shares outstanding - basic and diluted | 648,217 | 634,469 | 646,959 | 627,996 |
| Net loss per share - basic and diluted | $ (0.11) | $ (0.01) | $ (0.15) | $ (0.04) |

During the three and six months ended June 30, 2024 and 2023, outstanding share options, RSUs and PRSUs over 57.5 million and 48.5 million ordinary shares, respectively, were not included in the computation of diluted earnings per ordinary share, because to do so would be antidilutive.

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and related notes as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission on February 29, 2024 (the "2023 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 commercialization of Ohtuvayre, the development of our product candidates, including statements regarding the expected initiation, timing, progress and availability of data from our clinical trials and potential regulatory approvals, research and development costs, timing and likelihood of success, potential collaborations, the duration of our patent portfolio, our estimates regarding expenses, future revenues, capital requirements, debt service obligations and our need for additional financing, the funding we expect to become available under our various financing agreements and 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 management's 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 II, Item 1A of this Quarterly Report on Form 10-Q under the heading "Risk Factors" and Part I, Item 1A of the 2023 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 biopharmaceutical company focused on developing and commercializing innovative therapeutics for the treatment of respiratory diseases with significant unmet medical needs. Our product candidate, ensifentrine, is an novel, inhaled, selective, small molecule and dual inhibitor of the enzymes phosphodiesterase 3 and 4 ("PDE3" and "PDE4"), combining bronchodilator and non-steroidal anti-inflammatory activities in one molecule.

On June 26, 2024, the FDA approved Ohtuvayre (ensifentrine) for the maintenance treatment of chronic obstructive pulmonary disease ("COPD") in adult patients. Ohtuvayre is our first commercial product and the first inhaled therapy with a novel mechanism of action available for the maintenance treatment of COPD in more than 20 years. We believe Ohtuvayre is an important advancement in the treatment of COPD and will redefine the treatment paradigm for COPD.

We launched Ohtuvayre in the U.S. through an exclusive network of accredited specialty pharmacies in August 2024.

The approval of Ohtuvayre in the United States ("U.S.") was based on extensive data including the Phase 3 ENHANCE ("Ensifentrine as a Novel inHAled Nebulized COPD thErapy") trials, the results of which were published in the American Journal of Respiratory and Critical Care Medicine. Ensifentrine met the primary endpoint in both the ENHANCE-1 and ENHANCE-2 trials demonstrating statistically significant and clinically meaningful improvements in measures of lung function. In addition, other endpoint data demonstrated that ensifentrine substantially reduced the rate and risk of COPD exacerbations in ENHANCE-1 and ENHANCE-2. Ensifentrine was well tolerated in both trials.

We are commercializing Ohtuvayre for the maintenance treatment of COPD in the U.S. Ohtuvayre is not considered a drug device combination because patients use a readily available standard jet nebulizer to take Ohtuvayre. Outside the U.S., we intend to license Ohtuvayre to companies with expertise and experience in developing and commercializing products in those regions. To that end, we have entered into a strategic collaboration with Nuance Pharma Limited, a Shanghai-based specialty pharmaceutical company ("Nuance Pharma"), to develop and commercialize ensifentrine, including Ohtuvayre, in Greater China.

In Phase 2 clinical trials, ensifentrine has demonstrated positive results in patients with COPD, asthma and cystic fibrosis ("CF"). 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").

We have incurred recurring losses and negative cash flows from operations since inception, and have an accumulated deficit of $485.3 million as of June 30, 2024. We expect to incur additional losses and negative cash flows from operations until our product or product candidates potentially reach commercial profitability, if at all.

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

- operate a sales, marketing and distribution infrastructure, continue to increase production to commercial scale with our manufacturing and other Chemistry, Manufacturing and Controls activities to commercialize Ohtuvayre as well as any additional products for which we may obtain regulatory approval;
- continue the clinical development of a fixed-dose combination of ensifentrine and a long-acting muscarinic antagonist as well as our DPI and pMDI formulations of ensifentrine and research and development of other formulations of ensifentrine;
- initiate and conduct further clinical trials for ensifentrine for the treatment of NCFBE, 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 commercialization efforts and to support our continuing operations as a U.S. public company; and
- 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.

On May 9, 2024, we entered into a term loan facility (the "2024 Term Loans") of up to $400.0 million with Oaktree Fund Administration, LLC, a Delaware limited liability company, as administrative agent, and certain funds managed by each of Oaktree Capital Management, L.P. and OCM Life Sciences Portfolio LP party thereto (collectively, the "2024 Lenders"). At closing, we received net proceeds of $52.8 million and up to four additional advances of an aggregate $345.0 million were available subject to meeting certain commercial milestones and other specified conditions. On June 28, 2024, we received net proceeds of $68.6 million related to the second tranche of the 2024 Term Loans, which was available upon FDA approval for Ohtuvayre, as well as proceeds from the $100.0 million first tranche of the RIPSA. Refer to Note 6 - Debt to our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q for additional information regarding the 2024 Term Loans and the RIPSA.

We believe that our cash and cash equivalents as of June 30, 2024 and funding expected to become available under the 2024 Term Loans and the RIPSA will enable us to fund our planned operating expenses and capital expenditure requirements through at least the end of 2026, including the commercial launch of Ohtuvayre in the U.S. The remaining advances under the 2024 Term Loans and the RIPSA are contingent upon the achievement of commercial milestones and other specified conditions, and in the case of the Tranche E Term Loan under the 2024 Term Loans, at the sole discretion of the 2024 Lenders. No additional advances are available under the 2023 Term Loan following our termination and repayment in full of the 2023 Term Loan on May 9, 2024.

**Clinical development update**

**Phase 3 ENHANCE program**

The U.S. approval of Ohtuvayre was based on extensive data including the Phase 3 ENHANCE trials, the results of which were published in the American Journal of Respiratory and Critical Care Medicine.

We reported positive top-line results from ENHANCE-2 and ENHANCE-1 in August and December 2022, respectively. Ohtuvayre successfully met the primary endpoints in both trials, demonstrating statistically significant and clinically meaningful improvements in measures of lung function in moderate to severe COPD patients. Improvements in symptoms and quality of life measures were shown in both trials, which reached statistical significance in ENHANCE-1. Other endpoint data showed Ohtuvayre substantially reduced the rate and risk of moderate to severe COPD exacerbations and was well tolerated in both trials.

The ENHANCE trials were designed to evaluate Ohtuvayre as monotherapy and added onto a single bronchodilator. Each trial enrolled approximately 800 subjects, for a total of approximately 1,600 subjects, at sites primarily in the U.S. and Europe. The two trials provided replicate evidence of efficacy and safety data over 24 weeks and ENHANCE-1 also evaluated longer-term safety in approximately 400 subjects over 48 weeks.

Subject demographics and disease characteristics were well balanced between treatment groups in both trials.

- In ENHANCE-1 approximately 69% of subjects received background COPD therapy, either a long-acting muscarinic antagonist ("LAMA") or a long-acting beta-antagonist ("LABA"). Additionally, approximately 20% of all subjects received inhaled corticosteroids ("ICS") with concomitant LAMA or LABA.
- In ENHANCE-2 approximately 55% of subjects received background COPD therapy, either a LAMA or a LABA. Additionally, approximately 15% of all subjects received ICS with concomitant LAMA or LABA.

## Phase 3 data published in *American Journal of Respiratory and Critical Care Medicine*

| Endpoint | ENHANCE-1 (N=760) | ENHANCE-2 (N=789) |
|---|---|---|
| **Average $FEV_1$ AUC (0-12 hours)** | +87 mL (p<0.0001) vs placebo | +94 mL (p<0.0001) vs placebo |
| **Peak $FEV_1$** | +147 mL (p<0.0001) vs placebo | +146 mL (p<0.0001) vs placebo |
| **Morning Trough $FEV_1$** | +35 mL (p=0.0413) vs placebo | +49 mL vs placebo[a] |
| **Symptoms (E-RS Total Score)** | -1.0 units (p=0.0111) vs placebo | -0.6 units vs placebo[b] |
| **Quality of Life (SGRQ Total Score)** | -2.3 units (p=0.0253) vs placebo | -0.5 units vs placebo[b] |
| **Exacerbation rate** | 36% reduction in rate[c] | 43% reduction in rate[c] |
| **Time to first COPD exacerbation** | 38% reduction in risk[c] | 42% reduction in risk[c] |
| **Incidence of adverse events (AEs ≥1% and greater than placebo)** | Back Pain 1.8% vs 1.0%<br>Hypertension 1.7% vs 0.9%<br>UTI 1.3% vs 1.0%<br>Diarrhea 1.0% vs 0.7% | |

[a] Result was not statistically significant due to failure higher in the analysis hierarchy
[b] Not significant
[c] Pre-specified other endpoints were not part of the formal testing hierarchy
UTI = Urinary tract infection
*[1]Anzueto A, et al. Am J Respir Crit Care Med. 2023;208(4):406-416; [2]Barjaktarevic I, et al. Am J Respir Crit Care Med. 2023;207:A5008*

**Clinical Development Activities**

*Ensifentrine / Long-Acting Muscarinic Antagonist ("LAMA") fixed-dose combination*

Fixed-dose combination therapies such as LABA / LAMA, LABA / ICS and LABA / LAMA / ICS are commonly used in the treatment of COPD and, based on our market research, an unmet need exists for a nebulized fixed-dose combination therapy. We believe the combination of ensifentrine with a LAMA could provide COPD patients with the first nebulized fixed-dosed combination with the potential to provide bronchodilation through a dual mechanism and also non-steroidal anti-inflammatory effects via PDE inhibition.

We are developing a fixed-dose combination formulation with ensifentrine and glycopyrrolate, a LAMA, for the maintenance treatment of patients with COPD via delivery in a nebulizer. We have filed patent applications in multiple jurisdictions including the U.S. In July 2024, we submitted an investigational new drug application ("IND") to the FDA to allow initiation of the clinical program. Subject to clearance of the IND, we intend to initiate a Phase 2 dose-ranging trial in the third quarter of 2024.

*Non-cystic fibrosis bronchiectasis ("NCFBE")*

NCFBE is a chronic lung disease characterized by persistent cough, excess sputum production and frequent respiratory infections with more severe patients suffering exacerbations. The condition affects up to 500,000 adults in the U.S. and no therapies are specifically approved to treat it. Physicians currently use bronchodilators, antibiotics, steroids, mucus thinners and surgery.

Based on the clinical results of ensifentrine observed in patients with COPD, including improvements in lung function and symptoms of cough and sputum, we believe that ensifentrine could potentially be an effective treatment for NCFBE. We plan to commence a Phase 2 clinical trial to assess the efficacy and safety of nebulized ensifentrine in patients with NCFBE in the third quarter of 2024.

**Nuance Pharma**

In 2021, we entered into an agreement with Nuance Pharma for exclusive rights to develop and commercialize ensifentrine in Greater China, with future potential milestone payments up to $179 million plus royalties. In August 2022, Nuance Pharma received clearance from the Center of Drug Evaluation for its IND application to conduct both Phase 1 and Phase 3 studies with ensifentrine for the maintenance treatment of COPD in mainland China. Nuance Pharma initiated a Phase 1 trial with ensifentrine in healthy volunteers in March 2023. In April 2023, Nuance Pharma dosed the first subject in its pivotal Phase 3 clinical trial evaluating ensifentrine for the maintenance treatment of COPD in mainland China.

**Critical accounting estimates**

There were no material changes to the Company's critical accounting estimates described in the Company's 2023 Form 10-K during the six months ended June 30, 2024.

**Components of results of operations**

*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 share-based compensation. 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. Prior to obtaining regulatory approval for Ohtuvayre, the Company expensed costs relating to production of pre-launch inventory as research and development expense in its condensed consolidated statements of operations and comprehensive loss in the period incurred. All other research and development costs are expensed as incurred.

We expect our research and development costs to increase in the second half of 2024 and into future years related to our planned additional trials for a fixed-dose combination formulation for COPD patients and nebulized ensifentrine in patients with NCFBE.

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 the launch of Ohtuvayre and other commercial activities, 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 significantly increase as we commercially launch Ohtuvayre including costs related to our sales force, marketing and other launch related costs. As we develop our knowledge of the market and refine our commercial launch plans, expected costs may vary significantly from our current expectations.

*Other income/(expense)*

Other income/(expense) are driven by interest income and expense, foreign exchange movements on cash and cash equivalents and taxes receivable, and the U.K. research and development tax credits (the "R&D tax credit").

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. The credit recorded related to the 2022 financial year was received in the three months ended June 30, 2024, and the credit recorded in the 2023 financial year is expected to be received in 2024.

*Taxation*

We are subject to corporate taxation in the U.S. and the U.K. We have generated losses since inception and have therefore not paid U.K. corporation tax. The income taxes presented in our Condensed Consolidated Statements of Operations and Comprehensive Loss represent the tax impact from our financing and operating activities in the U.S.

U.K. 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, 2024 and 2023**

The following table shows our statements of operations for the three months ended June 30, 2024 and 2023 (in thousands):

| | Three months ended June 30, | | |
|---|---|---|---|
| | 2024 | 2023 | Change |
| **Operating expenses:** | | | |
| Research and development | $ 19,388 | $ (2,474) | $ 21,862 |
| Selling, general and administrative | 49,035 | 12,439 | 36,596 |
| **Total operating expenses** | 68,423 | 9,965 | 58,458 |
| **Operating loss** | (68,423) | (9,965) | (58,458) |
| **Other income/(expense):** | | | |
| Research and development tax credit | 847 | (1,934) | 2,781 |
| Loss on extinguishment of debt | (3,653) | — | (3,653) |
| Interest income | 3,140 | 3,402 | (262) |
| Interest expense | (1,757) | (740) | (1,017) |
| Foreign exchange gain/(loss) | 25 | 740 | (715) |
| **Total other (expense)/income, net** | (1,398) | 1,468 | (2,866) |
| **Loss before income taxes** | (69,821) | (8,497) | (61,324) |
| Income tax expense | (1,014) | (310) | (704) |
| **Net loss** | $ (70,835) | $ (8,807) | $ (62,028) |

*Research and development costs*

Research and development costs were $19.4 million for the three months ended June 30, 2024, compared to a net reversal of costs of $2.5 million for the three months ended June 30, 2023, a change of $21.9 million. This change was primarily due to accrual of the $6.3 million approval milestone due to Ligand, $2.5 million in share-based compensation largely driven by the recognition of PRSU expense and $1.7 million related to pre-launch inventory production. Further, we had $2.5 million in clinical trial and other development costs in the three months ended June 30, 2024 while in the three months ended June 30, 2023, we recorded a reversal of costs of $6.3 million related to the resolution of a supplier matter which resulted in net negative research and development expense for the three months ended June 30, 2023.

*Selling, general and administrative costs*

Selling, general and administrative costs were $49.0 million for the three months ended June 30, 2024, compared to $12.4 million for the three months ended June 30, 2023, an increase of $36.6 million. This increase was driven primarily by an accrual of the $15.0 million first sale milestone payment due to Ligand, an increase of $7.4 million for marketing and other commercial launch related activities and an increase of $2.3 million in other support costs including travel, professional and consulting fees and information technology costs. Additionally, share-based compensation increased by $8.0 million largely driven by the recognition of PRSU expense as well as an increase of $4.3 million in people-related costs as we built out our commercial organization including much of the field sales team.

*Other income/(expense)*

Other income/(expense), net for the three months ended June 30, 2024 was expense of $1.4 million compared to income of $1.5 million for the three months ended June 30, 2023, a change of $2.9 million. This increase in net expense was primarily due to the recognition of a loss on the extinguishment of our 2023 Term Loan of $3.7 million as well as an increase in interest expense of $1.0 million related to our higher average debt balance. This was partially offset by an increase in our research and development tax credit of $2.8 million primarily relating to the net reversal of expense in the three months ended June 30, 2023 relating to the resolution of the supplier matter.

**Results of operations for the six months ended June 30, 2024 and 2023**

The following table shows our statements of operations for the six months ended June 30, 2024 and 2023 (in thousands):

| | Six months ended June 30, | | |
|---|---|---|---|
| | 2024 | 2023 | Change |
| **Operating expenses:** | | | |
| Research and development | $ 26,152 | $ 10,136 | $ 16,016 |
| Selling, general and administrative | 69,469 | 22,028 | 47,441 |
| **Total operating expenses** | 95,621 | 32,164 | 63,457 |
| **Operating loss** | (95,621) | (32,164) | (63,457) |
| **Other income/(expense):** | | | |
| Research and development tax credit | 1,432 | 379 | 1,053 |
| Loss on extinguishment of debt | (3,653) | — | (3,653) |
| Interest income | 6,518 | 6,079 | 439 |
| Interest expense | (3,343) | (1,033) | (2,310) |
| Foreign exchange (loss)/gain | (194) | 1,672 | (1,866) |
| **Total other income, net** | 760 | 7,097 | (6,337) |
| **Loss before income taxes** | (94,861) | (25,067) | (69,794) |
| Income tax expense | (1,768) | (483) | (1,285) |
| **Net loss** | $ (96,629) | $ (25,550) | $ (71,079) |

*Research and development costs*

Research and development costs were $26.2 million for the six months ended June 30, 2024, compared to $10.1 million for the six months ended June 30, 2023, an increase of $16.0 million. This increase was primarily due to accrual of the $6.3 million approval milestone due to Ligand, $2.4 million in share-based compensation largely driven by the recognition of PRSU expense, $1.9 million related to pre-launch inventory production and $1.2 million for people-related costs. Additionally, we recorded a reversal of $1.5 million of costs in the six months ended June 30, 2023, which were expensed in the year ended December 31, 2022 related to the resolution of a supplier matter.

*Selling, general and administrative costs*

Selling, general and administrative costs were $69.5 million for the six months ended June 30, 2024 compared to $22.0 million for the six months ended June 30, 2023, an increase of $47.4 million. This increase was driven primarily by a charge of $15.0 million first sale milestone payment due to ligand, an increase of $11.4 million for marketing and other commercial launch related activities and an increase of $4.2 million in other support costs including travel, professional and consulting fees, rent and information technology. Additionally, we had an increase of $8.3 million in people related costs as we built out our commercial organization including much of the field sales team as well as an increase of $8.0 million related to share-based compensation largely driven by the recognition of PRSU expense.

*Other income/(expense)*

Other income for the six months ended June 30, 2024 was $0.8 million compared to $7.1 million for the six months ended June 30, 2023, a decrease of $6.3 million. This decrease was primarily due to the recognition of a loss on the extinguishment of our 2023 Term Loan of $3.7 million as well as an increase in interest expense of $2.3 million related to our higher average debt balance.

**Cash flows**

The following table summarizes our cash flows for the six months ended June 30, 2024 and 2023 (in thousands):

| | Six months ended June 30, | | |
|---|---|---|---|
| | 2024 | 2023 | Change |
| **Cash and cash equivalents at beginning of the period** | $ 271,772 | $ 227,827 | $ 43,945 |
| Net cash used in operating activities | (30,712) | (27,093) | (3,619) |
| Net cash used in investing activities | (45) | — | (45) |
| Net cash provided by financing activities | 163,709 | 68,809 | 94,900 |
| Effect of exchange rate changes on cash and cash equivalents | (125) | 1,184 | (1,309) |
| **Cash and cash equivalents at end of the period** | $ 404,599 | $ 270,727 | $ 133,872 |

*Operating activities*

Net cash used in operating activities was $30.7 million in the six months ended June 30, 2024, compared to $27.1 million during the six months ended June 30, 2023, an increase of $3.6 million. The increase in cash used in operating activities was primarily due to the increase of costs incurred in preparation for the commercial launch of Ohtuvayre as well as an increase in people related costs. This was partially offset by the receipt of $8.7 million related to the 2022 R&D tax credit from HMRC.

*Financing activities*

Net cash provided by financing activities was $163.7 million in the six months ended June 30, 2024, compared to $68.8 million in the six months ended June 30, 2023, an increase of $94.9 million. The increase in cash provided by financing activities was primarily due to net proceeds received of $167.9 million in the six months ended June 30, 2024 from the 2024 Term Loans and RIPSA, partially offset by the repayment of the 2023 Term Loans and debt issuance costs. In the six months ended June 30, 2023, the Company received $56.9 million related to the issuance of ordinary shares and as well as proceeds from the draw under our prior term loan with Oxford Finance Luxembourg S.À R.L. of $10.0 million.

**Liquidity and capital resources**

To date, we have financed our operations primarily through the issuances of our equity securities, including warrants, from borrowings under term loan facilities, from payments under the RIPSA and from a collaboration and license agreement (the "Nuance Agreement") with Nuance Pharma Limited ("Nuance Pharma") effective June 9, 2021.

We have incurred recurring losses since inception, including net losses of $96.6 million for the six months ended June 30, 2024, and $54.4 million for the year ended December 31, 2023. As of June 30, 2024, we had an accumulated deficit of $485.3 million. We expect to incur additional losses and negative cash flows from operations until we reach profitability, if at all, and we may continue to incur significant operating losses for the foreseeable future as we have increased our headcount significantly in 2024 and have experienced increasing expenses to support our commercial launch of Ohtuvayre as well as our costs to expand our research and development efforts, advance our clinical development of ensifentrine in other formulations or for other indications, and seek to obtain regulatory approval for and commercialize ensifentrine in various formulations or indications.

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, the 2024 Term Loans and the RIPSA.

*2024 Financing and Capital Transactions*

During the six months ended June 30, 2024, we had the following financing transactions:

- Entered into the 2024 Term Loans and RIPSA and drew on tranches of $225 million;
- Repaid the 2023 Term Loans in full.

Refer also to Note 6 - Debt to the unaudited condensed consolidated financial statements for additional information on the 2024 Term Loans.

**Funding requirements**

We believe that our cash and cash equivalents as of June 30, 2024, together with additional funding expected to become available under the 2024 Term Loans and the RIPSA, will enable us to fund planned operating expenses and capital expenditure requirements, including the commercial launch of Ohtuvayre, through at least the end of 2026. Future advances under the 2024 Term Loans and the RIPSA are contingent upon achievement of certain commercial milestones and other specified conditions, and in the case of the Tranche E Term Loan, at the sole discretion of the 2024 Lenders. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. In addition, our operating plan may change as a result of many factors unknown to us. These factors, among others, may necessitate that we seek additional capital sooner than currently planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at these institutions may exceed insured limits.

We may require additional capital to commercialize Ohtuvayre or to research and develop additional indications or additional formulations of or with ensifentrine. In addition, we may seek to initiate or conduct preclinical or clinical studies with ensifentrine in additional indications or to discover or in-license and develop additional product candidates. We may need to seek additional funding through public or private financings, debt financings, 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.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through equity securities offerings, the ownership interest of our ADS holders and shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect these holders' rights as holders of our ADSs. Debt financing, if available, could result in fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, to acquire, sell or license intellectual property rights, to make capital expenditures, to declare dividends, or other operating restrictions. If we raise additional funds through collaboration or licensing agreements, we may have to relinquish valuable rights to our technologies, future revenue streams or product

candidates or grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our ADS holders and shareholders, and may cause the market price of our ADSs to decline.

Our future capital requirements will depend on many factors, including:

- the cost, progress and results of any studies required to support the commercial positioning of Ohtuvayre for the maintenance treatment of COPD in adult patients and any future product candidates;
- the number of potential new product candidates we decide to in-license and develop;
- the cost, progress and results of any clinical trials evaluating ensifentrine for the treatment of NCFBE, CF, asthma or other targeted indications, or for other formulations of ensifentrine, including fixed-dose combination products;
- the cost of manufacturing clinical and commercial supplies of the ensifentrine active ingredient and derived formulated drug products and for other formulations of ensifentrine in development;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for ensifentrine in other target indications and of the development of DPI and pMDI formulations of ensifentrine, or fixed-dose combination formulations of ensifentrine for the maintenance treatment of COPD and potentially NCFBE, CF, asthma and other respiratory diseases;
- the costs involved in growing our organization to the size needed to allow for the research, development and commercialization of ensifentrine or any future product candidates;
- the costs, timing and outcomes of current and future commercialization activities, including manufacturing, marketing, sales and distribution, for Ohtuvayre;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the sales price and availability of adequate third-party coverage and reimbursement for Ohtuvayre;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for our products;
- 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 commercialization of Ohtuvayre, potential commercialization of ensifentrine in other indications or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization;
- the amount of revenue we may derive either directly or in the form of royalty payments from future sales of Ohtuvayre or any future product candidates, including ensifentrine in other indications;
- fully develop a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize Ohtuvayre and any product candidates for which we may obtain regulatory approval; and
- our ability to continue to operate as a public company.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

***Interest Rate Risk***

We are exposed to market risk related to changes in interest rates. As of June 30, 2024 and December 31, 2023, we had cash and cash equivalents of $404.6 million and $271.8 million, respectively, consisting primarily of money market funds. Our cash equivalents are subject to interest rate risk and the rate of return would be negatively impacted by a decrease in interest rates. Due to the short-term nature of our cash equivalents, a sudden change in interest rates would not be expected to have a material effect on our business, financial condition or results of operations. There has been no material change to our interest rate sensitivity during the three months ended June 30, 2024.

***Foreign Exchange Risk***

The Company is exposed to foreign exchange risk as a result of transactions in currencies other than its functional currency, the U.S. dollar. The Company's expenses in the three months ended June 30, 2024 were incurred primarily in U.S. dollars, but also included euros and pound sterling. As at June 30, 2024, approximately 5% of cash and cash equivalents and 7% of accounts payable were denominated in foreign currencies. In addition, the R&D tax credit receivable is in pound sterling. Due to the relative magnitude of our foreign currency holdings, a change of 1% in foreign exchange rates would not have a material effect on our business, financial condition or results of operations.

**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, 2024, 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, 2024 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**

Investing in our ADSs involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The occurrence of any of the events or developments described below could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our ADSs could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

**Risks Related to Our Business and Industry**

***We have a limited operating history and have never generated any product revenue.***

We are a biopharmaceutical company with a limited operating history, and have incurred significant operating losses since our inception. We had net losses of $70.8 million for the three months ended June 30, 2024, and $54.4 million for the year ended December 31, 2023. As of June 30, 2024, we had an accumulated deficit of $485.3 million. Our losses have resulted principally from expenses incurred in research and development of ensifentrine, and from general and administrative costs that we have incurred while building our business infrastructure. We may continue to incur significant operating losses for the foreseeable future as we expand our research and development efforts, advance our clinical development of ensifentrine in other formulations, and commercially launch ensifentrine under the brand name Ohtuvayre, which was approved by the FDA on June 26, 2024 for the maintenance treatment of chronic obstructive pulmonary disease ("COPD") in adult patients. We anticipate that our expenses will increase substantially as we:

- initiate and conduct clinical trials of ensifentrine for the treatment of non-cystic fibrosis bronchiectasis ("NCFBE"), cystic fibrosis ("CF"), asthma or other indications;
- initiate and conduct other future clinical trials of ensifentrine in other formulations, including in combination with other active ingredients including fixed-dose combinations, for the treatment of COPD or other indications;
- initiate and conduct clinical pharmacology studies with any formulation;
- seek to discover and develop or in-license additional respiratory product candidates;
- conduct pre-clinical studies to support ensifentrine and potentially other future product candidates;
- develop the manufacturing processes and produce clinical and commercial supplies of the ensifentrine active pharmaceutical ingredient and formulated drug products derived from it;
- seek additional regulatory approvals of ensifentrine;
- maintain and potentially expand commercial infrastructure to support the commercialization of Ohtuvayre, including sales, marketing, operations, reimbursement, distribution and manufacturing capabilities to commercialize Ohtuvayre;
- maintain, expand and protect our intellectual property portfolio;
- secure, maintain or obtain freedom to operate for our in-licensed technologies and products;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and
- expand our operations to support commercialization and research activities in the U.S. and elsewhere.

Our expenses may also increase substantially if we experience any delays or encounter any issues with any of the above, including, but not limited to, failed pre-clinical studies or clinical trials, complex results, safety issues or regulatory challenges.

We have devoted substantially all of our financial resources and efforts to the research and development, pre-clinical studies and clinical trials, and commercialization of Ohtuvayre for the maintenance treatment of COPD of adults in the U.S. We are continuing the development of ensifentrine in other formulations and for other targeted indications, and to support commercialization in other territories, if and when approved in such territories.

To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of ensifentrine in other formulations and other targeted indications, discovering and developing additional product candidates, obtaining additional regulatory approvals for ensifentrine and for any future product candidates that successfully complete clinical trials, establishing manufacturing, commercial and marketing capabilities and ultimately distributing and selling any products for which we obtain regulatory approval. We are only in the preliminary stages of some of these activities such as the commercial launch of Ohtuvayre. We may never succeed in these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, the European Medicines Agency ("EMA"), or other regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our planned clinical trials or the development of ensifentrine in additional formulations or for other targeted indications, or any other product candidates, our expenses could increase and revenue could be further delayed.

We have only had one product candidate recently approved for marketing in the U.S., none in any other jurisdiction, and may never receive approval beyond the one product approved to date. It could be several years, if ever, before we have a commercialized product that generates significant revenues through sales of Ohtuvayre or our product candidates, if approved. Even if we do generate revenue, we may never achieve or sustain profitability on a quarterly or annual basis. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. Our failure to sustain profitability would depress the market price of our ADSs and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our ADSs also could cause our ADS holders to lose all or a part of their investment.

***We may need additional funding to complete development and commercialization of any future product candidates and to commercialize Ohtuvayre. If we are unable to raise capital when needed, or if a failure of any financial institution where we maintain our cash and cash equivalents prevents or delays us from accessing uninsured funds, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.***

We expect our expenses to increase in connection with our ongoing and planned activities, particularly as we commercialize Ohtuvayre, and conduct clinical trials of ensifentrine in other formulations and for other targeted indications. We expect to incur significant commercialization expenses related to activities including product positioning studies, product manufacturing, medical affairs, marketing, sales and distribution. Furthermore, we expect to incur ongoing costs associated with operating as a public company in the U.S. and maintaining a listing on the Nasdaq Global Market, or Nasdaq. Accordingly, we may need to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We estimate that our existing cash resources and additional funding received and expected to become available under the 2024 Term Loans and the RIPSA will enable us to fund planned operating expenses and capital expenditure requirements through at least the end of 2026, including the commercial launch of Ohtuvayre in the U.S. Future advances under the 2024 Term Loans and the RIPSA are contingent upon achievement of certain regulatory and commercial milestones and other specified conditions. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. In addition, our operating plan may change as a result of many factors unknown to us. These factors, among others, may necessitate that we seek additional capital sooner than currently planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Our future capital requirements will depend on many factors, including:

- the cost, progress and results of any studies required to support the commercial positioning of Ohtuvayre for the maintenance treatment of COPD in adult patients and any future product candidates;
- the number of potential new product candidates we decide to in-license and develop;
- the cost, progress and results of any clinical trials evaluating ensifentrine for the treatment of NCFBE, CF, asthma or other targeted indications, or for other formulations of ensifentrine, including fixed-dose combination products;
- the cost of manufacturing clinical and commercial supplies of the ensifentrine active ingredient and derived formulated drug products and for other formulations of ensifentrine in development;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for ensifentrine in other target indications and of the development of DPI and pMDI formulations of ensifentrine, or fixed-dose combination formulations of ensifentrine for the maintenance treatment of COPD and potentially NCFBE, CF, asthma and other respiratory diseases;
- the costs involved in growing our organization to the size needed to allow for the research, development and commercialization of ensifentrine or any future product candidates;
- the costs, timing and outcomes of current and future commercialization activities, including manufacturing, marketing, sales and distribution, for Ohtuvayre;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the sales price and availability of adequate third-party coverage and reimbursement for Ohtuvayre;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for our products;
- 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 commercialization of Ohtuvayre, potential commercialization of ensifentrine in other indications or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization;
- the amount of revenue we may derive either directly or in the form of royalty payments from future sales of Ohtuvayre or any future product candidates, including ensifentrine in other indications;
- fully develop a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize Ohtuvayre and any product candidates for which we may obtain regulatory approval; and
- our ability to continue to operate as a public company.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize Ohtuvayre or our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect our business, the holdings or the rights of our shareholders, or the value of our ordinary shares or ADSs.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue our research and development programs relating to ensifentrine or any commercialization efforts, be unable to expand our operations, or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business and potentially cause us to discontinue operations.

***We depend solely on the success of ensifentrine, which was recently approved by the FDA as Ohtuvayre. If we are unable to commercialize Ohtuvayre, or successfully develop ensifentrine for other indications, or experience significant delays in doing so, our ability to generate revenue and our financial condition will be adversely affected.***

The FDA approved our New Drug Application ("NDA") for Ohtuvayre for the maintenance treatment of COPD in adult patients on June 26, 2024. We do not currently generate any revenues from sales of Ohtuvayre or any other products. We have invested substantially all of our efforts and financial resources on the development of Ohtuvayre and on preparation for its commercial launch, including costs related to commercial drug supply, sales, and marketing. Our ability to generate royalty and product revenues will depend heavily on its successful commercialization. In addition, we have not submitted a marketing authorization application ("MAA") to the EMA or comparable applications to other regulatory authorities for Ohtuvayre. The success of Ohtuvayre will depend on many factors, including the following:

- the potential and perceived efficacy and potential advantages over alternative treatments, including over direct competitors;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- the ability to offer Ohtuvayre for sale at a competitive price;
- publicity concerning our product, or competing products and treatments;
- the availability of third-party coverage and adequate reimbursement for Ohtuvayre;
- the possible occurrence of adverse clinical findings or decreased effectiveness of our product over time identified during continued monitoring and evaluation of patients;
- any restrictions on the use of our product together with other medications;
- interactions of our product with other medicines patients are taking; and
- the mix of private and governmental payers coverage, particularly if the percentage of patients receiving reimbursement from state Medicaid is high since such process can be slower to reimburse.

Even if a product displays a favorable efficacy and safety profile in clinical studies, market acceptance of the product will not be known until some period after it is launched. Our efforts to educate the medical community and payers on the benefits of Ohtuvayre may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors. Any of these factors may cause Ohtuvayre to be unsuccessful or less successful than anticipated.

The success of any product candidates, including our planned and ongoing development programs for ensifentrine, will depend on many factors, including the following:

- we may not be able to demonstrate that a product candidate is safe and effective as a treatment for our targeted indications to the satisfaction of the applicable regulatory authorities;
- the applicable regulatory authorities may require additional pre-clinical or clinical trials, which would increase our costs and prolong our development;
- the results of clinical trials of a product candidate may not meet the level of statistical or clinical significance required by the applicable regulatory authorities for marketing approval;
- the applicable regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the contract research organizations ("CROs") that we retain to conduct clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the applicable regulatory authorities may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of a product candidate outweigh its safety risks or may disagree with our interpretation of data;
- our ability to demonstrate a non-clinical safety profile that is acceptable to the applicable regulatory authorities;
- unexpected operational or clinical issues may prevent completion or interpretation of clinical study results;

- unexpected manufacturing issues, product performance issues or stability issues may delay or otherwise adversely affect the progress of our clinical development program;
- if regulatory authorities determine that inspections of the manufacturing facilities or clinical sites for our product candidates are required in connection with a marketing application, and such regulatory authorities are unable to conduct such inspections, whether due to geopolitical conflict, including war and terrorism, such as the ongoing conflicts in Europe and the Middle East, or travel restrictions, such as those imposed during the COVID-19 pandemic;
- the applicable regulatory authorities may not accept data generated at our clinical trial sites due to Good Clinical Practice ("GCP") compliance issues, misconduct, or other reasons;
- the applicable regulatory authorities may require development of a risk evaluation and mitigation strategy ("REMS") or similar risk management measures as a condition of approval;
- the applicable regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers;
- the applicable regulatory authorities may change their approval policies or adopt new regulations;
- if we license a product candidate to others, the efforts of those parties in completing clinical trials of, receiving regulatory approval for, and commercializing that product candidate;
- through our clinical trials, we may discover factors that limit the commercial viability of a product candidate or make the commercialization of such product candidate unfeasible;
- if we retain rights under a collaboration agreement for a product candidate, our efforts in completing pre-clinical studies and clinical trials of, receiving marketing approvals for, establishing commercial manufacturing capabilities for, and commercializing such product candidate; and
- if approved, acceptance of a product by patients, the medical community and third-party payors, effectively competing with other therapies, a continued acceptable safety profile following approval and qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

An unfavorable outcome in any of these factors could result in our experiencing significant delays or an inability to successfully commercialize our product candidates.

We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to manufacture and market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We have received FDA approval to commercialize ensifentrine in the U.S. for the maintenance treatment of COPD in adult patients under the brand name Ohtuvayre. We may in the future seek regulatory approval to commercialize ensifentrine in the European Union ("EU") and additional countries. While the scope of regulatory approval is similar in many countries, to obtain separate regulatory approval in multiple countries requires us to comply with the numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of ensifentrine, and we cannot predict success in these jurisdictions.

***Our limited operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability.***

Since our inception in 2005, we have devoted substantially all of our resources to developing ensifentrine, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. We have completed multiple Phase 1 and 2 clinical trials in different formulations of ensifentrine and for different indications, and two registrational Phase 3 clinical trials for nebulized ensifentrine for the maintenance treatment of COPD. While we have received approval for marketing ensifentrine in the U.S. for the maintenance treatment of COPD in adults, we have not yet conducted sales, marketing and distribution activities necessary for successful product commercialization. Additionally, we are not profitable and have incurred losses in each year since our inception, and we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of

factors, many of which are beyond our control. Consequently, any predictions investors make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

***The terms of our credit facility place restrictions on our operating and financial flexibility, and our existing and any future indebtedness could adversely affect our ability to operate our business.***

On May 9, 2024 (the "2024 Effective Date"), Verona Pharma, Inc. entered into a term loan facility of up to $400.0 million (the "2024 Term Loans" or the "2024 Term Loan Agreement"), 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 "2024 Lenders"), We received net proceeds of $68.6 million related to the Tranche B Term Loan on June 28, 2024 following FDA approval of Ohtuvayre. Each advance under the 2024 Term Loans accrues interest at a per annum rate equal to 11.00%.

Our outstanding indebtedness, including any additional indebtedness incurred beyond our borrowings under the 2024 Term Loans, combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product candidate development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our then existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under the 2024 Term Loans or any other debt instruments. Failure to satisfy our current and future debt obligations, including covenants to take or avoid specific actions, under the 2024 Term Loan Agreement could result in an event of default and, as a result, the 2024 Lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under the 2024 Term Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness while still pursuing our current business strategy. In addition, the 2024 Lenders could seek to enforce their security interests in any collateral securing such indebtedness.

Further, if we are liquidated, the 2024 Lenders' right to repayment would be senior to the rights of holders of our ADSs or our ordinary shares to receive any proceeds from the liquidation. Any declaration by the 2024 Lenders of an event of default could significantly harm our business and prospects and could cause the price of our ADS to decline. In addition, the covenants under the 2024 Term Loan Agreement, the pledge of our assets (including our intellectual property) as collateral could limit our ability to obtain additional debt financing. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

***The terms of the RIPSA place restrictions on our operating and financial flexibility, and if we fail to comply with certain covenants in the RIPSA, our results of operations and financial condition may be harmed.***

In May 2024, Verona Pharma plc and Verona Pharma, Inc. (collectively, the "Sellers") entered into a revenue interest purchase and sale agreement (the "RIPSA") with Oaktree Fund Administration, LLC, as administrative agent, and certain funds managed by each of Oaktree and OMERS party thereto (collectively, the "Purchasers"). Under the terms of the RIPSA, in exchange for the Purchasers' payment to us 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 interested to the Purchasers, including a right for the Purchasers to receive 6.50% on global net sales of ensifentrine by the Sellers and 5% on certain proceeds the Sellers receive from licenses engaged during the term of the RIPSA outside of the U.S. The Tranche A Purchase Price of $100.0 million was received on June 28, 2024 following FDA approval of Ohtuvayre. We are also eligible to receive an additional funding tranche equal to $150 million upon achievement of

a specified net sales milestone in any trailing six-month period after receipt of the Tranche A Purchase Price. The RIPSA contains covenants that impose on us certain obligations with respect to payment, diligence, reporting, intellectual property, license agreements, and certain other actions, as well as indemnification obligations. Among other things, these covenants require us to use commercially reasonable efforts to develop and commercialize ensifentrine in the U.S. and each major jurisdiction in which a marketing authorization is obtained, and limit our ability to create or incur liens or dispose of certain assets related to ensifentrine. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might otherwise be advantageous to us and our shareholders, including the holders of our ADSs. Pursuant to the RIPSA and related security agreement, we granted to the Purchasers a second-priority lien in certain of our intellectual property assets and other related assets to secure our obligations under the RIPSA. If we are unable to comply with our obligations, the Purchasers could seek to enforce their security interest in such assets.

Further, the RIPSA and our payment obligations to the Purchasers could have important negative consequences to holders of our securities. For example, a portion of our cash flow from operations will be needed to make required payments to the Purchasers and will not be available to fund future operations.

Payment requirements under the RIPSA will increase our cash outflows. Our future operating performance is subject to market conditions and business factors that are beyond our control. If our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sale would result in dilution to our shareholders. There is no assurance that if we are required to secure funding we can do so on terms acceptable to us, or at all. Failure to pay amounts owed to the Purchasers when due would result in a default under the RIPSA and could result in foreclosure on all or substantially all of our assets, which would have a material adverse effect.

***Raising additional capital may cause dilution to our holders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, the ownership interest of our ADS holders and shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect these holders' rights as holders of our ADSs. Debt financing, if available, could result in fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, to acquire, sell or license intellectual property rights, to make capital expenditures, to declare dividends, or other operating restrictions. If we raise additional funds through collaboration or licensing agreements, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our ADS holders and shareholders, and may cause the market price of our ADSs to decline.

***Our business may become subject to economic, political, regulatory and other risks associated with international operations.***

As a company based in the U.K. and whose securities are listed on Nasdaq, our business is subject to risks associated with conducting business internationally. Many of our suppliers and collaborative and clinical trial relationships are located outside the U.K. and the U.S.. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;

- changes in non-U.S. currency exchange rates of the euro and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, such as the ongoing conflicts in Europe and the Middle East, or natural disasters including earthquakes, typhoons, floods and fires, or public health emergencies, such as the COVID-19 pandemic.

***Exchange rate fluctuations may materially affect our results of operations and financial condition.***

Although we are based in the U.K., our financial statements are denominated in U.S. dollars and many of our business activities are carried out with partners outside the U.S. and U.K. and these transactions may be denominated in another currency. As a result, our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the currencies of other countries, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

**Risks Related to Development, Clinical Testing and Regulatory Approval**

***Clinical drug development and regulatory approval involve a lengthy and expensive process, with uncertain outcomes. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and regulatory approval of our product candidates.***

Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates, including our ensifentrine programs for additional targeted indications and formulations, are prolonged or delayed, or if such clinical trials fail to show the safety and efficacy required by regulatory authorities, we or our collaborators may be unable to obtain required regulatory approvals and be unable to commercialize our product candidates on a timely basis, or at all.

To obtain the requisite regulatory approvals to market and sell our product candidates, we or any collaborator must demonstrate through extensive pre-clinical studies and clinical trials that such product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early-stage clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. Regulators' interpretations of results may differ from our own, and expectations can change over time while a product is in clinical development.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. The FDA may require us to conduct additional pre-clinical studies or clinical trials that may not be successful, or may not be considered successful by regulators.

If we wish to commercialize ensifentrine in territories other than the U.S., the regulatory authorities in such territories may require us to conduct additional pre-clinical studies or clinical trials beyond those we successfully completed to obtain FDA approval of Ohtuvayre, and if we wish to commercialize ensifentrine in other formulations or for other targeted indications, we will also be required to conduct further clinical studies in the U.S. to support potential FDA approvals for such targeted indications and formulations.

We may experience delays in clinical trials of ensifentrine in different formulations, including fixed-dose combinations, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Our clinical trials can be delayed, suspended, or terminated, or the utility of data from these trials may be compromised, for a variety of reasons, including the following:

- inability to generate sufficient preclinical, toxicology, drug product characterizations or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in or failure to obtain regulatory agreement on clinical trial design or implementation, including dose and frequency of administration;
- delays in or failure to obtain regulatory authorization to commence a trial;
- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability of a CRO to meet their contracted obligations regarding subject enrollment, data collection, data monitoring, laboratory sample management, programming and analysis or other activities;
- delays in or failure to obtain institutional review board ("IRB"), or ethics committee approval or positive opinion at each site;
- delays in or failure to recruit suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial or committing gross misconduct or fraud;
- delays to the addition of new clinical trial sites;
- inability to achieve or maintain doubleblinding, when required by the applicable clinical trial protocol;
- unexpected technical issues during manufacture;
- variability in drug product performance and/or stability;
- discoveries that may reduce the commercial viability of the product candidate;
- inability to manufacture sufficient quantities of the applicable product candidates for use in clinical trials;
- the quality or stability of the product candidate falling below acceptable standards for either safety or efficacy;
- third-party actions claiming infringement by the product candidate in clinical trials and obtaining injunctions interfering with our progress;
- business interruptions resulting from geo-political actions, including war and terrorism, such as the ongoing conflicts in Europe and the Middle East, or natural disasters including earthquakes, typhoons, floods and fires;
- trade sanctions imposed by the U.S. or other governments impacting our ability to transfer money to certain countries, such as Russia, to pay clinical trials sites in those countries;
- safety or tolerability concerns causing us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies and guidelines;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- failure of our third-party research contractors to comply with regulatory requirements or to meet their contractual obligations to us in a timely manner, or at all; and
- difficulty in certain countries in identifying the sub-populations that we are trying to evaluate in a particular trial, which may delay enrollment.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory

authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, failure of our clinical trials to demonstrate adequate efficacy and safety, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority.

If we experience delays in the completion of any clinical trial of ensifentrine for any indication, or of any other product candidate, or any clinical trial of ensifentrine or any other product candidate is terminated, the commercial prospects of such product candidates may be harmed, and our ability to generate product revenues, if any, will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenue, if any. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and could impair our ability to commercialize our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of any product candidate.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA, EU rules and regulations and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs (or other ethics committees) at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of the product candidate produced under current good manufacturing practice ("cGMP") and similar foreign requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with GCP requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the EU and the U.S. may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-EU and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application ("CTA"), to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the U.K. will seek to align its regulations with the EU. The U.K. regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into U.K. law, through secondary legislation).

On January 17, 2022, the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA"), launched an eight-week consultation on reframing the U.K. legislation for clinical trials, which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The resulting legislative changes will be closely watched and will determine the extent to which the U.K. clinical trials framework aligns with or diverges from the (EU) CTR. Under the terms of the Protocol on Ireland/Northern Ireland, provisions of the (EU) CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. A decision by the U.K. Government not to closely align its regulations with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the U.K. compared with other countries.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

***Our product and product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during product development or following approval, if any, we may need to abandon our development programs, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.***

Undesirable side effects that may be caused by a product or product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive or less desirable label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in previous trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale clinical trials or, in some cases, after they are made available to patients on a commercial scale following approval. We have completed more than 20 Phase 1, 2 and 3 clinical trials of ensifentrine. In these trials, some patients have experienced mild to moderate adverse reactions, including urinary tract infection, back pain, hypertension, and diarrhea. An increase in psychiatric adverse events were reported with use of ensifentrine, although such events were rare and a causal relationship between ensifentrine and increased rates of psychiatric events could not be established at the time of FDA approval of Ohtuvayre.

Results of our future clinical trials could reveal a high and unacceptable severity and prevalence of adverse side effects. In such an event, our trials could be suspended or terminated and the FDA or other comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Additionally, if we or others identify undesirable or unacceptable side effects following regulatory approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products and require us to take them off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a REMS plan or similar risk management measures to ensure that the benefits of ensifentrine outweigh its risks;
- we may be required to change the way a product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote a product;
- product sales may be adversely impacted;
- we may be subject to litigation or product liability claims; and

- our reputation may suffer.

Any of these events could prevent us or any collaborators from achieving or maintaining market acceptance of any approved products, including Ohtuvayre, or could have significant negative consequences on the commercialization of such products, which in turn could delay or prevent us from generating significant revenue from the sale of such products.

***We may not be successful in our efforts to develop ensifentrine in different formulations, including fixed-dose combinations, and/or for other targeted indications, including NCFBE, CF, asthma or other respiratory diseases***.

Part of our strategy is to continue to develop ensifentrine in indications other than COPD, such as NCFBE, CF and asthma and other formulations including fixed-dose combinations, MDI and DPI. Although our research and development efforts to date have suggested that ensifentrine has the potential to treat NCFBE, CF and asthma, we may not be able to develop successfully ensifentrine to address these or any other diseases or conditions. In addition, the potential use of ensifentrine in other diseases may not be suitable for clinical development, including as a result of difficulties enrolling patients in any clinical studies we plan to initiate or the potential for harmful side effects or other characteristics that might suggest marketing approval and market acceptance are unlikely. We may find that it may not be feasible to develop an acceptable combination of ensifentrine with other products, including LAMAs, or that chemical stability or drug product stability does not support further development. If we do not continue to successfully develop, obtain regulatory approval for, and begin to commercialize ensifentrine for additional indications or formulations, we will face difficulty in obtaining product revenues in future periods, which could significantly harm our financial position.

***We depend on enrollment of patients in our clinical trials. If we are unable to enroll patients in our clinical trials, or enrollment is slower than anticipated, our research and development efforts could be adversely affected.***

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal and other external factors. Patient enrollment depends on many factors, including the size and nature of the patient population, the severity of the disease under investigation, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the ability to obtain and maintain patient consents, the risk that enrolled patients will drop out of a trial, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Higher than expected numbers of patients could also discontinue participation in the clinical trials. Delays in the completion of any clinical trial will increase our costs, slow down our development and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval.

***We may become exposed to costly and damaging liability claims, either when testing product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. The current and future use of product candidates by us and any collaborators in clinical trials, and the commercial sale of Ohtuvayre by us or partners, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling Ohtuvayre. Any claims against us, regardless of their merit, could be difficult and costly to defend and could adversely affect the market for Ohtuvayre or any prospects for commercialization of other product candidates. In addition, regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Ohtuvayre;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend related litigation;
- diversion of management's time and our resources;

- substantial monetary awards to trial participants or patients;
- regulatory investigation, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize or promote any approved products, including Ohtuvayre.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with warnings that identify known potential adverse effects and patients who should not use a product.

Although we maintain product liability insurance for our product candidates and commercial products, [including Ohtuvayre,] it is possible that our liabilities could exceed our insurance coverage. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

***The regulatory approval processes of the FDA, the EMA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for ensifentrine for the maintenance treatment of COPD in adult patients in jurisdictions outside the U.S. or for ensifentrine for additional targeted indications and formulations, our business will be substantially harmed.***

The time required to obtain approval by the FDA, the European Commission and comparable foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for ensifentrine outside of the U.S. and it is possible that ensifentrine or any product candidates we may develop in the future will never obtain the necessary or desired regulatory approvals.

Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidate is safe and effective for its intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidate are promising, such data may not be sufficient to support approval by the applicable regulatory authority. The FDA or foreign regulatory agencies may also require us to conduct additional preclinical studies or clinical trials prior to or post-approval, or it may object to elements of our clinical development program.

Product candidates could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that a product candidate's benefits outweigh its safety risks;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials or may find the data to be unacceptable;
- the data collected from clinical trials may, for various reasons, be insufficient to support the submission or approval of an NDA or supplemental NDA in the United States, a MAA in the EU, or other comparable submission to obtain regulatory approval in other countries;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- FDA or comparable regulatory authorities may identify issues of GCP noncompliance or unacceptable practices at clinical sites or CROs participating in our clinical studies, rendering clinical data insufficient to support approval;

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; and
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our proposed product specifications and performance characteristics.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain the necessary or desired regulatory approvals for our product candidates. The FDA, the EMA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for our products. Even if we believe the data collected from our clinical trials are promising, such data may not be sufficient to support approval by the FDA, the European Commission or any other regulatory authority.

In addition, even if we receive regulatory approvals for our product candidates, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for successful commercialization. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates, if approved at all.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revision may however have a significant impact on the biopharmaceutical industry and our business in the long term.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs, or modifications to cleared or approved drugs, to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

***Even though the FDA has approved Ohtuvayre, we remain subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, Ohtuvayre and any other approved products could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems.***

With respect to any products approved by the FDA or a comparable foreign regulatory, including Ohtuvayre, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record keeping for such product remains subject to extensive and ongoing regulatory requirements. These requirements include, among other things, payment of annual user fees, submissions of safety and other post-marketing information and reports, facility registration and drug listing, as well as continued compliance with cGMP and similar foreign requirements for the manufacture of the product and GCP requirements for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize any

approved products, including Ohtuvayre. In addition, any approval we may obtain could include significant limitations related to use, restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements.

We and our contract manufacturers will also be subject to periodic inspection by the FDA and other regulatory authorities to monitor compliance with these requirements. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

***The FDA and other foreign regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses which may result in significant liability if we are found to have violated such laws.***

If we are found to have improperly promoted off-label uses for our products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, the FDA has approved Ohtuvayre for the maintenance treatment of COPD in adult patients, and we are not permitted to promote Ohtuvayre for any other uses. Physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of Ohtuvayre and any other products for which we may obtain regulatory approval, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

In Europe, off-label use is not per se regulated by the EU pharmaceutical legislation and a difference is made between the strict regulation of medicinal product and the use of medicinal products in medical practice. Off-label use is deferred to national regulation and may vary depending on the EU Member State(s).

***We may never obtain approval or commercialize ensifentrine in other major markets outside of the U.S., which would limit our ability to realize its full market potential.***

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such country or territory regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in all major markets could result in significant delays, difficulties and costs for us and may require additional pre-clinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of ensifentrine in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. While we have received approval in the U.S. for Ohtuvayre for the maintenance treatment of COPD in adult patients, we currently do not have any product candidates approved for sale in any other jurisdiction, whether in the EU or any other international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be compromised.

***Our employees and independent contractors, including principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, the EU and other similar regulatory bodies and the EU, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our pre-clinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

***Interim, "top-line," or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also

remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

**Risks Related to Healthcare Laws and Other Legal Compliance Matters**

***Enacted and future legislation and regulation may increase the difficulty and cost for us to commercialize our products and may affect the prices we may set.***

In the United States, the EU and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, the ACA, was enacted, which substantially changes the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (which, as discussed below, will be replaced by a new manufacturer discount program beginning in 2025);
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected and not generally distributed through the retail channel;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in force as it currently exists.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 has, among other things, led to aggregate reductions of Medicare payments to providers, which, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional action is taken by Congress. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. These laws and any laws enacted in the future may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Most significantly, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap (with resulting prices for the initial ten drugs first effective in 2026); imposes rebates under Medicare Part B and Medicare Part D continue to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning 2024); and replaces the Part D coverage gap discount program originally established under the ACA with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on our company and the pharmaceutical industry cannot yet be fully determined but, is likely to be significant.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for ensifentrine or additional pricing pressures.

Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of health care in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our products, restrict or regulate post-approval activities and affect our ability to commercialize our

products, if approved. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products.

The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

***Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute ensifentrine, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows, or should know, it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- in the EU, interactions between pharmaceutical companies, health care professionals, and health care organizations are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the EU. Relationships with healthcare professionals and associations are subject to stringent anti-gift statutes and anti-bribery laws, the scope of which differs across the EU. In addition, national "Sunshine Acts" may require pharmaceutical companies to report/publish transfers of value provided to health care professionals and associations on a regular (e.g. annual) basis. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we

cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, or collectively HIPAA, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA"), requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may be required. Similar laws have passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the U.S.. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We are also subject to diverse laws and regulations relating to data privacy and security in the EU and the EEA, including the General Data Protection Regulation ("GDPR"). The GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. The GDPR imposes strict obligations on the ability to process health-related and other personal data of individuals within the EEA, including in relation to use, collection, analysis, and transfer (including cross-border transfer) of such personal data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S., and the efficacy and longevity of current transfer mechanisms between the EEA and the U.S. remains uncertain. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses—a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism—alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-U.S. Data Privacy Framework ("DPF"), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be

challenged and international transfers to the U.S. and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

Relatedly, since the beginning of 2021, following the U.K.'s withdrawal from the EEA and the European Union, and the expiry of the transition period, companies have had to comply with both the GDPR and the GDPR as incorporated into U.K. national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. On October 12, 2023, the U.K. Extension to the DPF came into effect (as approved by the U.K. Government), as a data transfer mechanism from the U.K. to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Compliance with applicable data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and third-party providers to comply with applicable data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

***The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.***

There has been increasing public focus by investors, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, we may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

***We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.***

Our sub-contracted operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could incur significant costs associated with civil or criminal fines, penalties or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed.

***We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses.***

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which any of our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We also are subject to other laws and regulations governing any international operations, including regulations administered by the governments of the U.K. and the U.S., and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, or, collectively, the Trade Control laws. In particular, we engaged a number of clinical trial sites in Russia in connection with our Phase 3 ENHANCE clinical program and, with the ongoing conflict between Russia and Ukraine, and resulting sanctions imposed by the U.S. and other governments, there is an increased risk that our ability to pay clinical sites or conduct clinical trials in Russia, may be impacted.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures and legal expenses. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by U.K., U.S. or other authorities, even if it is ultimately determined that we did not violate such laws, could be costly and time consuming, require significant personnel resources and harm our reputation.

We will seek to build and continuously improve our systems of internal controls and to remedy any weaknesses identified. There can be no assurance, however, that the policies and procedures will be followed at all times or effectively detect and prevent violations of the applicable laws by one or more of our employees, consultants, agents or collaborators and, as a result, we could be subject to fines, penalties or prosecution.

**Risks Related to Commercialization**

***We operate in a highly competitive and rapidly changing industry, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.***

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new products on a cost-effective basis and to market them successfully. We will face intense competition for our approved products from a variety of businesses, including large, fully integrated pharmaceutical companies, biopharmaceutical companies and specialty pharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the U.S. and other jurisdictions. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with our products.

Given the number of products already on the market to treat COPD, asthma, CF and NCFBE, we expect to face intense competition for our products, including for Ohtuvayre, and for ensifentrine, if approved for these additional indications. Companies including GlaxoSmithKline, AstraZeneca, Novartis, Vertex, Viatris, Theravance, Gilead and Genentech currently have treatments on the market for COPD, CF and asthma, and we anticipate that new companies will enter these markets in the future. While no treatments for NCFBE currently have marketing approval in the U.S. or EU, there are products in late-stage clinical development that could be approved in the future. Our products will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of, and rapid technological changes in, the biopharmaceutical and pharmaceutical industries could render our products obsolete, less competitive or uneconomical. Our competitors may, among other things:

- have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical and human resources than we do, and future mergers and acquisitions in the biopharmaceutical and pharmaceutical industries may result in even more resources being concentrated in our competitors;

- develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- establish superior proprietary positions covering our products and technologies;
- implement more effective approaches to sales, marketing and distribution; or
- form more advantageous strategic alliances.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, any collaborators we may have may decide to market and sell products that compete with our products. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than our products. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing or strengthening their market position before we are able to enter the market.

***The successful commercialization of Ohtuvayre will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies for it. Failure to obtain or maintain adequate coverage and reimbursement for Ohtuvayre could limit our ability to market it and decrease our ability to generate revenue.***

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as Ohtuvayre. Our ability to achieve and maintain acceptable levels of coverage and reimbursement by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize ensifentrine. Assuming we obtain coverage for Ohtuvayre by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Moreover, for drugs and biologics administered under the supervision of a physician, obtaining appropriate documentation for usage may be difficult because of the higher prices often associated with such products. We cannot be sure that coverage and reimbursement in the U.S., the EU or elsewhere will be available for Ohtuvayre or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider Ohtuvayre as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with Ohtuvayre, pricing of existing drugs may limit the amount we will be able to charge for Ohtuvayre. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in ensifentrine. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize Ohtuvayre, and may not be able to obtain a satisfactory financial return on Ohtuvayre.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for Ohtuvayre.

Obtaining and maintaining reimbursement status is time consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of Ohtuvayre

to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. Specifically, we believe that Ohtuvayre will be reimbursed under a medical benefit through either Medicare Part B or Medicare Advantage programs, and changes within how products are reimbursed under these programs could occur and those changes may affect the overall coverage of Ohtuvayre in the future.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of approved products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for ensifentrine. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of Ohtuvayre due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

In addition, even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

Medicaid is a joint federal and state program administered by the states for low income and disabled beneficiaries. We participate in and have certain price reporting obligations under the Medicaid Drug Rebate Program, or the MDRP, as a condition of having covered outpatient drugs payable under Medicaid and, if applicable, under Medicare Part B. The MDRP requires us to pay a rebate to state Medicaid programs every quarter for each unit of our covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The rebate is based on pricing data that we must report on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the MDRP and other governmental healthcare programs. These data include the average manufacturer price (AMP) for each drug and, in the case of innovator products, the best price, which in general represents the lowest price available from the manufacturer to certain entities in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. The Medicaid rebate consists of two components, the basic rebate and the additional rebate, which is triggered if the AMP for a drug increases faster than inflation. If we become aware that our MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP. In the event that CMS terminates our rebate agreement pursuant to which we participate in the MDRP, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Our failure to comply with our MDRP price reporting and rebate payment obligations could negatively impact our financial results.

The ACA made significant changes to the MDRP, as described under the risk factor “Enacted and future legislation and regulation may increase the difficulty and cost for us to commercialize our products and may affect the prices we may set,” above. In addition, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers’ MDRP rebate liability, effective January 1, 2024. Previously, under law enacted as part of the ACA, drug manufacturers’ MDRP rebate liability was capped at 100% of the AMP for a covered outpatient drug. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the MDRP. Additional legislation or the issuance of regulations relating to the MDRP could have a material adverse effect on our results of operations.

The recently-enacted IRA imposes rebates under Medicare Part B and Medicare Part D that are triggered by price increases that outpace inflation (first due in 2023), as described under the risk factor "Enacted and future legislation and regulation may increase the difficulty and cost for us to commercialize our products and may affect the prices we may set," above. The Medicare Part D rebate will be calculated on the basis of the AMP figures we report pursuant to the MDRP.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and, if applicable, Medicare Part B. We participate in the 340B program, which is administered by the Health Resources and Services Administration, or HRSA, and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes those prices to 340B covered entities. In addition, HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. Our failure to comply 340B program requirements could negatively impact our financial results. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA or other legislation or regulation could affect our 340B ceiling price calculations and also negatively impact our financial results.

In order for Ohtuvayre or any product candidates, if approved, to be paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we are required to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we must calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS pricing and contracting obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our innovator products on a Tricare Agreement in order for them to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements of pharmaceutical manufacturers under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. CMS, the Department of Health

& Human Services Office of Inspector General, and other governmental agencies have pursued manufacturers that were alleged to have failed to report these data to the government in a timely or accurate manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that any submissions we are required to make under the MDRP, the 340B program, the VA/FSS program, the Tricare Retail Pharmacy Program, and other governmental drug pricing programs will not be found to be incomplete or incorrect.

***If our products, including Ohtuvayre, do not gain market acceptance or if we fail to accurately forecast demand or manage our inventories, our business will suffer because we might not be able to fund future operations.***

Patients or the medical community may not accept or use Ohtuvayre in the U.S. If Ohtuvayre does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of Ohtuvayre will depend on a variety of factors, including:

- the timing of market introduction;
- the price of our product relative to other products for the same or similar treatment;
- the number and clinical profile of competing products;
- the clinical indication for which Ohtuvayre is approved;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience, frequency, and ease of administration;
- cost effectiveness;
- marketing, sales, and distribution support;
- availability of adequate coverage, reimbursement and adequate payment from health maintenance organizations and other insurers, both public and private; and
- other potential advantages over alternative treatment methods.

If our products do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new product candidates and expanding our sales and marketing efforts for our approved products, which would cause our business to suffer.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for Ohtuvayre and manage our inventory. To ensure adequate inventory supply, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for Ohtuvayre. Our ability to accurately forecast demand for Ohtuvayre could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for Ohtuvayre or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions.

We seek to maintain sufficient levels of inventory to protect ourselves from supply interruptions. As a result, we are subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

***Our commercial capabilities and infrastructure, including sales, marketing, operations, distribution, and reimbursement infrastructure, may not be adequate to successfully commercialize Ohtuvayre.***

We are continuing to develop sales, marketing, operations, distribution and reimbursement capabilities and infrastructure after receiving approval of Ohtuvayre in June 2024, and we have not previously marketed, sold or distributed pharmaceutical products prior to the approval of Ohtuvayre. The establishment of commercial capabilities and infrastructure, including sales, marketing, operations, distribution, and reimbursement with technical expertise and supporting distribution capabilities to commercialize Ohtuvayre, is expensive and time consuming. Some or all of these costs were incurred in preparation for approval and will continue as we commercialize Ohtuvayre for the maintenance treatment of COPD in adult patients. In addition, our sales force may not be sufficient in size or have adequate expertise in the medical markets that we intend to target, and we may have difficulty retaining our sales employees or attracting new employees. Any failure of our internal sales, marketing

and distribution capabilities on our own or through collaborations would adversely impact the commercialization of Ohtuvayre.

We are contracting third parties to perform certain services to support our sales, marketing, warehousing, distribution and reimbursement activities. To the extent that any of these third parties fail to perform their services in compliance with their obligations to us or other parties, we may not be successful in commercializing Ohtuvayre and our future product revenues may be adversely impacted.

To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold Ohtuvayre. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize Ohtuvayre. If we are not successful in commercializing Ohtuvayre, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***If we are unable to establish effective sales and marketing capabilities to market and sell our approved product, Ohtuvayre, we may be unable to generate adequate revenue.***

We have no previous experience in marketing and selling drug products. We are continuing to establish our infrastructure for the sales, marketing and distribution of Ohtuvayre, and the cost of establishing and maintaining such an organization may exceed the benefits of doing so.

We have established an initial in-house sales force to promote Ohtuvayre to appropriate healthcare providers including those that may be associated with hospital networks, Integrated delivery networks and third-party payers in the United States. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team.

We compete with other companies to recruit, hire, train and retain sales and marketing personnel. We cannot be sure that we will be able to hire a sufficient number of qualified sales representatives or that they will be effective at promoting Ohtuvayre. In addition, we will need to commit significant additional management and other resources to build our sales organization to the desired size, and we may not be successful in a cost-effective manner.

Factors that may inhibit our efforts to establish our sales and marketing capabilities include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about Ohtuvayre or our product candidates, once approved;
- higher fixed costs as compared to companies who market products using independent third parties, such as costs associated with employee benefits, training, and managing sales personnel; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, our business, results of operations, financial condition and prospects will be materially adversely impacted.

Beyond Ohtuvayre, we may leverage the sales and marketing capabilities that we establish for Ohtuvayre to commercialize additional product candidates or market Ohtuvayre for other indications, if approved by the FDA, in the United States. If we are unable to do so for any reason, we would need to expend additional resources to establish commercialization capabilities for those product candidates or Ohtuvayre for other indications, if approved.

**Risks Related to Our Dependence on Third Parties**

***We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approvals for or commercialize our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and CROs, to conduct our pre-clinical studies and clinical trials and to monitor and manage data for our ongoing pre-

clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we fail to exercise adequate oversight over any of our CROs or if we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot provide assurance that upon a regulatory inspection of us or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable cGMP and similar foreign regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our existing and future CROs have or may have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding CROs involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could materially impact our ability to meet our desired clinical development timelines. In addition, if our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approvals for, or commercialize, our product candidates. As a result, our results of operations and the commercial prospects would be harmed, our costs could increase and our ability to generate revenues could be delayed.

***The collaboration and license agreement with Nuance Pharma is important to our business. If Nuance Pharma is unable to develop and commercialize products containing ensifentrine in Greater China, if we or Nuance Pharma fail to adequately perform under the Nuance Agreement, or if we or Nuance Pharma terminate the Nuance Agreement, our business would be adversely affected.***

We entered into a collaboration and license agreement with Nuance Pharma effective June 9, 2021 (the "Nuance Agreement") under which we granted Nuance Pharma the exclusive rights to develop and commercialize products containing ensifentrine (the "Nuance Licensed Products") in Greater China (China, Taiwan, Hong Kong and Macau).

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

Termination of the Nuance Agreement could cause significant setbacks in our ability to develop and commercialize the Nuance Licensed Products in Greater China. Any suitable alternative collaboration or license agreement would take considerable time to negotiate and could also be on less favorable terms to us. In addition, under the Nuance Agreement, Nuance Pharma agreed to assume all costs related to clinical development and commercialization of the Nuance Licensed Products in Greater China. If the Nuance Agreement were to be terminated, and whether or not we identify another suitable collaborator, we may need to seek additional financing to support the clinical development

and commercialization of the Nuance Licensed Products in Greater China, which could have a material adverse effect on our business.

Under the Nuance Agreement, we are dependent upon Nuance Pharma to successfully develop and commercialize Nuance Licensed Products. Although we have formed a joint steering committee with Nuance Pharma to oversee and coordinate the overall conduct of the clinical development and commercialization of the Nuance Licensed Products in Greater China, we do not control all aspects of Nuance Pharma's development and commercialization or the resources it allocates to the development of the Nuance Licensed Products identified under the Nuance Agreement. Our interests and Nuance Pharma's interests may differ or conflict from time to time, or we may disagree with Nuance Pharma's level of effort or resource allocation. Nuance Pharma may internally prioritize programs under development within the collaboration differently than we would, or it may not allocate sufficient resources to effectively or optimally develop or commercialize the Nuance Licensed Products. If these events were to occur, our ability to receive revenue from the commercialization of the Nuance Licensed Products would be reduced, and our business would be adversely affected. In addition, under the Nuance Agreement, we have an obligation to supply Nuance Pharma with the ensifentrine drug product for their development and commercialization activities in Greater China and if our supply price is too high, the price at which Nuance Pharma sells the drug product in Greater China may not be competitive, which could have a material adverse effect on Nuance Pharma's ability to successfully commercialize Nuance Licensed Products and the returns that we generate under the Nuance Agreement. Furthermore, the safety and/or efficacy data from Nuance Pharma's clinical development activities could for various reasons differ from our data and could potentially impact our clinical development and commercialization activities, including our ability to obtain regulatory approval of ensifentrine in other countries.

***If we fail to enter into new strategic relationships for ensifentrine, our business, research and development and commercialization prospects could be adversely affected.***

Our development programs for our product candidates and, if approved, their commercialization will require substantial additional cash to fund expenses. Therefore, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for their development and commercialization. For example, we may seek a collaborator for development of our DPI or pMDI formulation of ensifentrine for the maintenance treatment of COPD and potentially asthma and other respiratory diseases.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of our product candidates, reduce or delay development programs, delay commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our products or product candidates to market and generate product revenue. If we do enter into collaboration agreements, we could be subject to the following risks, among others, any of which could adversely affect our ability to develop and commercialize our products and product candidates:

- we may not be able to control the amount and timing of resources that the collaborator devotes to the development of the product candidate;
- the collaborator may experience financial difficulties;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- safety and/or efficacy data from a collaborator's clinical development activities may conflict with our data and could potentially impact our global clinical development and commercialization activities;
- a collaborator may unlawfully use or disclose confidential information and materials in breach of confidentiality obligations to us;
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement;

- we or a collaborator could fail to adequately perform our obligations under the agreement and/or the agreement could fall into dispute; or
- we may be involved in lawsuits to protect or enforce patents covering our products or product candidates, or relating to the terms of our collaborations, which could be expensive, time consuming and unsuccessful.

***We currently rely on third-party manufacturers and suppliers for production of the active pharmaceutical ingredient ensifentrine and its derived formulated products. Our dependence on these third parties may impair the advancement of our research and development programs and the development of ensifentrine. Moreover, we rely on third parties to produce commercial supplies of Ohtuvayre, and commercialization could be stopped, delayed or made less profitable if those third parties fail to maintain the necessary approvals from the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of product in a timely manner or fail to do so at acceptable quality levels or prices or fail to otherwise complete their duties in compliance with their obligations to us or other parties.***

We do not own facilities for manufacturing ensifentrine and its derived formulated products. Instead, we rely on and expect to continue to rely on third-party contract manufacturing organizations ("CMOs"), for the supply of cGMP- or GMP-grade clinical trial materials of ensifentrine and its derived formulated products, including commercial quantities of Ohtuvayre. While we may contract with other CMOs in the future, we currently have one CMO for the manufacture of ensifentrine drug substance and one CMO for each formulation of ensifentrine. The facilities used to manufacture ensifentrine and its derived formulated products must be approved for the manufacture of ensifentrine by the FDA, and by comparable foreign regulatory authorities for approvals outside the U.S.. While we provide sponsor oversight of manufacturing activities, we do not and will not directly control the manufacturing process of, and are or will be essentially dependent on, our CMOs for compliance with cGMP and similar foreign requirements for the manufacture of ensifentrine and its derived formulated products. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA or a comparable foreign regulatory authority, it will not be able to secure or maintain regulatory approval for the manufacture of ensifentrine and its derived formulated products in its manufacturing facilities. In addition, we have little direct control over the ability of a CMO to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of ensifentrine and its derived formulated products or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, and obtain or maintain regulatory approval for or market ensifentrine and its derived formulated products. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacture of ensifentrine and its derived formulated products or that obtained approvals could be revoked. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our suppliers, CMOs and other third parties for the manufacture, storage and distribution of ensifentrine and its derived formulated products means that we are subject to the risk that ensifentrine and its derived formulated products may have manufacturing defects that we have limited ability to prevent, detect or control.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers the materials necessary to produce ensifentrine and its derived formulated products and the inhalation and nebulization devices to deliver ensifentrine. We do not and will not have any direct control over the process or timing of the acquisition and delivery of these supplies by any CMO or its third-party suppliers, or the quality or quantity of such supplies. These supplies could be interrupted from time to time and, if interrupted, we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost or quality, or at all. There are a limited number of suppliers for the raw materials that we may use to manufacture ensifentrine and for the drug delivery devices (e.g. nebulizers) that we use for clinical trials with ensifentrine, and we will need to assess alternate suppliers to prevent a possible disruption to our clinical trials and commercial sales. Although we generally do not begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of ensifentrine to complete the clinical trial, any significant delay in the supply of ensifentrine drug products, or the raw material components needed to produce, or devices needed to deliver, ensifentrine, for an ongoing clinical trial due to our CMOs or their third-party suppliers could considerably delay completion of our clinical trials, product testing and potential regulatory approval of ensifentrine. If our CMOs, their third-party supplies, or we are unable to purchase these supplies, the commercial launch of Ohtuvayre would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of Ohtuvayre. In addition, growth in the costs and

expenses of these supplies may impair our ability to cost-effectively manufacture ensifentrine. Additionally, CMOs are experiencing labor constraints which could impact their ability to manufacture and deliver ensifentrine.

We rely and will continue to rely on CMOs and third-party suppliers to comply with and respect the proprietary rights of others in conducting their contractual obligations for us. If a CMO or third-party suppliers fails to acquire the proper licenses or otherwise infringes third-party proprietary rights in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers, or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for, or market ensifentrine and any of its derived formulated products.

**Risks Related to Intellectual Property**

***We rely on patents and other intellectual property rights to protect our products and product candidates, the enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.***

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our products and product candidates, or on in-licensing such rights. The registrations of the assignment of each of these patents and patent applications with the relevant authorities in certain jurisdictions in which the patent and patent applications are registered have been granted, but there is no assurance that any additional registrations will be effected in a timely manner or at all. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could adversely affect our ability to develop and market Ohtuvayre or our product candidates.

The patent prosecution process is expensive and time-consuming, and we or our licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, in some circumstances we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot provide assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover ensifentrine, third parties may initiate an opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to ensifentrine. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, the date on which the U.S. patent filing system changed from a first-to-invent to a first-to-file standard, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop, manufacture and market our products and our product candidates, if approved.***

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of our products in any jurisdiction. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and, if approved, our product candidates. We may incorrectly determine that one of our products or product candidates is not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or, if approved, our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and, if approved, our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing our products or, if approved, our product candidates. We might, if possible, also be forced to redesign our products or product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

***We may be involved in lawsuits to protect or enforce patents covering our products or product candidates, which could be expensive, time consuming and unsuccessful, and issued patents could be found invalid or unenforceable if challenged in court.***

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. As enforcement of intellectual property rights is difficult, unpredictable, time consuming and expensive, we may fail in enforcing our rights — in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, however, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or product candidates, and then compete directly with us, without payment to us. If we in-license intellectual property rights, our agreements may give our licensors the first right to control claims of third-party infringement, or to defend validity challenges. Therefore, these patents and patent applications may not be enforced or defended in a manner consistent with the best interests of our business.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the U.S. or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product

candidates. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts, industry commentators or investors perceive these results to be negative, it could have an adverse effect on the price of our ADSs.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.***

Our commercial success depends, in part, upon our ability, and the ability of our future collaborators, to develop, manufacture, market and sell our products and, if approved, our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biopharmaceutical and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing ensifentrine. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products may be subject to claims of infringement of the intellectual property rights of third parties.

We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to Ohtuvayre and any existing or future product candidates, including interference or derivation proceedings, post grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Similarly, we or our licensors or collaborators may initiate such proceedings or litigation against third parties, for example, to challenge the validity or scope of intellectual property rights controlled by third parties. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. Such licenses may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us.

If we fail in any such dispute, we may be forced to pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights. We or our licensees may be temporarily or permanently prohibited from commercializing Ohtuvayre or from selling, incorporating, manufacturing or using our products or product candidates in the U.S. and/or other jurisdictions that use the subject intellectual property. We might, if possible, also be forced to redesign our products or product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign could be technically infeasible. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize Ohtuvayre or any existing or future product candidates.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, such perceptions could have a substantial adverse effect on the price of our ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

***If we fail to comply with our obligations under our existing and any future intellectual property licenses, the 2024 Loan Agreement, the RIPSA or any other future loan agreements with third parties, we could lose rights that are important to our business.***

We are party to a license agreement with Ligand, under which we in-license certain intellectual property and were assigned certain patents and patent applications related to our business. We may enter into additional license agreements in the future. We expect that any future license agreements would impose various diligence, milestone payment, royalty, insurance and other obligations on us. We also entered into the 2024 Loan Agreement with the 2024 Lenders. The 2024 Term Loans is secured by a first-priority lien on substantially all of the assets of Verona Pharma, Inc. and the Company, including intellectual property. We also entered into the RIPSA with the Purchasers. The RIPSA is secured by a second-priority lien on certain of our intellectual property. For further description of the 2024 Term Loans and RIPSA, see Note 6 - Debt to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Any uncured, material breach under any of these agreements could result in our loss of rights to practice the patent rights and other intellectual property under these agreements, and could compromise our development and commercialization efforts for our products. Moreover, our future licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

***We may not be successful in maintaining the necessary rights to our products or product candidates or obtaining other intellectual property rights important to our business through acquisitions and in-licenses.***

We currently own and have in-licensed rights to intellectual property, including patents, patent applications and know-how, and our success will likely depend on maintaining these rights. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. In addition, our products or product candidates may require specific formulations to work effectively and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights that we identify as necessary for our products or product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies also are pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to license or acquire third-party intellectual property rights on a timely basis, on terms that would allow us to make an appropriate return on our investment, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for a development program on acceptable terms, we may have to abandon that development program.

***We will need to obtain FDA approval of any newly proposed product names, and any failure or delay associated with such approval may adversely affect our business.***

Any proprietary name we intend to use for our future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA reviews proposed product names, considering both the potential for the name to lead to medical errors due to confusion with other product names and whether the proposed name is overly fanciful, misleadingly implies unique effectiveness or composition, or contributes to overstatement of product efficacy, minimization of risk, broadening of product indications or unsubstantiated superiority.

If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we could lose the benefit of any existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.***

We have registered trademarks in some territories and made applications to register the trademarks in other territories for potential trade names for our business and products and product candidates. We may not be able to obtain trademark protection for our trade names in territories that we consider of significant importance to us. If we register trademarks, our trademark applications may be rejected during trademark registration proceedings. Although we will be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential collaborators or customers in our markets of interest. Over the long-term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

***If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering Ohtuvayre and any of our product candidates, our ability to compete effectively could be impaired.***

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The issued patents covering the composition of matter for Ohtuvayre expired in 2020, and our other issued patents will expire in 2031 to 2041, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2031 to 2044. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering Ohtuvayre are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

One of our U.S. patents for Ohtuvayre may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable

deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

Generic drug manufacturers can also challenge the patents of a brand-name drug under the Hatch-Waxman Act. When a generic drug manufacturer files an Abbreviated New Drug Application (ANDA) with the FDA to seek approval for a generic version of a drug that is already on the market, they must make certain certifications regarding the patents listed for the reference listed drug in the Orange Book. The Orange Book lists patents that innovator drug companies assert cover their drug products or use of those products and a Paragraph IV certification is a legal challenge to the validity or enforceability of the patent(s) listed in the Orange Book. If the generic applicant makes a Paragraph IV certification, they must also notify the patent holder and the NDA (New Drug Application) holder that they have filed an ANDA with a Paragraph IV certification, providing detailed reasons why the patent is not valid or not infringed. The filing of a Paragraph IV certification can trigger a statutory stay of approval of the ANDA for 30 months while the parties engage in patent litigation, unless the litigation is resolved in favor of the generic applicant sooner or the court orders otherwise. This process can be a critical aspect of the generic drug approval pathway and may impact the timing of a generic drug's entry into the market.

***We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain jurisdictions, which may diminish the value of our intellectual property rights in those jurisdictions.***

We generally file our first patent application, or priority filing, at the U.K. Intellectual Property Office. International applications under the Patent Cooperation Treaty, or PCT, are usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe a product candidate may be marketed or manufactured. We have so far not filed for patent protection for our products in all national and regional jurisdictions where such protection may be available. Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S.. In addition, we may decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

Competitors may use our or our licensors' or collaborators' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors or collaborators have patent protection, but enforcement is not as strong as that in the U.S.. These products may compete with our product candidates, and our and our licensors' or collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S. and the EU, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected

significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- The patents of third parties may impair our ability to develop or commercialize our products or product candidates;
- We or our licensors or any future strategic collaborators might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- We or our licensors or any future collaborators might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- It is possible that our pending patent applications will not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- Third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license; and
- We may not develop additional technologies that are patentable.

***Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products or any existing or future product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, which was passed on September 16, 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO, after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard

in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaboration partners' patent applications and the enforcement or defense of our or our licensors' or collaboration partners' issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Finally, a Unitary Patent and Unified Patent Court (UPC) system were implemented in Europe on June 1, 2023. This new regime may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.***

We consider proprietary trade secrets and confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and confidential know-how are difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. However, current or former employees, consultants, contractors and advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Failure to obtain or maintain trade secrets and confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

***We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees, including our senior management, were previously employed at universities or at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaboration partners fail to maintain the patents and patent applications covering our products or product candidates, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize Ohtuvayre or any existing or future product candidate.

**Risks Related to Information Technology**

***Our information technology systems, and those of our manufacturers, suppliers and other third parties that we use to perform services for us or otherwise collaborate with, may fail or suffer security breaches, which could distract our operations and cause delays in our research and development and commercialization activities, and may adversely affect our business, operations and financial performance.***

In the ordinary course of our business, we and our manufacturers, suppliers and third parties that we use to perform services for us or otherwise collaborate with, collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information and personally identifiable information (collectively, "Confidential Information") of our clinical trial subjects and employees, in our and third-party data centers and on our and third-party networks. The secure processing, maintenance and transmission of Confidential Information is critical to our operations. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, and that of our manufacturers, suppliers and other third parties that we use to perform services for us or otherwise collaborate with, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of these information technology and other internal infrastructure systems could cause interruptions in our collaborations and delays in our research and development and commercialization activities.

Further, our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to damage, attack or interruption from computer viruses, malware (e.g ransomware), misconfigurations, "bugs" or other vulnerabilities, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, malicious code, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology

systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of a continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage or disrupt, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our and our manufacturers', suppliers' and other critical third parties' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

Despite security measures that we and our critical third parties (e.g., collaborators) implement, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to human error, technical vulnerabilities, malfeasance or other disruptions. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. Although to our knowledge we have not experienced any significant security breach to date, any such breach could compromise our information technology systems and the Confidential Information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal data, regulatory penalties, disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials and commercialize our product candidates, which could adversely affect our reputation and delay clinical development and commercialization of our product candidates. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. Any losses, costs or liabilities may not be covered by, or may exceed the coverage limits of, any or all applicable insurance policies.

**Risks Related to Employee Matters and Managing Growth**

***Our future growth and ability to compete depends on our ability to retain our key personnel and recruit additional qualified personnel.***

Our success depends upon the contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with ensifentrine and related technologies. Our key management individuals include our chief executive officer, David Zaccardelli, our chief financial officer, Mark Hahn, our general counsel, Andrew Fisher, our chief medical officer, Kathleen Rickard, our senior vice president, regulatory affairs, Caroline Diaz, our chief commercial officer, Christopher Martin, and our chief development officer, Tara Rheault. The loss of key personnel could impact our commercialization efforts and research and development activities. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to achieve our commercialization goals for Ohtuvayre and our product candidate development objectives, raise additional capital and implement our business strategy.

***We are continuing to expand our development, regulatory, commercial, sales, marketing, reimbursement and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We have experienced significant growth in the number of our employees and the scope of our operations, particularly in the areas of commercial operations and sales, marketing, reimbursement and distribution. To manage this growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The

expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

**Risks Related to Our ADSs**

***Certain of our shareholders, members of our board of directors, and senior management who own our ordinary shares (including ordinary shares represented by ADSs) may be able to exercise significant control over us.***

Depending on the level of attendance at our general meetings of shareholders, these shareholders either alone or voting together as a group may be in a position to determine or significantly influence the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the share capital present and voting at our general meetings of shareholders may control any shareholder resolution requiring a simple majority, including the appointment of board members, certain decisions relating to our capital structure, and the approval of certain significant corporate transactions. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our ADSs and ordinary shares.

***Because we do not anticipate paying any cash dividends on our ADSs or ordinary shares in the foreseeable future, capital appreciation, if any, will be our ADS holders' and shareholders' sole source of gains and they may never receive a return on their investment.***

Under current English law, a company's accumulated realized profits must exceed its accumulated realized losses (on a non-consolidated basis) before dividends can be paid. Therefore, we must have distributable profits before issuing a dividend. We have not paid dividends in the past on our ordinary shares. We intend to retain earnings, if any, for use in our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, on our ADSs or ordinary shares will be our ADS holders' and shareholders' sole source of gain for the foreseeable future, and they will suffer a loss on their investment if they are unable to sell their ADSs or ordinary shares at or above the price at which they were purchased. Investors seeking cash dividends should not purchase our ADSs or ordinary shares.

***Holders of our ADSs may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise their right to vote.***

Holders of our ADSs are not able to exercise voting rights attaching to the ordinary shares evidenced by our ADSs on an individual basis. Holders of our ADSs have appointed a depositary as their representative to exercise the voting rights attaching to the ordinary shares represented by their ADSs. Holders of our ADSs may not receive voting materials in time to instruct the depositary to vote, and it is possible that they, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise voting rights and may lack recourse if their ADSs are not voted as requested. In addition, holders of our ADSs will not be able to call a shareholders' meeting.

***Holders of our ADSs may not receive distributions on our ordinary shares represented by our ADSs or any value for them if it is illegal or impractical to make them available to them.***

The depositary for our ADSs has agreed to pay to holders of our ADSs the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. Holders of our ADSs will receive these distributions in proportion to the number of our ordinary shares their ADSs represent. However, in accordance with the limitations set forth in the deposit agreement entered into with the depositary, it may be unlawful or impractical to make a distribution available to holders of our ADSs. We have no obligation to take any other action to permit the distribution of our ADSs, ordinary shares, rights or anything else to holders of our ADSs. This means that holders of our ADSs may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make the distributions available to them. These restrictions may have a material adverse effect on the value of our ADSs.

***Holders of our ADSs may be subject to limitations on transfer of their ADSs.***

ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement

of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement. These limitations on transfer may have a material adverse effect on the value of our ADSs.

***The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.***

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act 2006, and by our Articles of Association. These rights differ in certain material respects from the rights of shareholders in typical U.S. corporations. As a result, investors in our ordinary shares or ADSs may not have the same protections or rights as they would if they had invested in a U.S. corporation. This may make our ADSs less attractive to such investors, which could harm the value of our ADSs.

***Claims of U.S. civil liabilities may not be enforceable against us.***

We are incorporated under English law. Substantially all of our assets are located outside the U.S.. The majority of our senior management and board of directors reside outside the U.S.. As a result, it may not be possible for investors to effect service of process within the U.S. upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

The U.S. and the U.K. do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the U.S., whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the U.K.. In addition, uncertainty exists as to whether U.K. courts would entertain original actions brought in the U.K. against us or our directors or senior management predicated upon the securities laws of the U.S. or any state in the U.S.. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of the U.K. as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met. Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty, is an issue for the court making such decision. If an English court gives judgment for the sum payable under a U.S. judgment, the English judgment will be enforceable by methods generally available for this purpose. These methods generally permit the English court discretion to prescribe the manner of enforcement.

As a result, U.S. investors may not be able to enforce against us or our senior management, board of directors or certain experts named herein who are residents of the U.K. or countries other than the U.S. any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ADSs.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. As we continue to transition to a commercial company following the FDA's approval of Ohtuvayre, our internal controls over financial reporting may become more complex, which could increase the probability of deficiencies in our internal controls in the future. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ADSs.

**Risks Related to Taxation**

***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.***

New income, sales use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows.

We carry out research and development activities including, but not limited to, developing ensifentrine for various indications and delivery methods, and as a result we currently benefit 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 Relief, which currently provides relief against U.K. Corporation Tax.

Broadly, SME R&D Relief comprises two elements, (a) allowing qualifying SMEs to deduct a total of 186% of their qualifying expenditure from their yearly profit for U.K. Corporation Tax purposes (the deduction is given by allowing an additional 86% deduction plus the usual 100% deduction), or the SME R&D Additional Deduction and, (b) where there are not sufficient profits for U.K. Corporation Tax purposes to fully utilize the SME R&D Additional Deduction, the excess ("surrenderable losses") can be carried forward to offset against future taxable profits, or a tax credit currently equal to 10% of such surrenderable loss can be claimed in cash, or the SME R&D Tax Credit.

Based on criteria established by HMRC a portion of expenditure incurred in relation to our research and development activities including, but not limited to, operating clinical trials, manufacturing, consultant and salary and related costs, is eligible for the SME R&D Additional Deduction. Our consequential surrenderable losses are currently eligible for the SME R&D Tax Credit, in accordance with HMRC criteria.

In the financial statements for the years ended December 31, 2023 and December 31, 2022, we recorded SME R&D Tax Credits of $2.3 million and $8.6 million, respectively. We received the credit relating to the year ended December 31, 2022 in June 2024. Based on the HMRC criteria, we expect to receive the credit relating to the year ended December 31, 2023 in the year ending December 31, 2024.

Changes to the U.K.'s SME R&D Relief regime may adversely affect our financial condition. At the 2023 Autumn Statement, the U.K. Government confirmed that it would introduce a single R&D relief regime which merges the current "RDEC" and SME R&D Relief scheme. The proposed credit rate under the draft legislation is 20% of qualifying expenditure, with the credit itself subject to U.K. corporation tax. The credit will therefore be reduced by the applicable rate of U.K. corporation tax (the main rate of which is currently 25%), although the notional tax rate that applies to loss-making companies will be set at the lower rate of 19% for the purposes of the new R&D relief regime. Therefore, under the proposed regime and current rates of U.K. corporation tax, profitable businesses subject to the main rate of U.K. corporation tax will effectively receive a credit of 15% of qualifying expenditure whilst loss-making businesses will receive a credit of 16.2%. The proposed legislation also contains restrictions on R&D relief which can be claimed where a company contracts R&D activity to a third party or makes payments for externally provided workers so that, broadly, a taxpayer will only be able to claim relief where the work is performed in the U.K. It is proposed that the only expenditure allowable outside the U.K. would be for activities which are necessary due to geographical, environmental or social conditions not present or replicable in the U.K. The proposed legislation also contains new rules relating to subcontracting of R&D activities to a third party.

In addition, it is proposed that for accounting periods beginning on or after 1 April 2024, the R&D intensive loss-making SME scheme threshold (broadly, the proportion of qualifying R&D expenditure compared to total expenditure) will be 30%. Therefore, loss-making SMEs with qualifying R&D expenditure of 30% or more of its total expenditure may claim an enhanced deduction of 86% and a repayable credit of 14.5%.

It is proposed that the new U.K. R&D tax relief regime will apply to accounting periods starting on or after 1 April 2024. The legislation for the new regime is not yet finalized and therefore the impact on our financial position cannot be fully known, however the proposed changes to the scheme and/or any further changes could have a material adverse effect on our financial position, results of operations or cash flows.

***If we were classified as a passive foreign investment company, certain adverse U.S. federal income tax consequences could apply to U.S. holders.***

Based on the composition of our income and assets and the value of our assets in the taxable year ended December 31, 2023, we believe that we are a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for our taxable year ended December 31, 2023. However, no assurances regarding our PFIC status can be provided for any past taxable years, the taxable year ending December 31, 2024, or any future taxable years. If we are classified as a PFIC for any taxable year during which a U.S. Holder (as defined below) holds our ordinary

shares or ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder, including (i) the treatment of all or a portion of any gain on disposition of our ordinary shares or ADSs as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends, and (iii) the obligation to comply with certain reporting requirements. We cannot provide any assurances that we will furnish to any U.S. Holder information that may be necessary to comply with the aforementioned reporting and tax payment obligations.

A non-U.S. corporation will generally be considered a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income or (ii) 50% or more of the value of its assets (generally determined on the basis of a quarterly average) consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as holding and receiving directly its proportionate share of the assets and income of such corporation. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into and our corporate structure. The composition of our income and assets is also affected by the spending of the cash we raise in any offering. Each U.S. Holder should consult its own tax advisors with respect to the potential adverse U.S. tax consequences to it if we are a PFIC.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares or ADSs, regardless of whether we continue to meet the PFIC tests described above, unless the U.S. Holder makes a specified election once we cease to be a PFIC.

A "U.S. Holder" is any beneficial owner of our ordinary shares or ADSs that, for U.S. federal income tax purposes, is or is treated as any of the following: a citizen or individual resident of the U.S.; a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the U.S., any state therein or the District of Columbia; an estate the income of which is subject to U.S. federal income taxation regardless of its source; or a trust that (i) is subject to the supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the United States Internal Revenue Code of 1986, as amended (the "Internal Revenue Code")), or (ii) has a valid election in effect to be treated as a United States person.

***If a U.S. Holder is treated as owning at least 10% of our ordinary shares or ADSs, such holder may be subject to adverse U.S. federal income tax consequences.***

If a U.S. Holder (as defined above) is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares or ADSs, such U.S. Holder would generally be treated as a "United States shareholder" (within the meaning of Section 951(b) of the Internal Revenue Code) with respect to each "controlled foreign corporation" (within the meaning of Section 957(a) of the Internal Revenue Code (a "CFC")) in our group, if any. Because our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as CFCs, regardless of whether we are treated as a CFC. A United States shareholder of a CFC may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by such CFC, regardless of whether such CFC makes any distributions. An individual that is a United States shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder's U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether we or any of our non-U.S. subsidiaries are treated as a CFC or whether such investor is treated as a United States shareholder with respect to any such CFCs. Further, we cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax payment obligations described in this risk factor. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs.

**General Risks**

***The price of our ADSs may be volatile and may fluctuate due to factors beyond our control.***

The trading market for publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. The market price of our ADSs may fluctuate significantly due to a variety of factors, including:

- positive or negative results from, or delays in, clinical trials of ensifentrine;
- developments in our competitors' businesses;
- delays in entering into collaborations and strategic relationships with respect to commercialization of Ohtuvayre or development of ensifentrine in other target indications or formulations, or entry into collaborations and strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of ensifentrine, including for our approved product Ohtuvayre;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts or commentators;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- the loss of any of our key scientific or senior management personnel;
- sales of our ADSs by us, our senior management or board members, and significant holders of our ADSs; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs and may otherwise negatively affect the liquidity of our ADSs. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of the holders of our ADSs were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities.

***Future sales, or the possibility of future sales, of a substantial number of our ADSs or ordinary shares could adversely affect the price of our ADSs.***

Future sales of a substantial number of our ADSs or ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ADSs. Sales in the U.S. of our ADSs and ordinary shares held by our directors, officers and affiliated shareholders are subject to restrictions. If these shareholders sell substantial amounts of ordinary shares or ADSs in the public market, or the market perceives that such sales may occur, the market price of our ADSs and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition and the price of our ADSs. The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate or the U.K. or the U.S. enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers or other third-party providers may not survive an economic downturn or recession. As a result, our business, results of operations and price of our ADSs may be adversely affected.

***If securities or industry analysts or commentators publish inaccurate or unfavorable research, about our business, the price of our ADSs and ordinary shares and our trading volume could decline.***

The trading market for our ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts or commentators publish about us or our business. If one or more of the analysts who cover us downgrade our ADSs or if they or other industry commentators publish inaccurate or unfavorable research or comments about our business, the price of our ADSs and ordinary shares would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our ADSs could decrease, which might cause the price of our ADSs and ordinary shares and trading volume to decline.

***We have incurred and expect to continue to incur increased costs as a result of operating as a public company in the U.S., and our senior management are required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a U.S. public company, we have incurred and expect to continue to incur significant legal, accounting and other expenses that we did not incur prior to becoming a U.S. public company, including in connection with our transition to large accelerated filer as of December 31, 2023. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel have devoted and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting and an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for and maintain compliance with Section 404(b), we have implemented a process of documenting and evaluating our internal control over financial reporting. In this regard, we have dedicated, and will need to continue to dedicate, internal resources, engage outside consultants and pursue a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting, which is both costly and challenging. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***Business interruptions could adversely affect our operations.***

Our operations are potentially vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity, public health crises and pandemic diseases, and other natural and man-made disasters or events beyond our control. Our facilities are located in regions that experience severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major tornado, flood, fire, earthquake, power loss, terrorist activity, public health crisis, pandemic diseases or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

**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**

***Rule 10b5-1 Trading Plans***

From time to time, our officers (as defined in Rule 16a-1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading plans (as each such term is defined in Item 408 of Regulation S-K). The trading plans are intended to satisfy the affirmative defense in Rule 10b5-1(c). During the three months ended June 30, 2024, no director or officer of the Company adopted, modified or terminated a Rule 10b5-1 trading plan or a non-Rule 10b5-1 trading plan.

**Item 6. Exhibits**

| | | Incorporated by Reference to Filings Indicated | | | | |
|---|---|---|---|---|---|---|
| Exhibit Number | Exhibit Description | Form | File No. | Exhibit No. | Filing date | Filed/Furnished Herewith |
| 3.1 | Articles of Association, as amended and as currently in effect | 6-K | 001-38067 | 1 | 12/30/2020 | |
| 10.1+ | Revenue Interest Purchase and Sale Agreement, dated as of May 9, 2024, between Verona Pharma, Inc., Verona Pharma plc and Oaktree Fund Administration, LLC, as the administrative agent and the other purchasers party thereto | | | | | * |
| 10.2+ | Credit Agreement and Guaranty, dated as of May 9, 2024, by and among Verona Pharma, Inc., as borrower, Verona Pharma plc, as guarantor, Oaktree Fund Administration, LLC, as administrative agent and the lenders party thereto | 10-Q | 001-38067 | 10.2 | 5/10/2024 | |
| 31.1 | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer | | | | | * |
| 31.2 | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer | | | | | * |
| 32.1 | Section 1350 Certification of Chief Executive Officer | | | | | ** |
| 32.2 | Section 1350 Certification of Chief Financial Officer | | | | | ** |
| 101.INS | Inline XBRL Instance Document | | | | | * |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | | | | | * |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | | | | | * |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document | | | | | * |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | | | | | * |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | | | | | * |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | | | | | * |

* Filed herewith.

** Furnished herewith.

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

## SIGNATURES

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

VERONA PHARMA PLC

Date: August 8, 2024

By: /s/ David Zaccardelli

David Zaccardelli, Pharm. D.
President and Chief Executive Officer

Date: August 8, 2024

By: /s/ Mark W. Hahn

Mark W. Hahn
Chief Financial Officer

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

Execution Version

**REVENUE INTEREST PURCHASE AND SALE AGREEMENT**

**Dated as of May 9, 2024**

**between**

**VERONA PHARMA, INC.,**

**VERONA PHARMA PLC,**

**THE PURCHASERS FROM TIME TO TIME PARTY HERETO,**

**and**

**OAKTREE FUND ADMINISTRATION, LLC,**

**as the Administrative Agent**

**U.S. $250,000,000**

**TABLE OF CONTENTS**

ARTICLE I

DEFINITIONS



ARTICLE II

PURCHASE OF ASSIGNED INTERESTS



ARTICLE III

REPRESENTATIONS AND WARRANTIES OF OBLIGORS

ARTICLE VII

MISCELLANEOUS



ARTICLE VIII

THE ADMINISTRATIVE AGENT

EXHIBITS

Exhibit A – Form of Security Agreement
Exhibit B – Form of Debenture
Exhibit C – Form of Funding Notice

**REVENUE INTEREST PURCHASE AND SALE AGREEMENT**

This **REVENUE INTEREST PURCHASE AND SALE AGREEMENT** (as amended, supplemented or otherwise modified from time to time, this "Agreement") is made and entered into as of May 9, 2024, by and between Verona Pharma, Inc., a Delaware corporation (the "Company"), Verona Pharma plc, a public limited company registered in England and Wales with company number 05375156 ("Holdings"), the entities listed in Schedule 1 hereto (the "Purchasers"), and Oaktree Fund Administration, LLC, as administrative agent for the Purchasers (in such capacity, the "Administrative Agent" and, together with the Company and the Purchasers, the "Parties", and each a "Party").

**WHEREAS,** the Company wishes to obtain financing in respect of the Commercialization (as hereinafter defined) of the Product (as hereinafter defined);

**WHEREAS,** the Company wishes to sell, assign, convey and transfer to the Purchasers the Assigned Interests (as hereinafter defined) in consideration for its payment of the Purchase Price (as hereinafter defined) to raise such financing; and

**WHEREAS,** the Purchasers wish to purchase from the Company the Assigned Interests, upon and subject to the terms and conditions hereinafter set forth;

**NOW, THEREFORE,** in consideration of the mutual covenants, agreements representations and warranties set forth herein, the parties hereto agree as follows:

## ARTICLE I

## DEFINITIONS

**Section 1.01 Definitions**.

The following terms, as used herein, shall have the following meanings:

"Acquisition" shall mean any transaction, or any series of related transactions, by which any Person (for purposes of this definition, an "acquirer") directly or indirectly, by means of amalgamation, consolidation, merger, purchase of assets, purchase of Equity Interests, exclusive licensing of Intellectual Property or otherwise, (i) acquires all or substantially all of the assets of any other Person, (ii) acquires (including via licensing and in-licensing) an entire business line, product, product line, unit or division of any other Person, (iii) with respect to any other Person that is managed or governed by a Board, acquires control of Equity Interests of such other Person representing more than fifty percent (50%) of the ordinary voting power (determined on a fully-diluted basis) for the election of directors of such Person's Board, or (iv) acquires control of more than fifty percent (50%) of the Equity Interests in any other Person (determined on a fully-diluted basis) that is not managed by a Board.

"Administrative Agent" shall have the meaning set forth in the preamble hereto.

"Affiliate" shall mean with respect to a specified Person, any Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common

control with the Person specified; provided, that, with respect to OCM Life Sciences Portfolio LP, an Affiliate shall include any Person in respect of which OMERS Administration Corporation, as administrator of the OMERS primary pension plan and trustee of the pension funds thereunder, holds, directly or indirectly, more than fifty percent (50%) of the Equity Interests of such Person. For purposes of this definition, "control" shall mean, in respect of a particular Person, the possession by one or more other Persons, directly or indirectly, of the power to direct or cause the direction of the management or policies of such particular Person, whether through the ability to exercise voting power, by contract or otherwise. "Controlling" and "controlled" have meanings correlative thereto.

"Affiliated Parties" shall have the meaning set forth in Section 7.19.

"Administrative Agent Fee Letter" shall mean that certain fee letter dated as of the date hereof by and between the Company and the Administrative Agent, as may be amended, amended and restated or modified from time to time.

"Agreement" shall have the meaning set forth in the first paragraph hereof.

"American Depositary Shares" shall mean American depositary shares listed on NASDAQ, each representing eight (8) Common Shares.

"Anti-Terrorism Laws" shall mean any laws relating to terrorism or money laundering, including, without limitation, (i) the Money Laundering Control Act of 1986 (e.g., 18 U.S.C. §§ 1956 and 1957), (ii) the Bank Secrecy Act of 1970 (e.g., 31 U.S.C. §§ 5311 – 5330), as amended by the Patriot Act, (iii) the laws, regulations and Executive Orders administered by the United States Department of the Treasury's Office of Foreign Assets Control ("OFAC"), (iv) the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 and implementing regulations by the United States Department of the Treasury, (v) the laws, regulations and orders administered by the UK Office of Financial Sanctions Implementation, (vi) any law prohibiting or directed against terrorist activities or the financing of terrorist activities (e.g., 18 U.S.C. §§ 2339A and 2339B), or (vii) any similar laws enacted in the United States, the United Kingdom, European Union or any other jurisdictions in which the parties to this agreement operate, and all other present and future legal requirements of any Governmental Authority governing, addressing, relating to, or attempting to eliminate, terrorist acts and acts of war.

"Applicable Funding Condition" shall mean, with respect to each tranche, the Tranche A Funding Condition or Tranche B Funding Condition, as applicable.

"Applicable Funding Date" shall mean, with respect to each tranche, the Tranche A Funding Date or Tranche B Funding Date, as applicable.

"Applicable Percentage" shall mean 6.50% for Net Sales during any Fiscal Year.

"Applicable Tranche" shall mean Tranche A or Tranche B, as applicable.

"Arm's Length Transaction" shall mean, with respect to any transaction, the terms of such transaction shall not be less favorable to any Obligor or any of its Subsidiaries than commercially

reasonable terms that would be obtained in a transaction not while in financial distress with a Person that is an unrelated Third Party.

"Assigned Interests" shall mean the Purchasers' right to receive the Assigned Interest Payments up to the Hard Cap.

"Assigned Interests Payments" shall have the meaning set forth in Section 2.02(a).

"Audit Costs" shall mean, with respect to any audit of the books and records of the Company with respect to amounts payable or paid under this Agreement, the reasonable and documented out-of-pocket cost of such audit, including all fees, costs and expenses incurred in connection therewith.

"Back-Up Security Interest" shall have the meaning set forth in Section 2.01(e).

"Bankruptcy Event of Default" shall mean the occurrence of any of the following:

(a) any Obligor or any of its Subsidiaries shall commence any case, proceeding or other action (i) under any existing or future law of any jurisdiction, domestic or foreign, relating to bankruptcy, insolvency, administration, reorganization, moratorium, liquidation, receivership, examinership, dissolution, winding up or relief of debtors (including by way of voluntary arrangement, scheme of arrangement, restructuring plan or otherwise) or the like, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts, or (ii) seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or any portion of its assets, or any Obligor or any of its Subsidiaries shall make a general assignment for the benefit of its creditors;

(b) there shall be commenced against any Obligor or any of its Subsidiaries any case, proceeding or other action of a nature referred to in clause (a) above which remains undismissed, undischarged, unbonded and in effect for a period of forty-five (45) days;

(c) there shall be commenced against any Obligor or any of its Subsidiaries any case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against (i) all or a substantial portion of the assets of such Obligor or such Subsidiary, and/or (ii) the Product or a substantial portion of the Product Intellectual Property, which results in the entry of an order for any such relief which shall not have been vacated, discharged, stayed, satisfied or bonded pending appeal within forty-five (45) days from the entry thereof; or

(d) an affirmative vote by the Board to commence any case, proceeding or other action described in clause (a) above.

"Benefit Plan" shall mean any employee benefit plan as defined in Section 3(3) of ERISA (whether governed by the laws of the United States or otherwise) to which any Obligor or any Subsidiary thereof incurs or otherwise has any obligation or liability, contingent or otherwise.

"Board" shall mean, with respect to any Person, the board of directors (or similar governing body) of such Person.

"Boxed Warning" shall mean a contraindication or serious warning required by the FDA to be presented in a box within the approved labeling of a drug product, as set forth in 21 C.F.R. Sections 201.57(a)(4) and 201.57(c)(1).

"Business Day" shall mean a day (other than a Saturday or Sunday) on which commercial banks are not authorized or required to close in New York City, Toronto, Canada, or London, England.

"Call Option" shall have the meaning set forth in Section 5.05(a).

"Call Option Closing Date" shall have the meaning set forth in Section 5.05(a).

"Call Price" shall mean, as of any date of determination, an amount sufficient, that, after giving effect to the payment of the Assigned Interests Payments made by the Company to the Purchasers pursuant to Section 2.02(a), (i) the MOIC equals 1.20x, if such date is on or before the one-year anniversary of the Tranche A Funding Date, (ii) the MOIC equals 1.40x, if such date is after the one-year anniversary of the Tranche A Funding Date and on or before the two-year anniversary of the Tranche A Funding Date, (iii) the MOIC equals 1.55x if such date is after the two-year anniversary of the Tranche A Funding Date and on or before the three-year anniversary of the Tranche A Funding Date, and (iv) the MOIC equals 1.75x if such date is after the three-year anniversary of the Tranche A Funding Date.

"Capital Lease Obligations" shall mean, as to any Person, the obligations of such Person to pay rent or other amounts under a lease of (or other agreement conveying the right to use) any property by such Person as lessee, which obligations are required to be classified and accounted for as a capital lease or finance lease on a balance sheet of such Person under GAAP, and for the purposes of this Agreement, the amount of such obligations shall be the capitalized amount thereof, determined in accordance with GAAP. "Capital Lease Obligations" shall not include any obligations under a straight-line or operating lease (including any lease that would not have been a capital lease under GAAP prior to giving effect to Accounting Standards Codification 842, Leases).

"Change of Control" shall mean an event or series of events (i) as a result of which any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Securities Act, but excluding any of such person or its Subsidiaries, and any Person acting in its capacity as trustee, agent or other fiduciary or administrator of any such Plan) becomes the "beneficial owner", directly or indirectly, of thirty-five percent (35%) or more of the Equity Interests of Holdings entitled to vote for members of the Board of Holdings on a fully-diluted basis (and taking into account all such Equity Interests that such person or group has the right to acquire pursuant to any Option Right); (ii) as a result of which, during any period of twelve (12) consecutive months, a majority of the members of the Board of Holdings cease to be composed of individuals (x) who were members of such Board on the first day of such period, (y) whose election, appointment or nomination to such Board was approved by individuals referred to in clause (x) above constituting at the time of such election, appointment or nomination, at least a majority of such Board or

equivalent governing body or (z) whose election, appointment or nomination to such Board was approved by individuals referred to in clauses (x) and (y) above constituting at the time of such election, appointment or nomination, at least a majority of such Board; (ii) an event or series of events that results in the sale of all or substantially all of the assets or businesses of Holdings and its Subsidiaries, taken as a whole, or (iii) except to the extent permitted by this Agreement, an event or series of events that results in Holdings' failure to own, directly or indirectly, beneficially and of record, one-hundred percent (100%) of all issued and outstanding Equity Interests of any Obligor (other than Holdings) (other than, in the case of this clause (iii), as a result of any Acquisition, liquidation, or dissolution and any Equity Interests in the nature of directors' qualifying shares required pursuant to applicable Law). For purposes of this definition, "beneficial owner" is as defined in Rules 13d-3 and 13d-5 under the Exchange Act, except that a person or group shall be deemed to have "beneficial ownership" of all Equity Interests that such person or group has the right to acquire, whether such right is exercisable immediately or only after the passage of time (such right, an "Option Right").

"Code" shall mean the Internal Revenue Code of 1986, as amended.

"Collateral" shall mean (i) "Collateral" as defined in the Security Agreement, (ii) "Charged Assets" as defined in the Debenture, and (iii) to the extent the transfer of the Assigned Interests contemplated hereby is held not to be a sale, the Assigned Interests and the Assigned Interest Payments, whether now owned or hereafter acquired, and any proceeds (as such term is defined in the UCC) thereof.

"Combination" shall have the meaning set forth in the definition of "Net Sales."

"Commercialization" shall mean any and all activities with respect to the manufacture, distribution, marketing, detailing, promotion, selling and securing of reimbursement and any other exploitation or commercialization of the Product in the applicable jurisdiction after Marketing Authorization for the Product has been obtained in such jurisdiction, which shall include, as applicable, seeking and negotiating pricing and reimbursement approvals for the Product, post-marketing approval studies, post-launch marketing, promoting, detailing, marketing research, distributing, customer service, selling the Product, importing, exporting or transporting the Product for sale, and regulatory compliance with respect to the foregoing in the applicable jurisdiction. When used as a verb, "Commercialize" shall mean to engage in Commercialization.

"Commercially Reasonable Efforts" shall mean, with respect to the efforts to be expended, or considerations to be undertaken, by the Company and its Affiliates with respect to any objective or activity to be undertaken hereunder, such efforts and resources normally used by a reasonably prudent company in the pharmaceutical or biotechnology industry of similar size and resources to the Company to accomplish a substantially similar objective or activity for a pharmaceutical product for which substantially the same regulatory structure is involved as for the Product and irrespective of whether such company has any other products that compete with such pharmaceutical product, which pharmaceutical product is owned or licensed in a similar manner as the Product, which pharmaceutical product is at a similar stage in its Development or product life cycle and is of similar market or profit potential as the Product, taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in a given jurisdiction, pricing/reimbursement for the pharmaceutical product in a given jurisdiction, the Intellectual

Property and regulatory protection of the pharmaceutical product in a given jurisdiction, the regulatory structure in such jurisdiction and the profitability of the pharmaceutical product in a given jurisdiction, all as measured by the facts and circumstances in existence at the time such efforts are due. It is anticipated that the level of effort and resources that constitute "Commercially Reasonable Efforts" with respect to a particular indication will change over time, reflecting changes in the status of the Product, as applicable.

"Commitment" shall mean, with respect to each Purchaser, the obligation of such Purchaser to fund its applicable Purchase Price set forth opposite such Purchaser's name on Schedule 1 (as such Schedule may be amended from time to time) under the caption "Applicable Commitment" on each of the Tranche A Funding Date and Tranche B Funding Date, as applicable, in accordance with the terms and conditions of this Agreement. The aggregate amount of Commitments on the date of this Agreement equals $250,000,000.

"Common Shares" shall mean the ordinary shares, nominal value £0.05 per share, of Holdings.

"Company" shall have the meaning set forth in the first paragraph hereof.

"Company Competitor" shall mean (i) any competitor of Holdings or any of its Subsidiaries primarily operating in the same line of business as Holdings or any of its Subsidiaries and (ii) any of such competitor's Affiliates (other than any Person that is a bona fide debt fund primarily engaged in the making, purchasing, holding or other investing in commercial loans, notes, bonds or similar extensions of credit or securities in the Ordinary Course) that are either clearly identifiable as an Affiliate of any such competitor on the basis of such Person's name or identified by name in writing by the Company to the Administrative Agent from time to time. Notwithstanding anything to the contrary contained in this Agreement, (a) the Administrative Agent shall not be responsible or have any liability for, or have any duty to ascertain, inquire into, monitor or enforce, compliance with the provisions hereof relating to Company Competitor, (b) the Obligors and the Purchasers acknowledge and agree that the Administrative Agent shall have no responsibility or obligation to determine whether any Purchaser or potential Purchaser is a Company Competitor and that the Administrative Agent shall have no liability with respect to any assignment or participation made to a Company Competitor and (c) in no event shall any Oaktree Purchaser or any OMERS Purchaser be deemed to be a Company Competitor.

"Company Indemnified Party" shall have the meaning set forth in Section 7.05(b).

"Confidential Information" shall mean, as it relates to the Company and its Affiliates and the Product, the non-public Intellectual Property, confidential business information, financial data and other like information (including ideas, research and development, know-how, formulas, schematics, compositions, technical data, specifications, customer and supplier lists, pricing and cost information, and business and marketing plans and proposals), inventory, ideas, algorithms, processes, computer software programs or applications (in both source code and object code form), client lists and tangible or intangible proprietary information or material, or such other information that either party identifies to the other as confidential or the nature of which or the circumstances of the disclosure of which would reasonably indicate that such information is confidential.

"Contracts" shall mean any contract, license, lease, agreement, obligation, promise, undertaking, understanding, arrangement, document, commitment, entitlement or engagement under which a Person has, or will have, any liability or contingent liability (in each case, whether written or oral, express or implied, and whether in respect of monetary or payment obligations, performance obligations or otherwise).

"Control" or "Controlled" shall mean, when used with respect to any item of Intellectual Property, the possession or control (whether by ownership, license, sublicense or other contractual right) by Company or any of its Affiliates, of the ability to assign or grant to any Third Party the license, sublicense or right to access, use or otherwise exploit such Intellectual Property as it relates to the manufacture, use, exploitation, Development and/or Commercialization of the Product, without paying any additional consideration to any other Third Party or violating the terms of any agreement or other arrangement with any other Third Party. Notwithstanding the foregoing, a Party and its controlled Affiliates will not be deemed to "Control" any Intellectual Property that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate that controls such acquired Party (or that merges or consolidates with such Party) after the Effective Date as a result of such Change of Control unless prior to the consummation of such Change of Control, such acquired Party or any of its controlled Affiliates also Controlled such Intellectual Property.

"Copyright" shall mean published and unpublished works of authorship whether or not copyrightable, including software, website and mobile content, data, databases, and other compilations of information, in each case, whether or not registered, and any and all copyrights in and to the foregoing, together with all common law rights and moral rights therein, and all copyrights, copyright registrations and applications for copyright registrations, including all renewals, extensions, restorations, derivative works and reversions thereof and all common law rights, moral rights and other rights whatsoever accruing thereunder or pertaining thereto throughout the world.

"Debenture" shall mean the debenture, dated as of the date hereof, between Holdings and the Administrative Agent (in its capacity as administrative agent for the benefit of the Secured Parties under this Agreement), which debenture shall be substantially in the form of Exhibit B, as may be amended, restated, amended and restated, supplemented or otherwise modified from time to time in accordance with the terms thereof.

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"Default" shall mean any Event of Default and any event that, upon the giving of notice, the lapse of time or both, would constitute an Event of Default.

"Designated Jurisdiction" shall mean any country or territory to the extent that such country or territory is the subject of country- or territory-wide Sanctions.

"Development" shall mean, with respect to the Product, any internal or external research or development activities (including preclinical and clinical trials), and any internal or external regulatory activities related to obtaining and maintaining Marketing Authorization for the Product, including development of data or information for the purpose of submission to a Governmental Authority to obtain authorization to conduct clinical trials and to obtain, support, or maintain Marketing Authorization of the Product and including activities directed toward the clinical

manufacture and manufacturing process development for the Product. "Develop," "Developing," and "Developed" will be construed accordingly.

"Disqualified Equity Interests" shall mean, with respect to any Person, any Equity Interest of such Person that, by its terms (or by the terms of any security or other Equity Interest into which it is convertible or for which it is exchangeable), or upon the happening of any event or condition (i) matures (excluding any maturity as the result of an optional redemption by the issuer thereof) or is mandatorily redeemable (in each case, other than solely for (a) Qualified Equity Interests and (b) customary cash in lieu of fractional shares), including pursuant to a sinking fund obligation or otherwise, (ii) is redeemable at the option of the holder thereof (other than solely for (a) Qualified Equity Interests and (b) cash in lieu of fractional shares), in whole or in part, (iii) provides for the scheduled payments of dividends or other distributions in cash (other than the payment of cash in lieu of fractional shares) or other securities that would constitute Disqualified Equity Interests, or (iv) is or becomes convertible into or exchangeable for (unless at the sole option of the issuer thereof) Indebtedness or any other Equity Interests that would constitute Disqualified Equity Interests, in each case, prior to the date that is ninety-one (91) days after the date this Agreement terminates in accordance with Section 6.01; provided, that, any Disqualified Equity Interests that would not constitute Disqualified Equity Interests but for provisions thereof giving holders of such Equity Interests (or the holders of any security into or for which such Equity Interests are convertible, exchangeable or exercisable) the right to require the issuer thereof to redeem or repurchase such Equity Interests upon the occurrence of a change in control (including for this purpose an asset sale that would require prepayment in full of the Obligations) occurring prior to the 91st day after the date this Agreement terminates in accordance with Section 6.01 shall not constitute Disqualified Equity Interests if such right to redemption or repurchase is subject, to the satisfaction of the Administrative Agent in its reasonable discretion, to the prior payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been asserted) under the Transaction Documents; provided, further, that, if such Equity Interests are issued pursuant to a customary employee benefits or equity incentive plan for the benefit of employees of Holdings or any Subsidiary or by any such plan to such employees, such Equity Interests shall not constitute Disqualified Equity Interests solely because (x) such employee may deliver such Equity Interests to Holdings and its Subsidiaries (or Holdings or such Subsidiary withholds such Equity Interests) in satisfaction of any exercise price or tax withholding obligations with respect to such Equity Interests, or (y) they may be required to be repurchased by Holdings or its Subsidiaries as a result of any such employee's termination, death or disability.

"Distressed Debt Investor" shall mean a vulture fund, distressed debt fund or any fund or investor whose principal business or principal portfolio or investment strategy is to invest in loans or other debt securities purchased with a view to owning the equity or gaining ownership of the equity in the business (directly or indirectly). In no event shall any Oaktree Purchaser or OMERS Purchaser be deemed to be a Distressed Debt Investor. Notwithstanding anything to the contrary contained in this Agreement, Administrative Agent shall not have any duty or obligation to carry out due diligence in order to identify or determine whether a Person would be a Distressed Debt Investor, and the Administrative Agent shall have no liability with respect to any assignment or participation made to a Distressed Debt Investor.

"Distributor" shall mean a Third Party that (a) purchases or has the option to purchase the Product in finished form from or at the direction of the Company or any of its Affiliates, (b) has

the right, option or obligation to distribute, market and sell the Product (with or without packaging rights) in one or more regions, and (c) does not otherwise make any royalty, milestone, profit share or other similar payment to the Company or its Affiliate based on such Third Party's sale of the Product. The term "packaging rights" in this definition shall mean the right for the Distributor to package or have packaged Product supplied in unpackaged bulk form into individual ready-for-sale packs.

"Dollars" and "$" shall mean lawful money of the United States of America.

"Effective Date" shall mean the first date upon which the conditions set forth in Section 2.05(a), shall have occurred. The Effective Date occurred on May 9, 2024.

"Eligible Transferee" shall mean and include (i) any commercial bank, (ii) any insurance company, (iii) any finance company, (iv) any financial institution, (v) any Person that is a bona fide debt fund primarily engaged in the making, purchasing, holding or other investing in commercial loans, notes, bonds or similar extensions of credit or securities in the Ordinary Course, (vi) with respect to any Purchaser, any of its Affiliates or such Purchaser's or Affiliate's managed funds or accounts, and (vii) any other "accredited investor" (as defined in Regulation D of the Securities Act) that is principally in the business of managing investments or holding assets for investment purposes; provided, that no Distressed Debt Investor or Company Competitor shall be an Eligible Transferee.

"Ensifentrine" shall mean 9,10-dimethoxy-2(2,4,6-trimethylphenylimino)-3-(n-carbamoyl-2-aminoethyl)-3,4,6,7-tetrahydro-2H-pyrimido[6,1-a]isoquinolin-4-one, a dual inhibitor of the enzymes phosphodiesterase 3 and 4, including any prodrugs, metabolites, salts, congeners, bases, anhydrides, hydrates, crystal forms, non-crystal forms, polymorphs, solvates, stereoisomers, radioisomers, or ester forms thereof and any other improvements, variations, and modifications thereto. "Ensifentrine" shall include all dosages, dosage forms and formulations of the foregoing.

"Ensifentrine Approval" shall mean the FDA has approved Company's NDA for Ensifentrine (NDA #217389) with an Indication and Usage section of the label stating that Ensifentrine is indicated for the maintenance treatment of certain patients with chronic obstructive pulmonary disease, with no Boxed Warning.

"Equity Interests" shall mean, with respect to any Person (for purposes of this defined term, an "issuer"), all shares of, interests or participations in, or other equivalents in respect of such issuer's capital stock, including all membership interests, partnership interests or equivalent, whether now outstanding or issued after the Effective Date, and in each case, however designated and whether voting or non-voting. Notwithstanding the foregoing, in no event shall any Indebtedness convertible or exchangeable into Equity Interests constitute "Equity Interests" hereunder.

"Equivalent Amount" shall mean, with respect to an amount denominated in one currency, the amount in another currency that could be purchased by the amount in the first currency determined by reference to the Exchange Rate at the time of determination. Where the permissibility of a transaction, accuracy of a representation or warranty or compliance with a

covenant hereunder is determined by reference to amounts stated in U.S. dollars (or the Equivalent Amount in other currencies), the time of determination shall, in each case, be the time at which any applicable transaction is entered into (e.g. the time at which Indebtedness is incurred or at which an Acquisition is made), financial covenant is tested, or representation or warranty is made, and the permissibility of actions taken under this Agreement shall not be affected by, and no Default or Event of Default shall arise as a result of, subsequent fluctuations in exchange rates.

"ERISA" shall mean the United States Employee Retirement Income Security Act of 1974, as amended.

"ERISA Affiliate" shall mean, collectively, any Obligor, any Subsidiary thereof, and any Person under common control, or treated as a single employer, with any Obligor or any Subsidiary thereof, within the meaning of Section 414(b), (c), (m) or (o) of the Code.

"ERISA Event" shall mean (i) a reportable event as defined in Section 4043 of ERISA with respect to a Title IV Plan, excluding, however, such events as to which the PBGC by regulation has waived the requirement of Section 4043(a) of ERISA that it be notified within thirty (30) days of the occurrence of such event; (ii) the applicability of the requirements of Section 4043(b) of ERISA with respect to a contributing sponsor, as defined in Section 4001(a)(13) of ERISA, to any Title IV Plan where an event described in paragraph (9), (10), (11), (12) or (13) of Section 4043(c) of ERISA is reasonably expected to occur with respect to such plan within the following thirty (30) days; (iii) a withdrawal by the Company or any ERISA Affiliate thereof from a Title IV Plan or the termination of any Title IV Plan resulting in liability under Section 4063 or 4064 of ERISA; (iv) the withdrawal of the Company or any ERISA Affiliate thereof in a complete or partial withdrawal (within the meaning of Sections 4203 and 4205 of ERISA) from any Multiemployer Plan if there is any potential liability therefore, or the receipt by the Company or any ERISA Affiliate thereof of written notice from any Multiemployer Plan that it is insolvent pursuant to Section 4245 of ERISA; (v) the filing of a notice of intent to terminate, the treatment of a plan amendment as a termination under Section 4041 or 4041A of ERISA, or the commencement of proceedings by the PBGC to terminate a Title IV Plan or Multiemployer Plan (but in the case of a multiple employer plan or a Multiemployer Plan, only once notice has been received from the plan administrator); (vi) the imposition of liability on the Company or any ERISA Affiliate thereof pursuant to Section 4062(e) or 4069 of ERISA or by reason of the application of Section 4212(c) of ERISA; (vii) the failure by the Company or any ERISA Affiliate thereof to make any required contribution to a Plan, or the failure to meet the minimum funding standard of Section 412 of the Code with respect to any Title IV Plan (whether or not waived in accordance with Section 412(c) of the Code) or the failure to make by its due date a required installment under Section 430 of the Code with respect to any Title IV Plan or the failure to make any required contribution to a Multiemployer Plan; (viii) the determination that any Title IV Plan is considered an at-risk plan or a plan in endangered to critical status within the meaning of Sections 430, 431 and 432 of the Code or Sections 303, 304 and 305 of ERISA; (ix) an event or condition which might reasonably be expected to constitute grounds under Section 4042 of ERISA for the termination of, or the appointment of a trustee to administer, any Title IV Plan or Multiemployer Plan (but in the case of a multiple employer plan or a Multiemployer Plan, only once notice has been received from the plan administrator); (x) the imposition of any liability under Title I or Title IV of ERISA, other than PBGC premiums due but not delinquent under Section 4007 of ERISA, upon the Company or any ERISA Affiliate thereof; (xi) an application for a funding waiver under Section 303 of

ERISA or an extension of any amortization period pursuant to Section 412 of the Code with respect to any Title IV Plan; (xii) the occurrence of a non-exempt prohibited transaction under Section 406 or 407 of ERISA for which any Obligor or any Subsidiary thereof would reasonably be expected to be directly or indirectly liable; (xiii) a violation of the applicable requirements of Section 404 or 405 of ERISA or the exclusive benefit rule under Section 401(a) of the Code by any fiduciary or disqualified person for which the Company or any ERISA Affiliate thereof would reasonably be expected to be directly or indirectly liable; (xiv) the occurrence of an act or omission which would reasonably be expected to give rise to the imposition on the Company or any ERISA Affiliate thereof of fines, penalties, taxes or related charges under Chapter 43 of the Code or under Section 409, 502(c), (i) or (1) or 4071 of ERISA; (xv) the assertion of a material claim (other than routine claims for benefits) against any Plan or the assets thereof, or against any Obligor or any Subsidiary thereof in connection with any such plan; (xvi) receipt from the IRS of notice of the failure of any Qualified Plan to qualify under Section 401(a) of the Code, or the failure of any trust forming part of any Qualified Plan to fail to qualify for exemption from taxation under Section 501(a) of the Code; or (xvii) the imposition of any lien (or the fulfillment of the conditions for the imposition of any lien) on any of the rights, properties or assets of the Company or any ERISA Affiliate thereof, in either case pursuant to Title I or IV, including Section 302(f) or 303(k) of ERISA or to Section 401(a)(29) or 430(k) of the Code.

"ERISA Funding Rules" shall mean the rules regarding minimum required contributions (including any installment payment thereof) to Title IV Plans, as set forth in Sections 412, 430, 431, 432 and 436 of the Code and Sections 302, 303, 304 and 305 of ERISA.

"Erroneous Payment" shall have the meaning set forth in Section 8.14(d).

"Erroneous Payment Deficiency Assignment" shall have the meaning set forth in Section 8.14(d).

"Erroneous Payment Impacted Assigned Interests" shall have the meaning set forth in Section 8.14(d).

"Erroneous Payment Return Deficiency" shall have the meaning set forth in Section 8.14(d).

"Erroneous Payment Subrogation Rights" shall have the meaning set forth in Section 8.14(d).

"Event of Default" shall mean any one of the following events:

(a) any Bankruptcy Event of Default; or

(b) a Change of Control shall have occurred; or

(c) a Tranche A Funding Event of Default; or

(d) any sale, out-licensing of all or substantially all of the rights in and to the Product or other form of divestment of all or substantially all of the rights in and to the Product, in each case other than any Permitted Licensing Agreement; or

(e) the Company shall fail (i) to pay, when and as required to be paid herein, any amount of any Royalty Interest Payment, U.S. Licensing / Participation Payment or Ex-U.S. Licensing / Participation Payment when and as the same shall become due and payable, whether at the due date thereof, at a date fixed for prepayment thereof or otherwise, or (ii) to pay or reimburse the Purchasers for any other Obligations not described in the preceding clause (i), and, in each case, such failure shall continue for a period of ten (10) Business Days following the due date therefor (or, if there is no due date therefor, within ten (10) Business Days following the Purchasers' demand for any such payment or reimbursement); or

(f) the Company shall fail to comply with Section 2.02(d) with respect to amounts in excess of $500,000 in the aggregate, and such failure shall continue for a period of ten (10) Business Days following the due date thereof; or

(g) Holdings or any Subsidiary shall breach any other material provision of this Agreement or of any of the other Transaction Documents (other than any provision embodied in or covered by any other clause of this definition), and, in the case of any such breach that is capable of cure, the same shall remain unremedied for thirty (30) days or more after an officer of Holdings or any Subsidiary first learns or acquires knowledge (after reasonable due inquiry) of such breach, including written notice from one or more of the Purchasers or the Administrative Agent.

"Event of Default Fee" shall mean, with respect to any Event of Default occurring after the Tranche A Funding Date, as of any date of determination, an amount sufficient that, after giving effect to the payment of the Event of Default Fee and the Royalty Interest Payments, U.S. Licensing / Participation Payments and Ex-U.S. Licensing / Participation Payments made by the Company to the Purchasers pursuant to Section 2.02(a), (i) the MOIC equals 1.20x, if such date is before the one-year anniversary of the Tranche A Funding Date, (ii) the MOIC equals 1.40x, if such date is on or after the one-year anniversary of the Tranche A Funding Date and before the two-year anniversary of the Tranche A Funding Date, (iii) the MOIC equals 1.55x if such date is on or after the two-year anniversary of the Tranche A Funding Date and before the three-year anniversary of the Tranche A Funding Date, and (iv) the MOIC equals 1.75x if such date is on or after the three-year anniversary of the Tranche A Funding Date.

"Exchange Rate" shall mean, as of any date, the rate at which any currency may be exchanged into another currency, as set forth on the relevant Reuters screen at or about 11:00 a.m. (Eastern time) on such date. In the event that such rate does not appear on the Reuters screen, the "Exchange Rate" shall be determined by reference to such other publicly available service for displaying exchange rates as may be reasonably designated by the Administrative Agent.

"Excluded Liabilities and Obligations" shall have the meaning set forth in Section 2.06.

"Excluded Taxes" shall mean any of the following Taxes imposed on or with respect to any Purchaser or required to be withheld or deducted from a payment to any Purchaser: (i) Taxes imposed on or measured by net income (however denominated), franchise Taxes and branch profits Taxes, in each case, (x) imposed as a result of such Purchaser being organized under the laws of, or having its principal office located in, the jurisdiction imposing such Tax (or any political subdivisions thereof) or (y) that are Other Connection Taxes, (ii) U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Purchaser pursuant to a law in effect on

the date on which (1) such Purchaser acquires the Assigned Interests or (2) such Purchaser changes its principal office, except in each case to the extent that, pursuant to Section 5.10, amounts with respect to such Taxes were payable to such Purchaser's assignor immediately before such Purchaser acquired the Assigned Interests or to such Purchaser immediately before it changed its principal office, (iii) Taxes attributable to such Purchaser's failure to comply with Section 5.10(b), and (iv) any withholding Taxes imposed under FATCA.

"Ex-U.S. Licensing / Participation Proceeds" shall mean the portion of all license fees, commercial or sales-based milestone payments, up-front payments, or royalties received by the Company or any of its Affiliates from any Ex-US Licensing Agreements for the Product during the Payment Period.

"Ex-U.S. Licensing / Participation Payment(s)" shall have the meaning set forth in Section 2.02(a).

"Ex-U.S. Licensing / Participation Percentage" shall mean 5.00%.

"Ex-U.S. Licensing Agreement" shall mean any license, commercialization, co-promotion, collaboration, distribution, marketing or partnering agreement or other arrangement entered into during the Term by the Company or any of its Affiliates under which a Third Party has a right and license under the Product Intellectual Property to Commercialize the Product outside of the United States.

"FATCA" shall mean Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Code.

"FD&C Act" shall mean the U.S. Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (or any successor thereto), as amended from time to time, and the rules and regulations, issued or promulgated thereunder.

"FDA" shall mean the United States Food and Drug Administration and any successor entity.

"Federal Funds Effective Rate" shall mean, for any day, the rate calculated by the Federal Reserve Bank of New York based on such day's federal funds transactions by depositary institutions (as determined in such manner as the Federal Reserve Bank of New York shall set forth on its public website from time to time) and published on the next succeeding Business Day by the Federal Reserve Bank of New York as the federal funds effective rate; provided, that (a) if such day is not a Business Day, the Federal Funds Effective Rate for such day shall be such rate on such transactions on the next preceding Business Day as so published on the next succeeding Business Day, and (b) if no such rate is so published on such next succeeding Business Day, the Federal Funds Effective Rate for such day shall be the average rate charged to three (3) major banks on such day on such transactions as determined by the Administrative Agent; provided,

further, that if the Federal Funds Effective Rate as so determined would be less than zero, such rate shall be deemed to be zero for the purposes of this Agreement.

"Financial Statements" shall mean the audited consolidated balance sheets of Holdings and its Subsidiaries as of December 31, 2023, and the related audited consolidated statements of operations and cash flows for the Fiscal Year then ended.

"Fiscal Quarter" shall mean each three (3) month period commencing January 1, April 1, July 1 or October 1; provided, however, that (a) the first Fiscal Quarter of the Term shall be the Fiscal Quarter in which the Tranche A Funding Date occurs and (b) the last Fiscal Quarter of the Term shall end upon the expiration or termination of this Agreement.

"Fiscal Year" shall mean the calendar year.

"Funded Amount" shall mean, as of any time of determination, the aggregate amount actually funded by the Purchasers under this Agreement in respect of Tranche A and Tranche B.

"Funding Notice" shall have the meaning set forth in Section 2.05(b)(i).

"GAAP" shall mean generally accepted accounting principles in (i) the United States of America, as in effect from time to time, set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants, in the statements and pronouncements of the Financial Accounting Standards Board and in such other statements by such other entity as may be in general use by significant segments of the accounting profession that are applicable to the circumstances as of the date of determination and (ii) in relation to a Guarantor incorporated in a jurisdiction other than the United States of America, generally accepted accounting principles consistently applied in the jurisdiction in which such Guarantor is incorporated and/or carries on business. All references to "GAAP" shall be to GAAP applied consistently with the principles used in the preparation of the financial statements delivered pursuant to Section 3.05.

"Governmental Approval" shall mean any consent, authorization, approval, order, license, franchise, permit, certification, accreditation, registration, clearance or exemption that is issued or granted by or from (or pursuant to any act of) any Governmental Authority, including any application or submission related to any of the foregoing, including, for the avoidance of doubt, the Ensifentrine Approval.

"Governmental Authority" shall mean any nation, government, branch of power (whether executive, legislative or judicial), state, province or municipality or other political subdivision thereof and any entity exercising executive, legislative, judicial, monetary, regulatory or administrative functions of or pertaining to government, including regulatory authorities, governmental departments, agencies, commissions, bureaus, officials, ministers, courts, bodies, boards, tribunals and dispute settlement panels, and other law-, rule- or regulation-making organizations or entities of any state, territory, county, city or other political subdivision of any country, in each case whether U.S. or non-U.S.

"Gross Sales" shall have the meaning set forth in the definition of "Net Sales."

"Guarantee" of or by any Person (the "Guarantor") shall mean any obligation, contingent or otherwise, of the guarantor guaranteeing or having the economic effect of guaranteeing any Indebtedness or other obligation (the "primary obligations") of any other Person (the "Primary Obligor") in any manner, whether directly or indirectly, and including any obligation of the guarantor, direct or indirect, (a) to purchase or pay (or advance or supply funds for the purchase or payment of) such primary obligations or to purchase (or to advance or supply funds for the purchase of) any security for the payment thereof, (b) to purchase or lease property, securities or services for the purpose of assuring the owner of such primary obligations of the payment thereof, (c) to maintain working capital, equity capital or any other financial statement condition or liquidity of the Primary Obligor so as to enable the Primary Obligor to pay such primary obligations or (d) as an account party in respect of any letter of credit or letter of guaranty (including any bank guarantee) issued to support such primary obligations; provided, that the term Guarantee shall not include endorsements for collection or deposit or guarantees of any straight-line or operating lease (including any lease that would not have been a capital lease under GAAP prior to giving effect to Accounting Standards Codification 842, Leases).

"Guarantor" shall have the meaning set forth in the definition of "Guarantee."

"Hard Cap" shall mean an amount equal to the product of (i) the Funded Amount, *multiplied by* (ii) 1.75.

"Healthcare Laws" shall mean, collectively, all Laws regulating the distribution, dispensing, importation, exportation, quality, manufacturing, labeling, promotion and provision of and payment for drugs, medical devices, medical or healthcare products, items and services, including, the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"); 42 U.S.C. § 1320a-7b (Criminal Penalties Involving Medicare or State Health Care Programs), commonly referred to as the "Federal Anti-Kickback Statute"; 42 U.S.C. § 1320a-7h (the Physician Payment Sunshine Act); the FD&C Act;; and all rules and regulations promulgated under or pursuant to any of the foregoing, including any non-U.S. equivalents.

"Hedging Agreement" shall mean any interest rate exchange agreement, foreign currency exchange agreement, commodity price protection agreement or other interest or currency exchange rate or commodity price hedging arrangement. Notwithstanding anything to the contrary in the foregoing, neither any Permitted Bond Hedge Transaction nor any Permitted Warrant Transaction shall be a Hedging Agreement.

"Holdings" shall have the meaning set forth in the first paragraph hereof.

"HIPAA" shall have the meaning set forth in the definition of "Healthcare Laws."

"IND" shall mean an investigational new drug application submitted to the FDA pursuant to 21 C.F.R. Part 312 for allowance to initiate human clinical trials in the United States, or any equivalent application submitted to a Governmental Authority outside of the United States, including all amendments that may be submitted with respect to the foregoing.

"Indebtedness" of any Person shall mean, without duplication, (i) all obligations of such Person for borrowed money, (ii) all obligations of such Person evidenced by bonds, debentures, notes, loan agreements or similar instruments, (iii) all obligations of such Person upon which

interest charges are customarily paid (excluding interest penalties for late payments under commercial contracts entered into in the Ordinary Course and, for the avoidance of doubt, which commercial contracts do not relate to obligations for borrowed money or purchase money indebtedness), (iv) all obligations of such Person under conditional sale or other title retention agreements relating to property acquired by such Person, (v) all obligations of such Person in respect of the deferred purchase price of property or services (it being agreed that seller notes or earn-out obligations are addressed in clause (xii)), (vi) all Indebtedness of others secured by (or for which the holder of such Indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on property owned or acquired by such Person, whether or not the Indebtedness secured thereby has been assumed, (vii) all Guarantees by such Person of Indebtedness of others, (viii) all Capital Lease Obligations of such Person, (ix) all obligations, contingent or otherwise, of such Person as an account party in respect of letters of credit and letters of guaranty, (x) obligations under any Hedging Agreement, currency swaps, forwards, futures or derivatives transactions, (xi) all obligations, contingent or otherwise, of such Person in respect of bankers' acceptances, (xii) all obligations under any earn-out and guaranteed minimum milestone and other payments of such Person under any license or other agreements appearing on such Person's balance sheet in accordance with GAAP (but excluding any payments based on sales under any such license or other agreement), (xiii) any Disqualified Equity Interests of such Person, and (xiv) all other obligations required to be classified as indebtedness of such Person under GAAP; provided that, notwithstanding the foregoing, Indebtedness shall not include (A) accrued expenses, deferred rent, Taxes, deferred compensation or customary obligations under employment agreements (including obligations in respect of early retirement or termination obligations, deferred compensatory or employee or director equity plans, pension fund obligations or contributions or similar claims, obligations or contributions or social security or wage taxes), or (B) accounts payable incurred in the Ordinary Course, in each case, not overdue by more than sixty (60) days, unless contested in good faith by appropriate proceedings and reserved for in accordance with GAAP. The Indebtedness of any Person shall include the Indebtedness of any other entity (including any partnership in which such Person is a general partner) to the extent such Person is liable therefor as a result of such Person's ownership interest in or other relationship with such entity, except to the extent the terms of such Indebtedness provide that such Person is not liable therefor.

"Indemnified Tax" shall mean (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of the Assigned Interests or any other Obligation and (ii) to the extent not otherwise described in clause (i), Other Taxes.

"Indications and Usage" shall mean the section of the FDA-approved labeling for a drug product that states such drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition, as set forth in 21 C.F.R. Section 201.57(c)(2).

"Intellectual Property" shall mean intellectual property or proprietary rights of any kind anywhere in the world, including any rights in or to Patents, Trademarks, Copyrights and Trade Secrets, and database rights, whether U.S. or non-U.S, together with all rights to claim priority from such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

"Intercreditor Agreement" shall mean the Intercreditor Agreement between Oaktree Fund Administration, LLC, as the administrative agent under the Oaktree Term Loan Facility, and Oaktree Fund Administration, LLC, as Administrative Agent on behalf of the Purchasers, acknowledged by the Company, Holdings and each other Grantor as named therein, providing for the relative rights and priorities of the First Lien Claimholders (as defined therein) and the Purchaser Claimholders (as defined therein) with respect to the Collateral as may be amended, restated, amended and restated, supplemented or otherwise modified from time to time in accordance with the terms thereof.

"Invention" shall mean any novel, inventive or useful art, apparatus, method, process, machine (including any article or device), manufacture or composition of matter, or any novel, inventive and useful improvement in any art, apparatus, method, process, machine (including article or device), manufacture or composition of matter.

"Law" shall mean, collectively, all U.S. or non-U.S. federal, state, provincial, territorial, municipal or local statute, treaty, rule, guideline, regulation, ordinance, code or administrative or judicial precedent or authority, including any interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority, in each case whether or not having the force of law.

"Legal & IP Expenses" shall have the meaning set forth in Section 7.15.

"Lien" shall mean (a) any mortgage, lien, license, pledge, hypothecation, charge, assignment, security interest, or other encumbrance of any kind or character whatsoever, whether or not filed, recorded or otherwise perfected under applicable Law, or any lease, title retention agreement, mortgage, restriction, easement, right-of-way, option or adverse claim (of ownership or possession) (including any conditional sale or other title retention agreement, any lease in the nature thereof, and any other encumbrance on title to real property, any option or other agreement to sell, or give a security interest in, such asset and any filing of or agreement to give any financing statement under the Uniform Commercial Code (or equivalent statutes of any jurisdiction)) or any preferential arrangement that has the practical effect of creating a security interest and (b) in the case of Equity Interests, any purchase option, call or similar right of a third party with respect to such Equity Interests.

"Licensing Agreement" shall mean any U.S. Licensing Agreement or Ex-U.S. Licensing Agreement, in each case, excluding contracts with Distributors.

"Long Stop Date" shall mean September 30, 2025.

"Losses" shall mean judgments, debts, liabilities, expenses, costs, damages or losses, contingent or otherwise, whether liquidated or unliquidated, matured or unmatured, disputed or undisputed, contractual, legal or equitable, including loss of value, professional fees, including fees and disbursements of legal counsel on a full indemnity basis, and all costs incurred in investigating or pursuing any claim or any proceeding relating to any claim.

"Majority Purchasers" shall mean, at any time, Purchasers having at such time in excess of fifty percent (50%) of the sum of (i) the Commitments then in effect and (ii) the outstanding Funded Amount.

"Marketing Authorization" shall mean, with respect to the Product, the Governmental Approval required by applicable Law to Commercialize the Product including, to the extent required by applicable Law for the Commercialization of the Product, all pricing approvals and government reimbursement approvals.

"Material Adverse Effect" shall mean a material adverse effect on (i) the business, operations, financial condition, assets or liabilities of Holdings and its Subsidiaries taken as a whole, (ii) the ability of the Obligors, taken as a whole, to perform their payment obligations under the Transaction Documents, as and when due, (iii) the legality, validity, binding effect or enforceability of the Transaction Documents, or (iv) the rights, remedies and benefits available to, or conferred upon, the Administrative Agent or the Purchasers under any of the Transaction Documents

"Material Contract" shall mean any contract specifically related to the Product and the Commercialization and/or Development thereof required to be disclosed (including amendments thereto) under regulations promulgated under the Securities Act of 1933 or Securities Exchange Act of 1934, as may be amended. Notwithstanding the foregoing, employment and management contracts shall not be Material Contracts.

"MOIC" shall mean, as of any date of determination, the aggregate amount of payments received by the Purchasers under this Agreement, *divided* by the Funded Amount as of such date.

"Multiemployer Plan" shall mean any multiemployer plan, as defined in Section 400l(a)(3) of ERISA, to which any ERISA Affiliate incurs or otherwise has any obligation or liability, contingent or otherwise.

"NDA" shall mean a new drug application, submitted to the FDA pursuant to 21 U.S.C. § 355 seeking approval to market a new drug in the United States, or any equivalent application submitted to a Governmental Authority outside of the United States, and all supplements or amendments thereto.

"Net Sales" shall mean the gross amount billed, invoiced or otherwise recorded for sales of the Product anywhere in the world ("Gross Sales") by (or on behalf of, including through a Distributor) the Company and any of its Affiliates (each of the foregoing persons and entities, for purposes of this definition, shall be considered a "Selling Party"), for sales or other dispositions of the Product across all marketed indications and delivery forms to a Third Party by a Selling Party, less the sum of the following (to the extent not reimbursed by any Third Party and without duplication):

(a) reasonable and customary rebates, chargebacks, quantity, trade and similar discounts, credits and allowances and other price reductions reasonably and actually granted, allowed, incurred or paid;

(b) discounts (including cash discounts and quantity discounts), coupons, retroactive price reductions, charge back payments and rebates for sales paid for by managed care organizations or to Governmental Authorities (including, but not limited to, payments made under the "Medicare Part D Coverage Gap Discount Program" and the "Annual Fee for Branded Pharmaceutical Manufacturers" specific to the Product), in each case, as applied to sales of the Product and actually given to customers;

(c) reasonable and customary credits and allowances taken upon rejection, return or recall of the Product;

(d) reasonable and customary freight and insurance costs incurred with respect to the shipment of the Product to customers, in each case if charged separately and invoiced to customers;

(e) customs duties, surcharges and other similar governmental charges incurred in connection with the exportation or importation of the Product to the extent included in the gross amount invoiced;

(f) Value Added Tax, and that portion of annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-148) and any other fee imposed by any equivalent applicable Law, in each of the foregoing cases, that is allocable to sales of the Product in accordance with the Selling Party's standard policies and procedures consistently applied across its products, as adjusted for rebates and refunds, imposed in connection with the sales of the Product to any Third Party (excluding any taxes based on income); and

(g) actual uncollectible debt amounts with respect to sales of the Product, provided that if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid.

Such amounts shall be determined consistent with a Selling Party's customary practices, and in accordance with GAAP.

Sale or transfer of a Product between any of the Selling Parties shall not result in any Net Sales (unless the Selling Party purchaser or transferee is the ultimate end user of the Product), with Net Sales to be based only on any subsequent sales or dispositions to a non-Selling Party. For clarity, (i) Net Sales shall not include amounts or other consideration received by a Selling Party from a non-Selling Party in consideration of the grant of a (sub)license or co-promotion or distribution right to such non-Selling Party, provided that such consideration is not in lieu of all or a portion of the transfer price of the Product, (ii) sales to a Third Party distributor, wholesaler, group purchasing organization, pharmacy benefit manager, or retail chain customer shall be considered sales to a non-Selling Party to the extent that no additional consideration is received by a Selling Party for the subsequent use or re-sale by any such distributor, wholesaler, group purchasing organization, pharmacy benefit manager, or retail chain customer, as applicable, (iii) Net Sales by a Selling Party to a non-Selling Party consignee are not recognized as Net Sales by such Selling Party until the non-Selling Party consignee sells the Product, (iv) if a Selling Party receives in-kind consideration for the sale of the Product, then Net Sales shall be calculated as the fair market value of all consideration received by a Selling Party in respect of the Product, whether

such consideration is in cash, payment in kind, exchange or other form, as determined in good faith by the Selling Party and (v) Net Sales shall exclude transfers or dispositions for charitable, promotional, pre-clinical, clinical, or regulatory purposes, to the extent consideration is not received for such transfers or dispositions that is in excess of the fully burdened manufacturing cost of the applicable quantity of the Product so transferred or disposed.

With respect to sales of the Product invoiced in U.S. dollars, Net Sales shall be determined in U.S. dollars. With respect to sales of the Product invoiced in a currency other than U.S. dollars, Net Sales shall be determined by converting the currencies at which the sales are made into US. Dollars, at rates of exchange determined in a manner consistent with the Selling Party's method for calculating rates of exchange in the preparation of such person's annual financial statements in accordance with GAAP consistently applied. No amount for which deduction is permitted pursuant to this definition shall be deducted more than once.

If any Product is sold in a territory in combination with one or more other active pharmaceutical ingredients or therapeutic agents for a single invoice price (each a "Combination"), then the Net Sales for any such Product included in such Combination shall be calculated territory-by-territory by multiplying actual Net Sales of such Combination by the fraction A/(A+B) where "A" is the weighted average invoice price of the Product, when sold separately in such territory during the applicable accounting period in which the sales of the Combination were made, and "B" is the combined weighted average invoice prices of all of the active pharmaceutical ingredients or therapeutic agents other than the Product contained in such Combination, when sold separately in such territory during such same accounting period. If the Product or any of the other active pharmaceutical ingredients or therapeutic agents contained in such Combination is not sold separately in such territory during such accounting period, the Company and Majority Purchasers shall mutually determine the Net Sales for the Product included in such Combination based on the relative contribution of the Product and the other active pharmaceutical ingredients and therapeutic agents in the Combination in good faith and shall take into account in good faith any applicable allocations and calculations that may have been made for the same period in other countries. Notwithstanding anything to the contrary in the foregoing, with respect to any Combination Developed by the Company or any of its Affiliates, so long as the Combination involves any Product, the Net Sales for any such Product shall include all Net Sales of such Combination.

If the Company or any of its Affiliates recover monetary damages, settlement amounts or other monetary recovery with respect to the Product from a Third Party in a claim brought for infringement, misappropriation or other violation of any Intellectual Property, (A) such damages will be allocated first to the reimbursement of any expenses incurred by the Company or such Affiliates, as applicable, for bringing such action (including reasonable attorney's fees) not already reimbursed from other damages awarded under the same action, and (B) any remaining amount of such damages will be reduced, if and to the extent applicable, to allocate recovered damages to Third Party licensors of such Intellectual Property (other than damages for lost royalties), only as required under any then pre-existing license or other agreements, then any other remaining amount of such damages, settlement amounts or other monetary recovery after application of (A) and (B) will be included as Net Sales (provided, that none of the deductions from Net Sales in subsections (a) through (g) may be applied to such amounts).

"Oaktree Purchaser" shall mean any Purchaser that is an Affiliate or managed fund or account of Oaktree Capital Management, L.P.

"Oaktree Term Loan Facility" shall mean the Credit Agreement and Guaranty, dated as of May 9, 2024, by and among Verona Pharma, Inc., as the borrower, Holdings, as the guarantor, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as the administrative agent (as amended, amended and restated, supplemented or otherwise modified from time to time in accordance with the terms of the Intercreditor Agreement).

"Obligations" shall mean any and all obligations of the Obligors under the Transaction Documents.

"Obligors" shall mean, collectively, Holdings, the Company and the other grantors under the Security Agreement or the Debenture and their respective successors and permitted assigns.

"OFAC" shall have the meaning set forth in the definition of "Anti-Terrorism Laws."

"OMERS Purchasers" shall mean OCM Life Sciences Portfolio LP or any of its Affiliates.

"Option Right" shall have the meaning set forth in the definition of "Change of Control."

"Ordinary Course" shall mean ordinary course of business or ordinary trade activities that are customary for similar businesses in the normal course of their ordinary operations and not while in financial distress.

"Organic Document" shall mean, for any Person, such Person's formation documents, including, as applicable, its certificate of incorporation, by-laws, certificate of name change, constitutional documents, certificate of partnership, partnership agreement, certificate of formation, limited liability agreement, operating agreement and all shareholder agreements, voting trusts and similar arrangements applicable to such Person's Equity Interests, or any equivalent document of any of the foregoing.

"Other Connection Taxes" shall mean, with respect to any Purchaser, Taxes imposed as a result of a present or former connection between such Purchaser and the jurisdiction imposing such Tax (other than connections arising from such Purchaser having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Transaction Document, or sold or assigned an interest in any Transaction Document).

"Other Product" shall mean a product, other than the Product, that is owned or controlled by Obligor or any of its Subsidiaries and is Commercialized or otherwise subject to or has completed a Phase 3 or registrational clinical trial at the time of determination.

"Other Taxes" shall mean all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security

interest under, or otherwise with respect to, this Agreement, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

"Patents" shall mean (i) all domestic, national, regional and foreign patents, patent rights, patent applications, provisional applications, patent disclosures and Invention disclosures issued or filed, (ii) any patent applications filed from such patents, patent rights, patent applications, provisional applications, patent disclosures and Invention disclosures claiming priority to any of these, including renewals, divisionals, continuations, continuations-in-part, substitutions, provisionals, converted provisionals, and continued prosecution applications, (iii) any patents that have issued or in the future issue from the foregoing described in clauses (i) and (ii), including utility models, petty patents and design patents and certificates of invention, and (iv) all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations, revisions, and term extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications described in clauses (i), (ii) and (iii), including the Inventions claimed in any of the foregoing and any priority rights arising therefrom.

"Patriot Act" shall mean the USA PATRIOT Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)).

"Payment Period" shall mean the period from, and including, the first day of the first Fiscal Quarter through, and including the Fiscal Quarter in which this Agreement terminates pursuant to Section 6.01.

"Payment Recipient" shall have the meaning set forth in Section 8.14(a).

"PBGC" shall mean the United States Pension Benefit Guaranty Corporation referred to and defined in ERISA and any successor entity performing similar functions.

"Permitted Bond Hedge Transaction" shall mean any call or capped call option (or substantively equivalent derivative transaction) relating to Holdings' Common Shares or American Depositary Shares representing such Common Shares (or other securities or property following a merger event, reclassification or other change of the Common Shares) that is (A) purchased by Holdings in connection with the issuance of any Permitted Convertible Debt, (B) settled in Common Shares or American Depositary Shares (or such other securities or property), cash or a combination thereof (such amount of cash determined by reference to the price of the Common Shares or American Depositary Shares), and cash in lieu of fractional shares of Common Shares and (C) on terms and conditions customary for bond hedge transactions as reasonably determined by Holdings.

"Permitted Cash Equivalent Investments" shall mean (i) marketable direct obligations issued or unconditionally guaranteed by the United States, United Kingdom or any member states of the European Union or any agency or any state thereof having maturities of not more than one (1) year from the date of acquisition, (ii) commercial paper maturing no more than two hundred seventy (270) days after the date of acquisition thereof and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., (iii) certificates of deposit maturing no more than one (1) year after issue that are issued by any bank organized under the

Laws of the United States, or any state thereof, the District of Columbia or any non-U.S. jurisdiction, or any U.S. branch of a foreign bank having, at the date of acquisition thereof, combined capital and surplus of not less than $500,000,000 (or the Equivalent Amount in other currencies), (iv) any money market or similar funds that exclusively hold any of the foregoing and (v) any other Investments permitted by the Obligors' investment policy as in effect on the date hereof, and as amended from time to time with the prior written consent of the Administrative Agent.

"Permitted Convertible Debt" shall mean unsecured Indebtedness of Holdings or any of its Subsidiaries pursuant to clause (B) below, that is either (i) convertible into a fixed number (subject to customary conversion and adjustment rights for broadly distributed 144A convertible bond transactions as of the date of issuance) of the Common Shares, or American Depositary Shares representing such Common Shares (or other securities or property following a merger event or other change of the Common Shares), cash or a combination thereof (such amount of cash determined by reference to the price of the Common Shares or American Depositary Shares or such other securities or property), or cash in lieu of fractional Common Shares or (ii) sold as units with call options, warrants or rights to purchase (or substantially equivalent equity derivative transactions) that are exercisable for the Common Shares, or American Depositary Shares representing such Common Shares (or other securities or property following a merger event or other change of the Common Shares), cash or a combination thereof (such amount of cash determined by reference to the price of the Common Shares or American Depositary Shares or such other securities or property), or cash in lieu of fractional shares of the Common Shares; provided that any such Indebtedness shall (A) not require any scheduled amortization or otherwise require, pursuant to its terms, payment of principal prior to, (other than in connection with (x) any offer to purchase such Indebtedness as a result of "change of control", "fundamental change", "free float event" or any comparable term under and as defined in any indenture or other documents governing any Permitted Convertible Debt, (y) any early conversion of such Indebtedness in accordance with the terms thereof and (z) any redemption of such Indebtedness upon satisfaction of a condition related to the stock price of the Common Shares or American Depositary Shares representing such Common Shares), at least 180 days after the date this Agreement terminates in accordance with Section 6.01; provided, further that any right to require the scheduled amortization, payment, redemption or repurchase of such Permitted Convertible Debt shall be subject, to the satisfaction of the Majority Purchasers in its sole discretion, to the prior payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been asserted), (B) have recourse only to Holdings or be exchangeable notes issued by a Subsidiary of Holdings using a so-called "cash box" structure, under which each of the following conditions are met: (I) such Subsidiary is an Obligor; (II) the only assets of such Subsidiary are the cash proceeds of such exchangeable notes; (III) such exchangeable notes are only exchangeable into securities of Holdings; and (IV) the cash proceeds of such exchangeable notes are either held by such Subsidiary or are otherwise paid directly to Holdings, and (C) not have an all-in-yield greater than 500 basis points as determined in good faith by the Administrative Agent (with any original issue discount equated to interest based on the convertible debt maturity date and excluding any additional or special interest that may become payable from time to time).

"Permitted First Lien Intercreditor Agreement" shall have the meaning set forth in Section 7.18.

"Permitted Hedging Agreement" shall mean a Hedging Agreement entered into by Holdings or any of its Subsidiaries in the Ordinary Course for the purpose of hedging currency risks or interest rate risks (and not for speculative purposes) and (x) with respect to hedging currency risks, in an aggregate notional amount for all such Hedging Agreements not in excess of $12,000,000 (or the Equivalent Amount in other currencies) and (y) with respect to hedging interest rate risks, in an aggregate notional amount for all such Hedging Agreements not more than 50%, of the aggregate principal amount of Loans outstanding at such time.

"Permitted Indebtedness" shall mean:

(a) any payment obligations hereunder to the extent constituting Indebtedness;

(b) Indebtedness existing on the date hereof and set forth on Schedule 3.17 (a) and Permitted Refinancings thereof; provided, that, if such Indebtedness is intercompany Indebtedness, any Permitted Refinancing of such Indebtedness shall also be intercompany Indebtedness among the same parties;

(c) Indebtedness of an Obligor owing to any other Obligor;

(d) Indebtedness consisting of guarantees resulting from the endorsement of negotiable instruments for collection in the Ordinary Course;

(e) Permitted Priority Debt;

(f) Indebtedness with respect to letters of credit that are at any time outstanding and issued on behalf of Holdings or any Subsidiary in an amount not to exceed $1,200,000 (or the Equivalent Amount in other currencies) in the aggregate at any time;

(g) Guarantees by any Obligor of Permitted Indebtedness of any other Obligor;

(h) Ordinary Course equipment and software financing and leasing (including Capital Lease Obligations and purchase money Indebtedness); provided that (i) if secured, the collateral therefor consists solely of the assets being financed, the products and proceeds thereof and books and records related thereto and (ii) the aggregate outstanding principal amount of such Indebtedness does not exceed $6,000,000 (or the Equivalent Amount in other currencies) in the aggregate at any time;

(i) Indebtedness under (i) Permitted Hedging Agreements and (ii) Permitted Bond Hedge Transactions not exceeding, net of the proceeds of any Permitted Warrant Transactions entered in connection therewith, 20% of the net proceeds obtained in the related Permitted Convertible Debt issuance;

(j) Indebtedness assumed pursuant to any Acquisition and Permitted Refinancings thereof; provided that (i) no such Indebtedness (individually) shall exceed 20% of the total purchase price paid in connection with such Acquisition, (ii) the aggregate outstanding principal amount of Indebtedness permitted pursuant to this clause (j) shall not exceed $12,000,000 (or the Equivalent Amount in other currencies) at any time outstanding and (iii) no such Indebtedness was created or incurred in connection with, or in contemplation of, such Acquisition;

(k) other unsecured Indebtedness in an aggregate outstanding principal amount not to exceed $6,000,000 (or the Equivalent Amount in other currencies);

(l) Permitted Convertible Debt in an aggregate principal amount not to exceed $360,000,000 in principal amount at any time outstanding;

(m) Indebtedness in respect of (i) letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments issued or created, or related to obligations or liabilities incurred, in the Ordinary Course, (ii) workers compensation claims, health, disability or other employee benefits, or performance of commercial contracts, (iii) leases, subleases or liability insurance or self-insurance, workshare arrangements, or (iv) other Indebtedness with respect to reimbursement-type obligations regarding workers compensation claims;

(n) Indebtedness arising in connection with the financing of insurance premiums in the Ordinary Course;

(o) Indebtedness in respect of (i) customary performance bonds, bid bonds, appeal bonds, surety bonds, customs bonds, government bonds, performance and completion guarantees and similar obligations in each case arising in the Ordinary Course and (ii) customary indemnification obligations to purchasers in connection with asset sales;

(p) Indebtedness in respect of (i) netting services, (ii) overdraft protections, (iii) business credit cards, (iv) purchasing cards, (v) payment processing, (vi) automatic clearinghouse arrangements, (vii) arrangements in respect of pooled deposit or sweep accounts, (viii) check endorsement guarantees, and (ix) otherwise in connection with deposit accounts or cash management services, in each case, in the Ordinary Course; provided that the aggregate amount outstanding under clause (iii) shall not exceed $3,600,000 at any one time outstanding;

(q) customary purchase price adjustments, indemnity payments and other deferred purchase price obligations in connection with any permitted Acquisition;

(r) Indebtedness arising under a Permitted Revenue Financing; and

(s) Permitted Warrant Transactions that constitute Indebtedness.

"Permitted Licensing Agreement" shall mean (i) licenses of off-the-shelf software that is commercially available to the public, (ii) intercompany licenses or grants of rights for development, manufacture, production, commercialization (including commercial sales to end users), marketing, promotion, co-promotion, sales or distribution, which may be exclusive if each party to such license or grant is an Obligor at the time such license or grant is entered into, (iii) each license agreement existing on the Closing Date and set forth on Schedule 2 and (iv) any out-bound license granted for the use of Intellectual Property of any Obligor for development, manufacture, production, commercialization (including commercial sales to end users), marketing, promotion, co-promotion, sales or distribution of any Product, in each case, entered into in the Ordinary Course, which license may be (A) non-exclusive or exclusive if the territorial scope of such license is outside the United States and (B) with respect to the United States as the licensed territory, may only be non-exclusive (and shall not be exclusive) and may only be granted to service providers, including contract research organizations, contract manufacturing organizations, clinical trial sites

and other contractors for the exploitation of the Product; provided, that, with respect to each such license or grant described in clause (ii) and this clause (iv), (a) no Default or Event of Default has occurred and is continuing at the time such license or grant, or the agreement governing such license or grant is entered into and (b) such license or grant constitutes an Arm's Length Transaction, the terms of which do not provide for a sale or assignment, or control of Intellectual Property.

"Permitted Liens" shall mean:

(a) Liens created in favor of the Purchasers on or after the Effective Date pursuant to the Security Agreement and any other Transaction Document;

(b) Liens securing Indebtedness permitted under clause (h) of the definition of Permitted Indebtedness; provided that such Liens are restricted solely to the collateral described in clause (h) of the definition of "Permitted Indebtedness."

(c) Liens imposed by operation of Law arising in the Ordinary Course related to carriers', warehousemen's, landlords', and mechanics' liens, liens relating to leasehold improvements and other similar Liens arising in the Ordinary Course and which (x) are not in respect of Indebtedness for borrowed money, (y) do not in the aggregate materially detract from the value of the property subject thereto or materially impair the use thereof in the operations of the business of such Person or (z) are being contested in good faith by appropriate proceedings, which proceedings diligently conducted have the effect of preventing the forfeiture or sale of the property subject to such Liens and for which adequate reserves have been made if required in accordance with GAAP;

(d) pledges or deposits made in the Ordinary Course (i) in connection with bids, leases, appeal bonds, workers' compensation, unemployment insurance or other similar social security legislation or (ii) securing liability for reimbursement or indemnification obligations of (including obligations in respect of letters of credit or bank guarantees) insurance carriers providing property, casualty or liability insurance to Holdings or any Subsidiary;

(e) Liens for Taxes, assessments and other governmental charges not delinquent or that are being contested in good faith by appropriate proceedings diligently conducted, for which adequate reserves with respect thereto are being maintained in accordance with GAAP;

(f) any Liens set forth on Schedule 3.04(a) and renewals and extensions thereof in connection with Permitted Refinancings of the Indebtedness being secured by such Lien; provided that (i) no such Lien (including any renewal or extension thereof) shall extend to any other property or asset of any Obligor or any of its Subsidiaries (other than improvements and accession to such property or asset) and (ii) any such Lien shall secure only those obligations which it secures on the date hereof and renewals, extensions and replacements thereof in connection with Permitted Refinancings of the Indebtedness being secured by such Lien that do not increase the outstanding principal amount thereof (other than by an amount equal to unpaid interest and premiums thereon, required prepayment premiums, and any customary underwriting discounts, fees, commissions and expenses associated with such extension, renewal or replacement);

(g) servitudes, easements, rights of way, restrictions and other similar encumbrances on real property imposed by any Law and Liens consisting of zoning or building restrictions, easements, licenses, restrictions on the use of real property or minor imperfections in title thereto which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any Obligor or its Subsidiaries;

(h) with respect to any real property, (i) such defects or encroachments as might be revealed by an up-to-date survey of such real property, and such other defects in title that (A) do not interfere in any material respect with its ability to conduct its business as currently conducted or to utilize such properties for their intended purposes and (B) could not reasonably be expected to prevent or interfere with the ability of any Obligor or any of its Subsidiaries to conduct any Product Commercialization and Development Activities with respect to Ensifentrine in any material respect; (ii) the reservations, limitations, provisos and conditions expressed in the original grant, deed or patent of such property by the original owner of such real property pursuant to all applicable Laws; and (iii) rights of expropriation, access or user or any similar right conferred or reserved by or in any Law, which, in the aggregate for clauses (i), (ii) and (iii), are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any of any Obligor or its Subsidiaries;

(i) (i) Liens that are contractual or common law rights of set-off relating to (A) the establishment of depository relations in the Ordinary Course with banks not given in connection with the issuance of Indebtedness or (B) pooled deposit or sweep accounts of Holdings and any Subsidiary to permit satisfaction of overdraft or similar obligations incurred in the Ordinary Course, (ii) other Liens securing cash management obligations with depositary institutions (that do not constitute Indebtedness) in the Ordinary Course and (iii) Liens encumbering customary initial deposits and margin deposits and similar Liens attaching to commodity trading accounts or other brokerage accounts incurred in the Ordinary Course;

(j) Liens securing Indebtedness described in clause (j) of "Permitted Indebtedness"; provided that (i) such Lien is not created in contemplation of or in connection with such Acquisition pursuant to which such Indebtedness was assumed, (ii) such Lien shall not apply to any other property or assets of Holdings or any of its Subsidiaries and (iii) such Lien shall secure only those obligations that it secured immediately prior to the consummation of such Acquisition and any Permitted Refinancings thereof;

(k) Liens securing Indebtedness described in clauses (f), (m), (n), (o) and (p)of the definition of "Permitted Indebtedness;"

(l) any judgement Lien or Liens arising from decrees or attachments not constituting an Event of Default;

(m) Liens arising from precautionary UCC financing statement filings regarding operating leases of personal property and consignment arrangements entered into in the Ordinary Course;

(n) other Liens which secure obligations in an aggregate amount not to exceed $3,000,000 (or the Equivalent Amount in other currencies) at any time outstanding;

(o) Liens securing Indebtedness described in clause (e) and clause (r) of "Permitted Indebtedness" and subject to the Intercreditor Agreement or a Permitted First Lien Intercreditor Agreement and, if applicable, a Permitted Pari Passu Intercreditor Agreement;

(p) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods and incurred in the Ordinary Course;

(q) Liens on cash and Permitted Cash Equivalent Investments securing obligations under Permitted Hedging Agreements;

(r) (i) Liens to secure payment of workers' compensation, employment insurance, old age pensions, social security and other like social and welfare obligations incurred in the Ordinary Course (other than Liens imposed by ERISA) and (ii) deposits in respect of letters of credit, bank guarantees or similar instruments issued for the account of any Obligor or any Subsidiary in the Ordinary Course supporting obligations of the type set forth in clause (i) above;

(s) (i) with respect to Product Intellectual Property, Permitted Licensing Agreements, (ii) solely with respect to assets owned by third parties and licensed or leased to such Obligor or any of its Subsidiaries, retained interests or title of licensors or lessors that do not conflict with such Obligor's or any such Subsidiaries' use thereof and (iii) leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the Ordinary Course of any Obligor or any Subsidiary thereof;

(t) Liens solely on any cash earnest money deposits or customary cash escrow arrangements made by Holdings or any of the Subsidiaries in connection with any letter of intent or purchase agreement in respect of an Acquisition or other investment;

(u) Liens arising out of any sale-leaseback transaction, so long as such Liens attach only to the property sold and being leased in such transaction and any accessions and additions thereto or proceeds and products thereof and related property;

(v) Liens of sellers of goods to Holdings and any Subsidiaries arising under Article 2 of the UCC or otherwise in the Ordinary Course, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses; and

(w) any Lien arising under conditional sale, title retention, consignment or similar arrangements for the sale of goods in the Ordinary Course; provided that such Lien attaches only to the goods subject to such sale, title retention, consignment or similar arrangement;

provided that no Liens otherwise permitted under any of the foregoing shall apply to any Product Intellectual Property other than Liens incurred pursuant to clauses (a), (l), (o) and (s) of this "Permitted Liens" definition.

"Permitted Pari Passu Intercreditor Agreement" shall have the meaning set forth in Section 7.18.

"Permitted Priority Debt" shall mean:

(a) Indebtedness permitted under the Intercreditor Agreement in connection with a debtor-in-possession financing and

(b) Indebtedness in an aggregate principal amount not to exceed $480,000,000 at any time, so long as (i) such debt consists of the Oaktree Term Loan Facility, any Permitted Refinancing thereof or any other Indebtedness that does not refinance Permitted Priority Debt (and such other Indebtedness is subject to clauses (b) – (e) of the definition of Permitted Refinancing) and (ii) with respect to such Permitted Refinancings or other Indebtedness that does not refinance Permitted Priority Debt (and such other Indebtedness is subject to clauses (b) – (e) of the definition of Permitted Refinancing), as of the date of incurrence of such Indebtedness:

(1) the amounts drawn under all such Permitted Refinancings or other Indebtedness do not exceed the aggregate principal amount (i) that was drawn on the Oaktree Term Loan Facility plus (ii) an amount equal to 20% of the aggregate principal amount that was drawn under (A) the Oaktree Term Loan Facility or (B) if all commitments under the Oaktree Term Loan Facility have expired or been terminated and all obligations (other than contingent indemnification obligations not yet due) arising under the Oaktree Term Loan Facility have been paid in full in cash, any Permitted Refinancing of the Oaktree Term Loan Facility, plus (iii) any amounts that were undrawn but where the Company met:

(w) with respect to Tranche B Term Loans (as defined in the Oaktree Term Loan Facility), the Applicable Funding Condition (as defined in the Oaktree Term Loan Facility),

(x) with respect to Tranche C Term Loans (as defined in the Oaktree Term Loan Facility), Net Sales (as defined in the Oaktree Term Loan Facility and as of the end of a fiscal quarter on or prior to December 31, 2025) for the trailing six (6) consecutive month period exceeding $[***],

(y) with respect to Tranche D Term Loans (as defined in the Oaktree Term Loan Facility), Net Sales (as defined in the Oaktree Term Loan Facility and as of the end of a fiscal quarter on or prior to June 30, 2026) for the trailing twelve (12) consecutive month period exceeding $[***] and

(z) with respect to Tranche E Term Loans (as defined in the Oaktree Term Loan Facility), the consent of the applicable Lenders (as defined in the Oaktree Term Loan Facility); provided that such Tranche E Term Loans (as defined in the Oaktree Term Loan Facility) may only be included in this calculation if the conditions set forth above in clause (b)(1)(y) with respect to the funding of the Tranche D Term Loans (as defined in the Oaktree Term Loan Facility) has been met, and

(2) any future drawings under such Permitted Refinancings or other Indebtedness are subject to funding conditions that contain commercial milestone achievements related to Ensifentrine containing products (as agreed between the Company and the lender of such Permitted Refinancing or Indebtedness).

"Permitted Refinancing" shall mean, with respect to any Indebtedness permitted to be refinanced, extended, renewed or replaced hereunder, any refinancings, extensions, renewals and replacements of such Indebtedness; provided that such refinancing, extension, renewal or replacement shall not (a) increase the outstanding principal amount of the Indebtedness being refinanced, extended, renewed or replaced, except by an amount equal to accrued interest, any required prepayment premium and customary fees and expenses reasonably incurred, in connection with such refinancing, extension, renewal or replacement and by an amount equal to any existing commitments unutilized thereunder to the extent permitted under Permitted Priority Debt, (b) contain terms relating to amortization (if any), maturity, collateral security (if any) or subordination (if any), or other material terms that, taken as a whole, are less favorable in any material respect to the Obligors and their respective Subsidiaries or the Purchasers than the terms of any agreement or instrument governing such existing Indebtedness (as determined in good faith by the Company, provided, that if such Indebtedness is a revolving facility, the terms of such Indebtedness may have applicable market terms as determined in good faith by the Company), (c) have an applicable interest rate which does not exceed the greater of (i) the rate of interest of the Indebtedness being replaced and (ii) the then applicable market interest rate, (d) contain any new requirement to grant any Lien or to give any Guarantee that was not an existing requirement of such Indebtedness, and (e) after giving effect to such refinancing, extension, renewal or replacement, no Default shall have occurred (or would reasonably be expected to occur) as a result thereof.

"Permitted Revenue Financing" shall mean any additional revenue interest purchase and sale agreement or revenue interest financing agreement for the sale or pledge to a Person of no more than [***]% of Net Sales in the aggregate generated in the United States; provided, that such agreement shall be entered into no later than December 31, 2025, and such transaction is subject to a Permitted First Lien Intercreditor Agreement and a Permitted Pari Passu Intercreditor Agreement.

"Permitted Warrant Transaction" shall mean any call option, warrant or right to purchase (or substantively equivalent derivative transaction) relating to the Common Shares or American Depositary Shares representing such Common Shares (or other securities or property following a merger event, reclassification or other change of the Common Stock) sold by Holdings, substantially concurrently with any purchase by Holdings of a Permitted Bond Hedge Transaction and settled in Common Shares or American Depositary Shares, cash or a combination thereof (such amount of cash determined by reference to the price of the Common Shares or American Depositary Shares or such other securities or property), and cash in lieu of fractional shares of the Common Shares.

"Person" shall mean an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, but not including a government or political subdivision or any agency or instrumentality of such government or political subdivision.

"Plan" shall mean any employee pension benefit plan (other than a Multiemployer Plan) subject to the provisions of Title IV of ERISA or Section 412 of the Code or Section 302 of ERISA, and in respect of which the Company or any ERISA Affiliate is (or, if such plan were terminated, would under Section 4069 of ERISA be deemed to be) an "employer" as defined in Section 3(5) of ERISA.

"Pre-Funding Change of Control" shall mean a "Change of Control" that occurs prior to the Tranche A Funding Date.

"Pre-Funding Event of Default Fee" shall mean, (a) with respect to an Event of Default occurring prior to the Tranche A Funding Date (other than a Tranche A Funding Event of Default), an amount equal to $3,000,000 and (b) with respect to a Tranche A Funding Event of Default, an amount equal to $12,500,000.

"Primary Obligor" shall have the meaning set forth in the definition of "Guarantee."

"Product" shall mean (a) Ensifentrine in all dosage forms and indications, and (b) any current or future pharmaceutical product that contains Ensifentrine, either alone or in combination with one or more other active pharmaceutical ingredients of therapeutic agents.

"Product Agreement" shall have the meaning set forth in Section 3.14.

"Product Authorizations" shall mean any and all Governmental Approvals, whether U.S. or non-U.S. (including all applicable NDAs, INDs, supplements, amendments, governmental price and reimbursement approvals and approvals of applications for regulatory exclusivity) of any regulatory authority, in each case, necessary to be held or maintained by, or for the benefit of, any Obligor or any of its Subsidiaries for the ownership, use, Development and/or Commercialization of any Product or for any Product Commercialization and Development Activities with respect thereto in any country or jurisdiction.

"Product Commercialization and Development Activities" shall mean, with respect to any Product, any combination of research, Development, manufacture, import, use, sale, licensing, importation, exportation, shipping, storage, handling, design, labeling, marketing, promotion, supply, distribution, testing, packaging, purchasing or other Commercialization activities, receipt of payment in respect of any of the foregoing (including, in respect of licensing, royalty milestone or similar payments), or any similar or other activities the purpose of which is to commercially exploit such Product.

"Product Intellectual Property" shall mean Intellectual Property that (a) is Controlled by any Obligor or any of its Subsidiaries and (b) (i) claims, is embodied in, or covers the Product (or the manufacture or other use thereof) or (ii) is otherwise directly related to or otherwise necessary for any Product Commercialization and Development Activities, including any non-published and proprietary information or data contained in any NDA for the Product, including any U.S. Governmental Approvals of the Product, including U.S. Product Authorizations.

"Product Material Adverse Effect" shall mean (i) Material Adverse Effect or (ii) any material adverse effect on the Product, including the Obligors' ability to distribute, market and/or otherwise Commercialize the Product.

"Product Patent" shall mean any Patent that constitutes Product Intellectual Property.

"Prohibited Payment" shall mean any bribe, rebate, payoff, influence payment, kickback or other payment or gift of money or anything of value (including meals or entertainment) to any officer, employee or ceremonial office holder of any government or instrumentality thereof, political party or supra-national organization (such as the United Nations), any political candidate, any royal family member or any other person who is connected or associated personally with any of the foregoing that is prohibited under any Law for the purpose of influencing any act or decision of such payee in his official capacity, inducing such payee to do or omit to do any act in violation of his lawful duty, securing any improper advantage or inducing such payee to use his influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality.

"Proportionate Share" shall mean, with respect to any Purchaser, the percentage obtained by dividing (i) the sum of the Commitments then in effect and the outstanding Funded Amount of such Purchaser by (ii) the sum of the Commitments then in effect and the outstanding Funded Amount of all Purchasers.

"Purchase Price" shall mean, with respect to each tranche, the Tranche A Purchase Price and the Tranche B Purchase Price, as applicable.

"Purchasers" shall have the meaning set forth in the first paragraph hereof, and shall also include any permitted successors or assigns thereof.

"Purchasers Indemnified Party" shall have the meaning set forth in Section 7.05(a).

"Qualified Equity Interest" shall mean, with respect to any Person, any Equity Interest of such Person that is not a Disqualified Equity Interest.

"Qualified Plan" shall mean an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (i) that is or was at any time maintained or sponsored by the Company or any ERISA Affiliate thereof or to which the Company or any ERISA Affiliate thereof has ever made, or was ever obligated to make, contributions, and (ii) that is intended to be tax qualified under Section 401(a) of the Code.

"Quarterly Report" shall mean, with respect to the relevant Fiscal Quarter of the Company, a report showing (i) the Royalty Interest Payment, U.S. Licensing / Participation Payment and Ex-U.S. Licensing / Participation Payment due to the Administrative Agent for such Fiscal Quarter, which report shall include a calculation of Royalty Interest Payments, U.S. Licensing / Participation Payment and Ex-U.S. Licensing / Participation Proceeds, in each case, reconciled, to the extent applicable, with the consolidated statements of operations of Holdings and its Subsidiaries, including the calculation and adjustment from which such Royalty Interest Payments, Sales, U.S. Licensing / Participation Payment or Ex-U.S. Licensing / Participation Proceeds are derived, (ii) Net Sales as a percentage of Gross Sales for such Fiscal Quarter, and (iii) the number of units of the Product sold in such Fiscal Quarter; provided that, with respect to U.S. Licensing / Participation Payment and Ex-U.S. Licensing / Participation Payments received from a licensee of the Company, if the Company receives the applicable reporting from such licensee necessary for the Company to determine such licensee's U.S. Licensing / Participation Payment or Ex-U.S.

Licensing / Participation Payment fewer than ten (10) Business Days prior to the due date for a Quarterly Report (so long as the timing for receipt of such reporting is not set up in contemplation of this Agreement), the Company may, at its option, include such U.S. Licensing / Participation Payment or Ex-U.S. Licensing / Participation Payment, as applicable, on the Quarterly Report for the subsequent Fiscal Quarter and pay such U.S. Licensing / Participation Payment or Ex-U.S. Licensing / Participation Payment, as applicable, concurrently with delivery of such subsequent Quarterly Report in accordance with Section 2.02(c).

"Registered Product IP" shall mean all Product Intellectual Property that is issued by, registered with, renewed by or the subject of a pending application before any Governmental Authority or domain name registrar.

"Regulatory Agency" shall mean a Governmental Authority with responsibility for the approval of the manufacture, use, storage, import, export, transport, or Commercialization of the Product in the applicable jurisdiction.

"Requested Audit" shall have the meaning set forth in Section 5.01(d).

"RIPSA Account" shall mean that certain segregated deposit account for purposes of holding only the proceeds pursuant to Section 2.02(d)(i)and any minimum amounts required by the applicable depositary bank, which deposit account shall be at all times subject to an account control agreement pursuant to Section 5.18.

"RIPSA Sweep Amount" shall have the meaning set forth in Section 2.02(d).

"Royalty Interest Payment(s)" shall have the meaning set forth in Section 2.02(a).

"Sanction" shall mean any international economic or financial sanction or trade embargo imposed, administered or enforced from time to time by the United States Government (including, without limitation, OFAC), the United Nations Security Council, the European Union or its Member States, the United Kingdom (including His Majesty's Treasury) or other relevant sanctions authority where the Company is located or conducts business.

"Sanctioned Person" shall mean, at any time, (i) any Person listed in any Sanctions-related list of designated Persons maintained by the United States Government (including OFAC), the United Nations Security Council, the European Union or its Member States, the government of the United Kingdom (including His Majesty's Treasury), or other relevant sanctions authority, (ii) any Person organized or resident in a Designated Jurisdiction or (iii) any Person fifty percent (50%) or more owned or is controlled by any such Person or Persons described in the foregoing clause (i) or (ii).

"SEC" shall mean the U.S. Securities and Exchange Commission and any successor agency thereto.

"Secured Parties" shall mean the Purchasers, the Administrative Agent and any of their respective permitted transferees or assigns.

"Security Agreement" shall mean the Security Agreement among the Company, the other grantors thereto, and the Administrative Agent (in its capacity as administrative agent for the benefit of the Secured Parties under this Agreement), which Security Agreement shall be substantially in the form of Exhibit A, as may be amended, restated, amended and restated, supplemented or otherwise modified from time to time in accordance with the terms thereof.

"Subsidiary" shall mean, with respect to any Person (the "parent") at any date, any corporation, limited liability company, partnership, association or other entity of which securities or other ownership interests representing more than fifty percent (50%) of the equity or more than fifty percent (50%) of the ordinary voting power or, in the case of a partnership, more than fifty percent (50%) of the general partnership interests are, as of such date, owned, controlled or held, directly or indirectly. Unless otherwise specified, all references herein to a "Subsidiary" or to "Subsidiaries" shall refer to a Subsidiary or Subsidiaries of Holdings.

"Tax" or "Taxes" shall mean any federal, state, local or foreign tax, levy, impost, duty, assessment, fee, deduction or withholding (including backup withholding) or other charge, including all excise, sales, use, value added, transfer, stamp, documentary, filing, recordation and other fees imposed by any taxing authority (and interest, fines, penalties and additions related thereto).

"Tax Return" shall mean any report, return, form (including elections, declarations, statements, amendments, claims for refund, schedules, information returns or attachments thereto) or other information supplied or required to be supplied to a Governmental Authority with respect to Taxes.

"Term" shall have the meaning set forth in Section 6.01.

"Term Sheet" shall mean the Letter of Intent between Holdings and Oaktree Capital Management, L.P., dated March 15, 2024.

"Third Party" shall mean any Person other than the Purchasers or the Company and its Affiliates.

"Title IV Plan" shall mean an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (i) that is or was at any time maintained or sponsored by the Company or any ERISA Affiliate thereof or to which the Company or any ERISA Affiliate thereof has ever made, or was obligated to make, contributions, and (ii) that is or was subject to Section 412 of the Code, Section 302 of ERISA or Title IV of ERISA.

"Trade Secrets" shall mean all know-how, trade secrets and other proprietary or confidential information, any information of a scientific, technical, or business nature in any form or medium, Inventions and Invention disclosures, all documented research, developmental, demonstration or engineering work (including all novel manufacturing methods), and all other technical data, clinical data and information related thereto, including laboratory notebooks, chemical and biological materials (including any compounds, DNA, RNA, clones, vectors, cells and any expression product, progeny, derivatives or improvements thereto) and the results of experimentation and testing, including samples.

"Trademarks" shall mean all trade names, trademarks and service marks, trade dress, corporate names, logos, Internet domain names, IP addresses, social media handles, uniform resource locators and other indicia of origin, trademark and service mark registrations, and applications for trademark and service mark registrations, whether or not registered, and any and all common law rights thereto, including (a) all renewals of trademark and service mark registrations and (b) all rights whatsoever accruing thereunder or pertaining thereto throughout the world, together, in each case, with the goodwill of the business connected with the use thereof and symbolized thereby.

"Tranche A" shall mean a funding in the amount of the Tranche A Purchase Price.

"Tranche A Funding Condition" shall mean the occurrence of each of (i) Ensifentrine Approval by September 30, 2024, (ii) the actual funding of the Tranche B Term Loans (as defined in the Oaktree Term Loan Facility) and (iii) no Default, Event of Default, or Material Adverse Effect shall have occurred or be continuing. For the avoidance of doubt, the Tranche A Funding Conditions shall solely apply to funding and activities in connection with Tranche A and shall not apply with respect to Tranche B or any other event hereunder.

"Tranche A Funding Date" shall have the meaning set forth in Section 2.05(c) .

"Tranche A Funding Event of Default" shall have the meaning set forth in Section 2.05(b)(ii).

"Tranche A Purchase Price" shall mean $100,000,000.

"Tranche B" shall mean a funding in the amount of the Tranche B Purchase Price.

"Tranche B Funding Condition" shall mean the occurrence of (i) Tranche A Funding Date, (ii) Net Sales in the United States exceeding $[***] during any trailing six (6) month period, (iii) no Default or Event of Default shall have occurred or be continuing, and (iv) no Material Adverse Effect shall have occurred or be continuing.

"Tranche B Funding Date" shall have the meaning set forth in Section 2.05(c).

"Tranche B Purchase Price" shall mean an amount equal to $250,000,000 *minus* the Tranche A Purchase Price.

"Transaction Documents" shall mean, collectively, this Agreement, the Security Agreement, the Debenture, the Intercreditor Agreement, each Permitted First Lien Intercreditor Agreement, each Permitted Pari Passu Intercreditor Agreement, the Administrative Agent Fee Letter and any related ancillary documents or agreements (provided, for the avoidance of doubt, that any documents related to the Oaktree Term Loan Facility and any other Permitted Priority Debt other than the Intercreditor Agreement and any applicable Permitted First Lien Intercreditor Agreement or Permitted Pari Passu Intercreditor Agreement shall not be Transaction Documents).

"UCC" shall mean, with respect to any applicable jurisdictions, the Uniform Commercial Code as in effect in such jurisdiction, as may be modified from time to time.

"UCC Financing Statements" shall mean the UCC-1 financing statements, in form and substance reasonably satisfactory to the Administrative Agent and the Purchasers, that shall be filed by the Administrative Agent at or promptly following the Effective Date, as well as any additional UCC-1 financing statements or amendments thereto as reasonably requested from time to time, to perfect the Purchasers' security interest in the Collateral (as defined in the Security Agreement) and the Back-Up Security Interest.

"United States" or "U.S." shall mean the United States of America (including the District of Columbia, its territories and Puerto Rico).

"U.S. Licensing / Participation Proceeds" shall mean the portion of all license fees, commercial or sales-based milestone payments, up-front payments, or royalties (other than sales-based royalties) received by the Company or any of its Affiliates pursuant to any U.S. Licensing Agreements for the Product during the Payment Period.

"U.S. Licensing / Participation Payment(s)" shall have the meaning set forth in Section 2.02(a).

"U.S. Licensing / Participation Percentage" shall mean 6.50%.

"U.S. Licensing Agreement" shall mean any license, commercialization, co-promotion, collaboration, distribution, marketing or partnering agreement or other arrangement entered into during the Term by the Company or any of its Affiliates under which a Third Party has a right and license under the Product Intellectual Property to Commercialize the Product in the United States.

"Withdrawal Liability" shall mean, at any time, any liability incurred (whether or not assessed) by any ERISA Affiliate and not yet satisfied or paid in full at such time with respect to any Multiemployer Plan pursuant to Section 4201 of ERISA.

## ARTICLE II

## PURCHASE OF ASSIGNED INTERESTS

**Section 2.01 Purchase**.

(a) Upon the terms and subject to the conditions set forth in this Agreement, including the satisfaction of the Tranche A Funding Condition, the Company agrees to sell, assign, transfer and convey, and hereby sells, assigns, transfers and conveys, to the Purchasers, and the Purchasers agree, severally and not jointly, to purchase, acquire and accept, and hereby purchase, acquire and accept, from the Company, free and clear of all Liens (except Permitted Liens), all of the Company's rights, title and interests in and to the Assigned Interests on the Tranche A Funding Date, in accordance with such Purchasers' Proportionate Share as set forth on Schedule 1. The Purchasers' ownership interest in the Assigned Interests so acquired shall vest immediately and automatically upon the Company's receipt of payment of the Tranche A Purchase Price for such Assigned Interests, pursuant to Section 2.05(b), subject to the termination provisions of Section 6.01.

(b) The Company and Purchasers intend and agree that the sale, assignment, transfer and conveyance of the Assigned Interests under this Agreement shall be, and is, a true sale by the Company to Purchasers that is absolute and irrevocable and that provides Purchasers with the full benefits of ownership of the Assigned Interests, and neither the Company nor Purchasers intend the transactions contemplated hereunder to be, or for any purpose characterized as, a loan from Purchasers to the Company or a pledge or security agreement. The Company waives any right to contest or otherwise assert that this Agreement is other than a true sale by the Company to Purchasers under applicable Law, which waiver shall be enforceable against the Company in any bankruptcy or insolvency proceeding relating to the Company.

(c) The Company hereby consents to the recording and filing by the Administrative Agent, for the benefit of the Purchasers, financing statements and other security instruments (and any continuation statements or similar instruments with respect to such financing statements or security instruments when applicable) meeting the requirements of applicable Law in such manner and in such jurisdictions as are necessary or appropriate to (i) evidence, attach or perfect the sale, assignment, transfer and conveyance by the Company to Purchasers, and the purchase, acquisition and acceptance by Purchasers from the Company, of the respective Assigned Interests and (ii) perfect the security interest in the Assigned Interests granted by the Company to the Administrative Agent, for the ratable benefit of the Purchasers, pursuant to Section 2.01(e).

(d) The Company intends for the conveyance to Purchasers of the Assigned Interests to be reflected on the Company's balance sheet and other financial statements as a sale of the Assigned Interests to Purchasers and shall be reflected on Purchasers' balance sheets and other financial statements as a purchase of the Assigned Interests from Company; provided that the foregoing statements shall not bind the parties hereto regarding the reporting of the transactions contemplated by the Transaction Documents for GAAP and SEC reporting purposes in accordance with applicable Law.

(e) Notwithstanding that the Company and Purchasers expressly intend for the sale, assignment, transfer and conveyance of the Assigned Interests to be a true, complete, absolute and irrevocable sale and assignment, in the event that any transfer of the Assigned Interests contemplated by this Agreement is held not to be a sale, the Company hereby assigns, conveys, grants and pledges to the Administrative Agent, for the ratable benefit of the Purchasers, as security for the Company's Obligations hereunder, a security interest in and to all of the Company's right, title and interest in, to and under the Assigned Interests, whether now owned or hereafter acquired, and any proceeds (as such term is defined in the UCC) thereof (the "Back-Up Security Interest") and, solely in such event, this Agreement shall constitute a security agreement. The Company agrees to, and to cause its Affiliates to, promptly execute, acknowledge, deliver and cause to be filed all instruments and documents and take all other actions as the Administrative Agent may from time to time request in order to assure, obtain, perfect, preserve and protect the Back-Up Security Interest. The Company authorizes the Administrative Agent on behalf of the Purchasers to file any UCC Financing Statements or other filings in any jurisdiction (or similar filings) in respect of the Back-Up Security Interest in form and substance reasonably satisfactory to the Administrative Agent naming the Company as the debtor and describing the collateral covered thereby as the Back-Up Security Interest.

(f) Each of Obligors agrees to, and to cause its Subsidiaries to grant a security interest in the Product Intellectual Property and the RIPSA Account and any proceeds of and all amounts received or receivable under the Product Intellectual Property and the RIPSA Account including executing the Security Agreement and the Debenture and any other collateral documents, promptly execute, acknowledge, deliver and cause to be filed all instruments and documents and take all other actions as the Administrative Agent may from time to time reasonably request in order to assure, obtain, perfect, preserve and protect such security interest.

**Section 2.02 Payments by the Company**.

(a) Payments in Respect of the Assigned Interests. In connection with the purchase of the Assigned Interests, and subject to the terms and conditions of this Agreement, the Purchasers shall be entitled to receive (i) an amount equal to the product of the Applicable Percentage multiplied by the applicable Net Sales during the Payment Period (such payments, the "Royalty Interest Payments"), (ii) an amount equal to the product of the U.S. Licensing / Participation Percentage multiplied by the U.S. Licensing / Participation Proceeds during the Payment Period (such payments, the "U.S. Licensing / Participation Payments") and (iii) an amount equal to the product of the Ex-U.S. Licensing / Participation Percentage multiplied by the Ex-U.S. Licensing / Participation Proceeds during the Payment Period (such payments, the "Ex-U.S. Licensing / Participation Payments") ((i), (ii) and (iii) together, the "Assigned Interest Payments"), as provided in this Section 2.02.

(b) Hard Cap. Notwithstanding anything else set forth herein to the contrary, in no event shall the aggregate amount of Royalty Interest Payments, U.S. Licensing / Participation Payments and Ex-U.S. Licensing / Participation Payments made by Company to the Purchasers under this Agreement exceed the Hard Cap as calculated at such time.

(c) Quarterly Payments. On a quarterly basis for each Fiscal Quarter during the Payment Period (subject to the Hard Cap), concurrently with the delivery of the Quarterly Report to the Administrative Agent as set forth in Section 5.01(f) (but in no event later than sixty (60) days following the end of each Fiscal Quarter), the Company shall pay to the Administrative Agent, for the account of the Purchasers, an amount equal to the Royalty Interest Payments, U.S. Licensing / Participation Payments and the Ex-U.S. Licensing / Participation Payment, as applicable, for such Fiscal Quarter to the Administrative Agent for the account of the Purchasers. Except as otherwise provided in this Agreement, each payment by the Company will be deemed to be made ratably in accordance with the Purchasers' Proportionate Shares.

(d) Payments into the RIPSA Account.

(i) Each Obligor shall, and shall cause all of its Subsidiaries to, deposit into the RIPSA Account (such amount, collectively, the "RIPSA Sweep Amount"):

(A) 4.50% of the amounts actually received by the Company and any of its Affiliates for the sales or other dispositions of the Product (x) between the first day of each calendar month to the 15th day of the calendar month, by no later than five (5) Business Days after the 15th day of each calendar month and (y) between the 16th day of

the calendar month through the end of the calendar month, by no later than five (5) Business Days after the end of each calendar month,

(B) 5.0% of any Ex-U.S. Licensing / Participation Proceeds received by the Company or any of its Affiliates, by no later than seven (7) Business Days after any such receipt,

(C) 6.50% of any U.S. Licensing / Participation Proceeds received by the Company or any of its Affiliates, by no later than seven (7) Business Days after any such receipt,

(ii) By no later than forty-five (45) days after each Fiscal Quarter, the Company shall calculate the Assigned Interest Payment with respect to such Fiscal Quarter, and shall (x) deposit into the RIPSA Account an amount equal to the extent the Assigned Interest Payment exceeds the balance in the RIPSA Account or (y) withdraw from the RIPSA Account an amount equal to the extent the balance in the RIPSA Account exceeds the Assigned Interest Payment.

(iii) Payment Procedure. Any payments to be made by the Company to the Purchasers hereunder or under any other Transaction Document shall be made by wire transfer of immediately available funds to the account designated by the Administrative Agent prior to the date thereof. In the event that any payment is due on a day that is not a Business Day, such payment shall be due on the next Business Day. Any payments to be made by the Company to the Purchasers hereunder or under any other Transaction Document shall be properties of the Purchasers and shall be deemed to be held by the Company in trust for the Purchasers.

(e) Effectiveness. Notwithstanding the foregoing, the payment provisions set forth in Section 2.02 shall only become operative upon the occurrence of the Tranche A Funding Date.

**Section 2.03 Payment in Respect of Event of Default**.

(a) Payment in Respect of Pre-Funding Change of Control. With respect to a Pre-Funding Change of Control, the Company shall notify the Purchasers and the Administrative Agent in writing as soon as possible and in any event at least six (6) Business Days prior to the occurrence of such Pre-Funding Change of Control. The applicable Pre-Funding Event of Default Fee shall automatically be due and payable concurrently with the consummation of such Pre-Funding Change of Control. The payment of such Pre-Funding Event of Default Fee shall be made by wire transfer of immediately available funds to the Administrative Agent for the account of the Purchasers. The Purchasers may not fund Tranche A or Tranche B upon the Company's entry into any agreement that would result in a Pre-Funding Change of Control.

(b) Payment in Respect of Tranche A Funding Event of Default. With respect to a Tranche A Funding Event of Default, the applicable Pre-Funding Event of Default Fee shall automatically be due and payable immediately upon the occurrence of such Tranche A Funding Event of Default, the payment of which shall be made by wire transfer of immediately available funds to the Administrative Agent for the account of the Purchasers.

(c) Payment in Respect of Bankruptcy Event of Default. With respect to a Bankruptcy Event of Default, the Company shall notify the Purchasers and the Administrative Agent in writing as soon as possible. Immediately upon the occurrence of such Bankruptcy Event of Default, the applicable Pre-Funding Event of Default Fee (in the event such Bankruptcy Event of Default occurs prior to the Tranche A Funding Date) or Event of Default Fee (in the event such Bankruptcy Event of Default occurs after the Tranche A Funding Date) shall automatically (without any action or notice by any of the Purchasers) be due and payable, the payment of which shall be made by wire transfer of immediately available funds to the Administrative Agent for the account of the Purchasers.

(d) Payment in Respect of Other Event of Default. With respect to an Event of Default other than a Pre-Funding Change of Control, Tranche A Funding Event of Default or Bankruptcy Event of Default, the Company shall notify the Purchasers and the Administrative Agent in writing as soon as possible and in any event (i) within two (2) Business Days following the occurrence of any Event of Default during the Term (other than a Change of Control) or (ii) with respect to a Change of Control, at least six (6) Business Days prior to the occurrence (whereby occurrence shall mean closing) of such Change of Control, identifying the nature of such Event of Default. Upon the occurrence of such Event of Default, the Purchasers may demand, unanimously and in writing, the payment of a Pre-Funding Event of Default Fee (in the event such Event of Default occurs prior to the Tranche A Funding Date) or an Event of Default Fee (in the event such Event of Default occurs after the Tranche A Funding Date) and terminate the Agreement pursuant to Section 6.01. In the event the Purchasers unanimously make such demand in writing, (i) the Pre-Funding Event of Default Fee or Event of Default Fee (other than in respect of a Change of Control occurring after the Tranche A Funding Date), as applicable, shall be due and payable within five (5) Business Days after delivery of such demand in writing and (ii) the Event of Default Fee in respect of a Change of Control occurring after the Tranche A Funding Date shall be due and payable concurrently with the consummation of such Pre-Funding Change of Control. The payment of such Pre-Funding Event of Default Fee or Event of Default Fee shall be made by wire transfer of immediately available funds to the Administrative Agent for the account of the Purchasers.

(e) Liquidated Damages Treatment. The Company agrees that each of the Pre-Funding Event of Default Fee and Event of Default Fee shall be presumed to be the liquidated damages sustained by each Purchaser (including in the case of a Pre-Funding Event of Default Fee or Event of Default Fee in respect of a Bankruptcy Event of Default), and the Company agrees that such presumption is reasonable under the circumstances currently existing. Each of the Pre-Funding Event of Default Fee and Event of Default Fee shall also be due and payable in the event that this Agreement is satisfied or released by foreclosure (whether or not by power of judicial proceeding), deed in lieu of foreclosure or any other means. In the event the Pre-Funding Event of Default Fee or Event of Default Fee is determined not to be due and payable by order of any court of competent jurisdiction, including by operation of the Bankruptcy Code, despite such an Event of Default having occurred, the Pre-Funding Event of Default Fee or Event of Default Fee shall nonetheless constitute Obligations for all purposes. THE COMPANY EXPRESSLY WAIVES THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE OR LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF THE PRE-FUNDING EVENT OF DEFAULT FEE OR EVENT OF DEFAULT FEE, WHETHER SUCH DEFENSE MAY BE BASED IN PUBLIC POLICY, AMBIGUITY, OR OTHERWISE. The Company and the Purchasers acknowledge and

agree that any Pre-Funding Event of Default Fee or Event of Default Fee due and payable in accordance with this Agreement shall not constitute unmatured interest, whether under Section 502(b)(3) of the Bankruptcy Code or otherwise. The Company further acknowledges and agrees, and waives any argument to the contrary, that payment of such amount does not constitute a penalty or an otherwise unenforceable or invalid obligation. The Company expressly agrees that (i) each of the Pre-Funding Event of Default Fee and Event of Default Fee is reasonable and is the product of an Arm's Length Transaction between sophisticated business people, ably represented by counsel, (ii) each of the Pre-Funding Event of Default Fee and Event of Default Fee shall be payable notwithstanding the then-prevailing market rates at the time payment is made, (iii) there has been a course of conduct between the Purchasers and the Company giving specific consideration in the transactions contemplated hereby for such agreement to pay the Pre-Funding Event of Default Fee and Event of Default Fee, (iv) the Company shall not challenge or question, or support any other Person in challenging or questioning, the validity or enforceability of the Pre-Funding Event of Default Fee or Event of Default Fee, and shall be estopped from raising or relying on any judicial decision or ruling questioning the validity or enforceability of any such fee similar or comparable to the Pre-Funding Event of Default Fee or Event of Default Fee, or from claiming differently than as agreed to in this Section 2.03(e) , and (v) each of the Pre-Funding Event of Default Fee and Event of Default Fee represents a good faith, reasonable estimate and calculation of the lost profits, losses or other damages of the Purchasers and that it would be impractical and extremely difficult to ascertain the actual amount of damages to the Purchasers or profits lost by the Purchasers as a result of such event. The Company expressly acknowledges that its agreement to pay the Pre-Funding Event of Default Fee and Event of Default Fee to the Purchasers as herein described are individually and collectively a material inducement to Purchasers to enter into this Agreement.

**Section 2.04 Agent Fees**. The Company agrees to pay to the Administrative Agent such fees and expenses in the amounts and at the times separately agreed upon as set forth in the Administrative Agent Fee Letter. Such fees shall be fully earned when paid and shall not be refundable for any reason whatsoever.

**Section 2.05 Effective Date; Effective Date Deliveries; Payment of Purchase Price; Payments by the Company**.

(a) Effective Date. This Agreement shall become effective subject to the fulfillment, to the sole satisfaction of the Purchasers, of all of the following conditions precedent:

(i) This Agreement and the other Transaction Documents shall have been executed and delivered to the Purchasers by each party thereto, and the Obligors shall have delivered, or caused to be delivered, such other documents as the Administrative Agent reasonably requests, in each case, in form and substance satisfactory to the Administrative Agent.

(ii) The Company shall have delivered to the Administrative Agent (x) a copy of a good standing certificate of the Company, dated a date reasonably close to the Effective Date, and (y) a duly executed secretary's certificate of each Obligor, each dated as of the Effective Date, as to: (a) resolutions of the Board of the applicable Obligor, then in full force and effect authorizing the execution, delivery and performance of each Transaction Document to be executed by the applicable Obligor; (b) the incumbency and signatures of officers authorized to execute and deliver

each Transaction Document to be executed by the applicable Obligor; and (c) the full force and validity of the articles or certificate of incorporation or bylaws (or other organizational or constitutional documents) of each Obligor, and copies thereof; which certificate shall be in form and substance reasonably satisfactory to the Administrative Agent.

(iii) The Purchasers shall have received executed counterparts of the Security Agreement and the Debenture, each in form and substance reasonably acceptable to the Purchasers, dated as of the Effective Date, duly executed and delivered by the applicable grantors, together with all documents required to be delivered or filed under the Security Agreement and the Debenture and evidence satisfactory to it that arrangements have been made with respect to all registrations, notices or actions required under the Security Agreement and the Debenture to be effected (including the UCC Financing Statements), given or made in order to establish a valid and perfected security interest in the Collateral in accordance with the terms of the Security Agreement, the Debenture and the Intercreditor Agreement.

(iv) The representations and warranties made by the Company in Article III hereof and in the other Transaction Documents shall be true and correct in all material respects as of the Effective Date, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall be true and correct in all material respects as of such earlier date (except that any representation or warranty that is qualified as to "materiality" or "Material Adverse Effect" shall be true and correct in all respects).

(v) [Reserved].

(vi) No Default, Event of Default or Material Adverse Effect shall have occurred or be continuing.

(vii) The Purchasers shall have received satisfactory evidence that each Obligor has obtained all required consents and approvals of all Persons to the execution, delivery and performance of this Agreement and the other Transaction Documents and the consummation of the transactions contemplated hereunder and thereunder.

(viii) The Company shall have delivered to the Administrative Agent and the Purchasers an opinion of counsel to each Obligor reasonably acceptable to the Administrative Agent and the Purchasers, and their respective counsel as to matters relating to the Obligors and the Transaction Documents.

(ix) The Administrative Agent shall have received the Financial Statements, or such information shall be publicly available on "EDGAR".

(x) The Administrative Agent shall have received a certificate in form and substance reasonably satisfactory to the Purchasers, dated as of the Effective Date, duly executed and delivered by an officer of the Company, certifying that the conditions set forth in clause (iv) and (vi) of this Section 2.05(a) have been satisfied.

(xi) The Administrative Agent shall be satisfied with Lien searches regarding the Obligors made as of a date reasonably close to the Effective Date.

(xii) Tranche A Term Loans (as defined under the Oaktree Term Loan Facility) shall have been funded.

(b) Purchase Procedures.

(i) The obligation of the Company to sell each Applicable Tranche, and of each Purchaser to pay the applicable Purchase Price is subject to (i) with respect to Tranche A, (x) satisfaction of the Tranche A Funding Condition and (y) a request by the Company for the Tranche A funding, made by the Company within three (3) Business Day after satisfaction of the Tranche A Funding Condition by delivering to the Administrative Agent and the Purchasers an irrevocable funding notice ("Funding Notice") in the form of Exhibit C signed by a duly authorized representative of the Company (which notice, if received by the Purchasers on a day that is not a Business Day or after 10:00 A.M. (Eastern time) on a Business Day, shall be deemed to have been delivered on the next Business Day), and (ii) with respect to Tranche B, (x) satisfaction of the Tranche B Funding Condition and (y) a request by the Company for the Tranche B funding, made by the Company at least five (5) Business Days prior to the requested funding date by delivering to the Administrative Agent and the Purchasers an irrevocable Funding Notice in the form of Exhibit C signed by a duly authorized representative of the Company (which notice, if received by the Purchasers on a day that is not a Business Day or after 10:00 A.M. (Eastern time) on a Business Day, shall be deemed to have been delivered on the next Business Day). Each Funding Notice shall be for the full amount of the Applicable Tranche and no Funding Notice for less than such full amount shall be permitted.

(ii) The funding of Tranche A shall not be optional and the Company shall be obligated to request the Tranche A funding within three (3) Business Days of the satisfaction of the Tranche A Funding Condition. It shall be a Tranche A Funding Event of Default if the Company fails to request the Tranche A funding within three (3) Business Days of satisfaction of the Tranche A Funding Condition (a "Tranche A Funding Event of Default"). The funding of Tranche B shall be at the Company's option, and the Company has no obligation to request or accept the Tranche B funding.

(c) Payment of Purchase Price. Each Purchaser shall pay its Proportionate Share of the Tranche A Purchase Price or Tranche B Purchase Price, as applicable, solely by wire transfer in immediately available funds, by 2:00 p.m. New York City Time on the fifth ($5^{th}$) day following such Purchaser's receipt of a Funding Notice from the Company (respectively, the "Tranche A Funding Date" and "Tranche B Funding Date") to the account of the Administrative Agent most recently designated by it for such purpose by notice to the Purchasers. The requirement of the Purchasers to pay its Proportionate Share of the Applicable Tranche shall be subject to the representations and warranties being made by the Company in Article III hereof being true and correct in all material respects as of the Applicable Funding Date, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall be true and correct in all material respects as of such earlier date (except that any representation or warranty that is qualified as to "materiality" or "Material Adverse Effect" shall be true and correct in all respects). The Applicable Funding Condition may be waived by mutual agreement by the Purchasers and the Company each in their sole discretion.

(d) Payment of the Purchase Price by the Purchasers shall have no contingencies other than as set forth in Section 2.05(b) above.

(e) Notwithstanding anything to the contrary in this Agreement, in no event shall the Tranche B Funding Date occur after the Long Stop Date.

**Section 2.06 No Assumed Obligations**. Notwithstanding any provision in this Agreement or any other writing to the contrary, the Purchasers are acquiring only the Assigned Interests and are not assuming any liability or obligation of the Company or any of its Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter, whether under any Transaction Document or otherwise (the "Excluded Liabilities and Obligations"). The Purchasers expressly do not assume or agree to be responsible for any Excluded Liabilities and Obligations and all such liabilities and obligations shall be retained by and remain solely obligations and liabilities of the Company or its Affiliates.

**Section 2.07 No Financial Accommodation**. The Company hereby acknowledges, covenants and agrees that: (i) this Agreement does not, and shall not, constitute a "financial accommodation agreement" pursuant to Section 365(c)(2) of the Bankruptcy Code, (ii) it shall not take a position to the contrary in any court of competent jurisdiction including any bankruptcy court, and (iii) it will not initiate, or assert in, any litigation or other legal proceeding that this Agreement does or may constitute a "financial accommodation agreement" under Section 365(c)(2) of the Bankruptcy Code.

## ARTICLE III

## REPRESENTATIONS AND WARRANTIES OF OBLIGORS

Each Obligor hereby represents and warrants to the Administrative Agent and the Purchasers, as of the Effective Date and as of each Applicable Funding Date, the following:

**Section 3.01 Power and Authority**. Each of the Obligors and its Subsidiaries (i) is duly organized or incorporated, as applicable, and validly existing under the laws of its jurisdiction of organization, (ii) has all requisite corporate or other power, and has all Governmental Approvals necessary to own its assets and carry on its business as now being or as proposed to be conducted, except to the extent that failure to have the same would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (iii) is qualified to do business and is in good standing in all jurisdictions in which the nature of the business conducted by it makes such qualification necessary except where failure so to qualify would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, and (iv) has full power, authority and legal right to enter into and perform its obligations under each of the Transaction Documents to which it is a party and, in the case of the Obligors, to incur the Obligations under the Transaction Documents.

**Section 3.02 Authorization; Enforceability**. Each transaction as contemplated under the Transaction Documents to which an Obligor is a party (or to which it or any of its assets or properties is subject) is within such entity's corporate or other organizational powers and has been duly authorized by all necessary corporate or other organizational action including, if required,

approval by all necessary holders of Equity Interests. This Agreement has been duly executed and delivered by the Company and constitutes, and each of the other Transaction Documents to which any Obligor is a party when executed and delivered by such entity will constitute, a legal, valid and binding obligation of such entity, enforceable against such entity in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium receivership, liquidation, examinership or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

**Section 3.03 Governmental and Other Approvals; No Conflicts**. None of the execution, delivery and performance by each Obligor of the Transaction Documents to which it is a party or the consummation by each Obligor of the transactions thereunder, (i) requires any Governmental Approval of, registration or filing with, or any other action by, any Governmental Authority or any other Person, except for (x) such as have been obtained or made and are in full force and effect (y) filings and recordings in respect of perfecting or recording the Liens created pursuant to the Security Agreement and the Debenture and (z) filings required under applicable securities laws, (ii) will violate (1) any Law, (2) any Organic Document of any Obligor or any of its Subsidiaries or (3) any order of any Governmental Authority, that in the case of Clause (ii)(1) or (ii)(3), individually or in the aggregate, would reasonably be expected to result in a Material Adverse Effect, (iii) will violate or result in a default under any Product Agreement binding upon any Obligor or any of its Subsidiaries that, individually or in the aggregate, would reasonably be expected to result in a Material Adverse Effect or (iv) will result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of any Obligor or any of its Subsidiaries.

**Section 3.04 Ownership**.

(a) Upon the Tranche A Funding Date, the Purchasers will have acquired good and marketable title to the Assigned Interests, free and clear of all Liens, except for any Lien contemplated by clauses (a), (c), (d), (e), or (i) of the definition of Permitted Liens.

(b) The Obligors Control all of the Product Intellectual Property and any other Governmental Approvals directly related to the Product that such Obligors purport to Control, in each case, free and clear of all Liens (other than Permitted Liens). None of the Obligors has entered into any Product Agreement granting any license or covenant not to sue under any Product Intellectual Property, except for Permitted Licensing Agreements.

(c) The Obligors own, and are the sole holders of, and/or have and hold a valid, written, enforceable and subsisting license to, all of those other assets of which such Obligors are aware that are material to, or otherwise necessary for, the conduct of their business related to the Product (including any Product Commercialization and Development Activities), in each case free and clear of any and all Liens (other than Permitted Liens). Except as set forth on Schedule 3.04(c), none of the Obligors has transferred, sold, or otherwise disposed of, or agreed to transfer, sell, or otherwise dispose of any portion of the Net Sales or Assigned Interests other than as contemplated by this Agreement.

**Section 3.05 Financial Statements; Material Adverse Event**.

(a) As of the Effective Date, the Company has heretofore furnished to the Purchasers the Financial Statements. The Company has heretofore furnished to the Administrative Agent (who shall forward to the Purchasers) consolidated financial statements required to be delivered pursuant to this Agreement. Such financial statements or Financial Statements, as applicable, present fairly, in all material respects, the consolidated financial position and results of operations and cash flows of Holdings and its Subsidiaries as of such dates and for such periods in all material respects in accordance with GAAP.

(b) Since December 31, 2023, there has been no Material Adverse Event.

**Section 3.06 No Undisclosed Liabilities**. Except for those liabilities (a) identified in the Financial Statements (including the notes thereto), (b) incurred by the Obligors in the Ordinary Course since December 31, 2023, or (c) in connection with the Obligations under the Transaction Documents, there are no material liabilities of any Obligor or its Subsidiaries related to the Product, of any kind whatsoever, whether accrued, contingent, absolute, determined or determinable.

**Section 3.07 Solvency**. Assuming consummation of the transactions contemplated by the Transaction Documents, (a) the present fair saleable value of the Obligors and their Subsidiaries' assets on a consolidated basis is greater than the total amount of liabilities of the Obligors and their Subsidiaries as such liabilities mature, (b) the Obligors and their Subsidiaries, taken as a whole, do not have unreasonably small capital with which to engage in its business, and (c) the Obligors and their Subsidiaries, taken as a whole, have not incurred, nor do they have present plans to or intend to incur, debts or liabilities beyond their ability to pay such debts or liabilities as they become absolute and matured.

**Section 3.08 Litigation**. Other than as disclosed on Schedule 3.08 : (a) there is no action, suit, arbitration proceeding, claim, investigation or other proceeding pending or, to the knowledge of any Obligor, threatened in writing against any Obligor or its Subsidiaries or any governmental inquiry pending or, to the knowledge of any Obligor, threatened in writing against any Obligor or its Subsidiaries, in each case which would question the validity of, or would have a Material Adverse Effect on the transactions contemplated by any of the Transaction Documents; and (b) there is no action, suit, arbitration proceeding, claim, investigation or other proceeding pending or, to the knowledge of any Obligor, threatened in writing against any Obligor or its Subsidiaries or, to the knowledge of any Obligor, any other Person relating to the Product, the Product Intellectual Property, the Governmental Approvals of the Product, or the Assigned Interests.

**Section 3.09 Compliance with Laws and Agreements**.

(a) None of the Obligors or their Subsidiaries (i) is in material violation of, or to the knowledge of any Obligor, is under investigation with respect to, or, (ii) to the knowledge of any Obligor, has been threatened to be charged with or been given notice of any material violation of, in each case (i) and (ii), any law, rule, ordinance or regulation of, or any judgment, order, writ, decree, permit or license entered by any Governmental Authority applicable to such Obligor, or the Assigned Interests. Each Obligor is in compliance with all Contracts binding upon it or its

property, except, in each case, where the failure to do so would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(b) The Obligors are, and all Product Commercialization and Development Activities of such Persons are being conducted, in compliance with all applicable Healthcare Laws, except where such failure to comply would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

**Section 3.10 Conflicts**. Neither the execution and delivery of any of this Agreement or the other Transaction Documents to which any Obligor is a party nor the performance or consummation of the transactions contemplated hereby or thereby will: (a) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects any provisions of: (i) any law, rule, ordinance or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which any Obligor or its Subsidiaries or any of their respective assets or properties may be subject or bound; or (ii) any contract, agreement, commitment or instrument to which any Obligor or its Subsidiaries is a party or by which any Obligor or its Subsidiaries or any of their respective assets or properties is bound or committed; (b) contravene, conflict with or result in a breach or violation of any provisions of the articles or certificate of incorporation or bylaws (or other organizational or constitutional documents) of any Obligor or its Subsidiaries; (c) except for the filing of the UCC Financing Statements required hereunder and filings with the United States Patent and Trademark Office, require any notification to, filing with, or consent of, any Person or Governmental Authority, except such consents that are obtained on or prior to the Effective Date; (d) give rise to any right of termination, cancellation or acceleration of any right or obligation of any Obligor, its Subsidiaries or any other Person or to a loss of any benefit relating to the Net Sales or the Assigned Interests; or (e) other than pursuant to the Security Agreement or any other Transaction Document, result in the creation or imposition of any Lien on the Collateral, except, in the case of the foregoing clauses (a), (c) or (d), for any such breaches, defaults or other occurrences that would not, individually or in the aggregate, be material.

**Section 3.11 Subordination**. Except pursuant to the Intercreditor Agreement or any Permitted First Lien Intercreditor Agreement or Permitted Pari Passu Intercreditor Agreement as in effect from time to time, the claims and rights of Purchaser created by any Transaction Document in and to the Assigned Interests are not and shall not be contractually subordinated in right of payment to any creditor of any Obligor or any other Person.

**Section 3.12 Intellectual Property; Privacy**.

(a) The Obligors are the sole and exclusive legal and beneficial (and to the extent applicable, record) owners of all right, title and interest in and to all Product Intellectual Property that is owned or purported to be owned by the Obligors, free and clear of any Liens other than Permitted Liens. The Obligors own or have sufficient and valid rights to use and otherwise exploit all other Product Intellectual Property for the Product Commercialization and Development Activities. Without limiting the foregoing, and except as set forth in Schedule 3.12(a):

(i) other than customary restrictions in in-bound licenses of Intellectual Property and non-disclosure Contracts or pursuant to Permitted Licensing Agreements, there are

no judgments, covenants not to sue, grants, Liens (other than Permitted Liens), or other claims or Contracts relating to any Product Intellectual Property, in each case, which materially restrict any Obligor or any of its Subsidiaries with respect to the enforcement or other exploitation of any Product Intellectual Property for Product Commercialization and Development Activities;

(ii) except as has not resulted in, and would not reasonably be expected to result in, any material liability or business disruption, the operation and conduct of Product Commercialization and Development Activities by or on behalf of any Obligor or any of its Subsidiaries, including their use of their respective Product Intellectual Property, does not infringe, misappropriate or otherwise violate, or has not in the past three (3) years infringed, misappropriated or otherwise violated, any Intellectual Property Controlled of any other Person;

(iii) (1) there are no pending claims or any claims threatened in writing, against any Obligor or any of its Subsidiaries asserted by any other Person relating to Product Intellectual Property, including any material claims alleging ownership, invalidity or unenforceability of any Product Intellectual Property, or infringement, misappropriation, or other violations of such Person's rights in or with respect to Product Intellectual Property; and (2) neither any Obligor nor any of its Subsidiaries has received any notice from any claim by, any Person that the Product Development and Commercialization Activities of any Obligor or any of its Subsidiaries (including their use of Product Intellectual Property), infringes upon, misappropriates or violates, any Intellectual Property of any other Person in each case of clauses (1) and (2), that would reasonably be expected to result in a Material Adverse Effect;

(iv) to the knowledge of any Obligor and its Subsidiaries, (1) no Product Intellectual Property is being infringed, misappropriated or violated by any other Person; (2) neither any Obligor nor any of its Subsidiaries has put any other Person on notice of such actual or potential infringement, misappropriation or violation of any such Product Intellectual Property, and (3) neither any Obligor nor any of its Subsidiaries has initiated any claim with respect to any such Product Intellectual Property, in each case of (1), (2) and (3), that would reasonably be expected to result in a Material Adverse Effect;

(v) all current and former employees and contractors that have developed or contributed to the development of any material Product Intellectual Property for or on behalf of any Obligor or any of its Subsidiaries has executed a valid, written confidentiality and invention assignment Contracts with such Obligor or such Subsidiary, as applicable, that irrevocably and presently assign to such Obligor or such Subsidiary, as applicable, all rights of such employees and contractors to any such material Product Intellectual Property; and

(vi) each Obligor and each of its Subsidiaries has taken reasonable precautions to protect the secrecy, confidentiality and value of its Product Intellectual Property consisting of Trade Secrets and no such Trade Secret constituting material Product Intellectual Property has been used or discovered by, or disclosed to, any Person except pursuant to written, valid and enforceable non-disclosure agreements protecting the confidentiality thereof, which agreements, to the knowledge of each Obligor and its Subsidiaries, have not been breached in any material respect.

(b) Except as set forth in Schedule 3.12(b), and without limiting the representations and warranties in Section 3.12(a):

(i) each of the issued claims of each Product Patent owned or to the knowledge of the Obligors otherwise Controlled by Company or its Affiliates is valid and enforceable;

(ii) subsequent to the issuance of each Product Patent owned or to the knowledge of the Obligors otherwise Controlled by Company or its Affiliates, neither any Obligor nor any of its Subsidiaries or predecessors-in-interest has filed any disclaimer or made or permitted any other voluntary reduction in the scope of the Inventions claimed in such Product Patents, or any such disclaimer or reduction in scope would reasonably be expected to result in a Material Adverse Effect;

(iii) to the knowledge of any Obligor and its Subsidiaries, no allowable or allowed subject matter of any Product Patents is subject to any competing conception claims of allowable or allowed subject matter of any patent applications or patents of any third party and have not been the subject of any interference, and are not and have not been the subject of any re-examination, opposition or any other post-grant proceedings, nor is any Obligor or its Subsidiaries aware of any basis for any such interference, re-examination, opposition, *inter partes* review, post grant review, or any other post-grant proceedings;

(iv) no Product Patents that are material to the Product Commercialization and Development Activities have ever been finally adjudicated to be invalid, unpatentable or unenforceable for any reason in any administrative, arbitration, judicial or other proceeding, and, with the exception of publicly available documents in the applicable patent office with respect to any such Patents, no Obligor nor any of their Subsidiaries has received any written notice asserting that such Patents are invalid, unpatentable or unenforceable; and

(v) all maintenance fees, registration fees, renewal fees, annuities, and the like due or payable on or with respect to any Registered Product IP owned or Controlled by the Company or its Affiliates have been timely paid, or the failure to so pay would not reasonably be expected to result in a Material Adverse Effect.

(c) Each Obligor and each of its Subsidiaries, and each of their respective attorneys, agents and relevant employees, have met the duty of candor and good faith required under 37 C.F.R. § 1.56, which includes a duty to disclose all information known to that individual to be "material to patentability," as such is defined in 37 C.F.R. § 1.56, and complied with any analogous Laws outside the United States in connection with the Product Patents owned or Controlled by the Company or its Affiliates.

**Section 3.13 Regulatory Approval**.

(a) Each Obligor and each of its Subsidiaries holds, and will continue to hold, either directly or through licensees and agents, all Product Authorizations necessary or required for the Borrower and each of its Subsidiaries to conduct their respective operations and businesses in the manner currently conducted and to conduct its Product Commercialization and Development Activities in each case except where the failure to hold any such Product Authorizations would not reasonably be expected to result in a Material Adverse Effect.

(b) During the past two (2) years, neither any Obligor, nor any of their respective Subsidiaries has received any written notice from the FDA or any Governmental Authority that (i) it is considering suspending, revoking or materially limiting any Product Authorization or (ii) it will not approve any applications submitted to such Governmental Authority with respect to any of the Products or any Material Agreement, where such suspension, revocation, limitation or non-approval, would reasonably be expected to result in a Material Adverse Effect. The Obligors and their Subsidiaries have made all material required notices, registrations and reports and other filings with respect to the Products and Product Commercialization and Development Activities, in each case except where the failure to make the same would not reasonably be expected to result in a Material Adverse Effect.

(c) Except as set forth on Schedule 3.13(c): (i) no Obligor, nor any of its Subsidiaries nor, to the knowledge of any Obligor, any of their respective agents, suppliers, licensors or licensees have received any inspection reports, warning letters or notices or similar documents with respect to any Product or any Product Commercialization and Development Activities from any Governmental Authority within the last two (2) years that asserts material lack of compliance with any applicable Healthcare Laws or Product Authorizations; (ii) no Obligor, nor any of its Subsidiaries nor, to the knowledge of any Obligor, any of their respective agents, suppliers, licensors or licensees have received any material notification from any Governmental Authority within the last two (2) years asserting that any Product or any Product Commercialization and Development Activities lacks a required Product Authorization; (iii) there is no pending regulatory action, investigation or inquiry (other than non-material routine or periodic inspections or reviews) against any Obligor, any of its Subsidiaries or, to the knowledge of any Obligor, with respect to any Product or any Product Commercialization and Development Activities, and, to the knowledge of any Obligor, there is no reasonable basis in fact for any material adverse regulatory action against such Obligor or any of its Subsidiaries or, to the knowledge of such Obligor, any of their respective agents, suppliers, licensors or licensees with respect to any Product or any Product Commercialization and Development Activities; (iv) during the past two (2) years, no Obligor, nor any of its Subsidiaries nor, to the knowledge of any Obligor, any of their respective manufacturers has experienced any significant failures in the manufacturing or supply of the Product that, individually or in the aggregate, have had or would reasonably be expected to result in, if such failure occurred again, a Material Adverse Effect; and (v) no criminal, injunctive, seizure, detention or civil penalty action has been commenced or threatened in writing by any Governmental Authority within the last two (2) years with respect to or in connection with any Product or any Product Commercialization and Development Activities, and there are no consent decrees (including plea agreements) that relate to any Product or any Product Commercialization and Development Activities. No Obligor nor any of its Subsidiaries, nor, to the knowledge of any Obligor, any of their respective agents, suppliers, licensees or licensors, is employing or utilizing the services of any individual, in connection with Product Commercialization and Development Activities, who has been debarred from any federal healthcare program, where such debarment would reasonably be expected to have a Material Adverse Effect.

**Section 3.14 Product Agreements**. As of the date hereof, Schedule 3.14 sets forth a list of all Licensing Agreements. A true, correct and complete copy of each Material Contract and Licensing Agreement (collectively, the "Product Agreements") have been provided to the Purchasers in a data room available to the Purchasers. Except as set forth on Schedule 3.14, no Obligor nor its Subsidiaries is in material breach of or in material default under any Product

Agreement. To the knowledge of any Obligor, nothing has occurred and no condition exists that would permit any other party thereto to terminate any Product Agreement. No Obligor nor its Subsidiaries has received any notice or, to the knowledge of any Obligor, any threat of termination of any such Product Agreement. To the knowledge of any Obligor, no other party to a Product Agreement is in breach of or in default under such Product Agreement. All Product Agreements are valid and binding on the applicable Obligor or its Subsidiaries and, to the knowledge of such Obligor, on each other party thereto, and are in full force and effect.

**Section 3.15 Broker's Fees**. Each Obligor and its Subsidiaries have not taken any action that would entitle any Person to any commission or broker's fee in connection with this Agreement; provided that, for the avoidance of doubt, fees payable to each Obligor's bankers and financial advisers in their capacities as such do not constitute commission or broker's fees.

**Section 3.16 Pension Matters**. Except as would not, in the aggregate, reasonably be expected to result in a Material Adverse Effect, each Qualified Plan, and each trust thereunder, intended to qualify for tax exempt status under Section 401 or 501 of the Code or other Laws so qualifies. Except for those that would not, in the aggregate, reasonably be expected to result in a Material Adverse Effect, (x) each Benefit Plan is in compliance with applicable provisions of ERISA, the Code and other Laws, (y) there are no existing or pending (or to the knowledge of the Company or any of its Subsidiaries, threatened) claims (other than routine claims for benefits in the normal course), sanctions, actions, lawsuits or other proceedings or investigation involving any Benefit Plan to which the Company or any Subsidiary thereof incurs or otherwise has or would have an obligation or any liability or claim and (z) no ERISA Event is reasonably expected to occur. Except as would not, in the aggregate, reasonably be expected to result in a Material Adverse Effect, the Company and each of its ERISA Affiliates has met all applicable requirements under the ERISA Funding Rules with respect to each Title IV Plan, and no waiver of the minimum funding standards under the ERISA Funding Rules has been applied for or obtained.

**Section 3.17 Indebtedness and Liens**. Set forth on Schedule 3.17 (a) is a complete and correct list of all Indebtedness of each Obligor and each of its Subsidiaries (other than intercompany indebtedness) outstanding as of the Effective Date. Set forth on Schedule 3.17(b) is a complete and correct list of all Liens granted by each Obligor and each of its Subsidiaries with respect to their respective property and outstanding as of the Effective Date.

**Section 3.18 [Reserved]**.

**Section 3.19 [Reserved]**.

**Section 3.20 Taxes**. Except as set forth on Schedule 3.20, each Obligor and each of its Subsidiaries has timely filed or caused to be filed (taking into account all applicable extensions of due dates) all income Tax Returns and other material Tax Returns required to have been filed and has paid or caused to be paid all Taxes required to have been paid by it, except (a) Taxes that are being contested in good faith by appropriate proceedings and for which such Obligor or such Subsidiary, as applicable, has set aside on its books adequate reserves with respect thereto in accordance with GAAP or (b) in each case, to the extent that the failure to so file or pay would not reasonably be expected to have an Material Adverse Effect.

**Section 3.21 Full Disclosure**. None of the reports, financial statements, certificates or other written information furnished by or on behalf of any Obligor or any of its Subsidiaries to the Administrative Agent (on behalf of itself and the Purchasers) in connection with the negotiation of this Agreement and the other Transaction Documents or delivered hereunder or thereunder (as modified or supplemented by other information so furnished, including Holdings' filings publicly available on "EDGAR") contains any material misstatement of material fact or omits to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that, with respect to projected financial information, the Company represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time, and it being understood that such projected financial information and all other forward looking information are not to be viewed as facts and are subject to uncertainties and contingencies, many of which are beyond the control of the Company or any its Affiliates, and that actual results during the period or periods covered thereby may differ from such projected results and that the differences may be material.

**Section 3.22 OFAC; Anti-Terrorism Laws**.

(a) No Obligor nor any of its Subsidiaries is in violation of any Anti-Terrorism Law or engages in or conspires to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the Anti-Terrorism Laws.

(b) No Obligor nor any of its Subsidiaries, nor, to the knowledge of any Obligor, any of their respective directors, officers, or employees (i) is currently the target of any Sanctions, (ii) is located, organized or residing in any Designated Jurisdiction in violation of Sanctions, or (iii) is or has been (within the previous five (5) years) engaged in any transaction with, or for the benefit of, any Person who is now or, was then the target of Sanctions or who is located, organized or residing in any Designated Jurisdiction, in violation of Sanctions. None of the proceeds received from the Purchasers have been or will be used, directly or, to the knowledge of any Obligor, indirectly, to lend, contribute or provide to, or has been or will be otherwise made available for the purpose of funding, any activity or business in any Designated Jurisdiction in violation of Sanctions or for the purpose of funding any activity or business of any Person located, organized or residing in any Designated Jurisdiction or who is the subject of any Sanctions, in violation of Sanctions, or in any manner that will result in any violation by any party to this Agreement of Sanctions.

**Section 3.23 Anti-Corruption**. No Obligor nor any of its Subsidiaries, nor, to the knowledge of any Obligor, any of their respective directors, officers or employees, while acting on behalf of the Company, has directly or, to the knowledge of any Obligor, indirectly (i) materially violated or is in material violation of any applicable anti-corruption Law, or (ii) made, offered to make, promised to make or authorized the payment or giving of, directly or, to the knowledge of any Obligor, indirectly, any Prohibited Payment.

## ARTICLE IV

## REPRESENTATIONS AND WARRANTIES OF THE PURCHASERS

Each Purchaser, severally and not jointly, represents and warrants to the Company, solely with respect to such Purchaser, the following:

**Section 4.01** **Organization**. Such Purchaser is duly formed and validly existing under the laws of the jurisdiction of its incorporation or formation.

**Section 4.02** **Authorization**. Such Purchaser has all necessary power and authority to enter into, execute and deliver the Transaction Documents and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. The Transaction Documents have been duly authorized, executed and delivered by such Purchaser and each Transaction Document constitutes the valid and binding obligation of such Purchaser, enforceable against such Purchaser in accordance with their respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or general equitable principles.

**Section 4.03** **Broker's Fees**. Such Purchaser has not taken any action that would entitle any Person to any commission or broker's fee in connection with the transactions contemplated by the Transaction Documents.

**Section 4.04** **Conflicts**. Neither the execution and delivery of this Agreement or any other Transaction Document to which such Purchaser is a party nor the performance or consummation of the transactions contemplated hereby or thereby will: (a) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects any provisions of: (i) any law, rule, ordinance or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which such Purchaser or any of its assets or properties may be subject or bound; or (ii) any contract, agreement, commitment or instrument to which such Purchaser is a party or by which such Purchaser or any of its assets or properties is bound or committed; (b) contravene, conflict with or result in a breach or violation of any provisions of the organizational or constitutional documents of such Purchaser; or (c) require any notification to, filing with, or consent of, any Person or Governmental Authority, except, in the case of the foregoing clauses (a) or (c), for any such breaches, defaults or other occurrences that would not, individually or in the aggregate, have a material adverse effect on the ability of such Purchaser to perform any of their obligations under the Transaction Documents.

Section 4.05 **Sanctions**. Such Purchaser is not a Sanctioned Person.

## ARTICLE V

## COVENANTS

From the date hereof through and including the termination of this Agreement pursuant to Section 6.01, the following covenants shall apply:

**Section 5.01 Access; Information**.

(a) Product Agreement Notices. Subject to any applicable confidentiality restrictions, the Company shall promptly provide the Administrative Agent (which shall, in turn, provide the Purchasers) with copies of any written notices of material breach or default received or given by any Obligor under any Product Agreement, and to the extent the Company is barred from providing the Administrative Agent with copies of such notices due to any applicable confidentiality restrictions, the Company shall inform the Administrative Agent of the existence of such notice. The Company shall promptly notify the Administrative Agent (which shall, in turn, notify the Purchasers) of any breaches or alleged breaches under any Product Agreements and of any other events with respect to any Product Agreement or the subject matter thereof which would reasonably be expected to have a Material Adverse Effect or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products. The Company shall promptly notify the Administrative Agent (which shall, in turn, notify the Purchasers) of entering into any new Product Agreement by any Obligor, or any material amendment to any Product Agreement, and provide a copy of such new agreement or amendment to the Administrative Agent.

(b) Litigation or Investigations. The Company shall promptly notify the Administrative Agent (which shall, in turn, notify the Purchasers) of (i) any action, suit, claim, cause of action, proceeding or investigation pending or, to the knowledge of any Obligor, threatened in writing against any Obligor or its Subsidiaries, or (ii) proceeding or inquiry of any Governmental Authority pending or, to the knowledge of any Obligor, threatened in writing against any Obligor, in each case that is related to any Product Agreement, the Product, the Product Intellectual Property, Marketing Authorization, any Transaction Document or the Back-Up Security Interest, in each case, that would reasonably be expected to result in a Material Adverse Effect or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

(c) Maintenance of Books and Records. Each Obligor shall keep and maintain, or cause to be kept and maintained, at all times full and accurate books of account and records adequate to correctly reflect all payments paid and/or payable with respect to the Net Sales and Assigned Interests for three (3) years from the year of creation of such records.

(d) Inspection Rights. The Administrative Agent shall have the right to designate a Third Party independent public accounting firm (the "Purchasers Representative") to visit each Obligor and its Subsidiaries' offices and properties where such Obligor and its Subsidiaries keep and maintain their books and records relating or pertaining to the Net Sales, the Assigned Interests, the Royalty Interest Payments, U.S. Licensing / Participation Payments and the Ex-U.S. Licensing / Participation Payments payable hereunder for purposes of conducting an audit of such books and

records, and to inspect and audit such books and records. Any such audit or inspection must (i) be limited to the three-year period during which each Obligor is required to maintain such records pursuant to Section 5.01(c), (ii) not be exercised more than once in any calendar year, (iii) take place during normal business hours, and (iv) follow at least seven (7) Business Days' prior written notice given by the Administrative Agent to the Company. In connection with any such audit, each Obligor will provide the Purchasers Representative reasonable access to such books and records maintained by such Obligor, and shall permit the Purchasers Representative to discuss the business, operations, properties and financial and other condition of such Obligor or any of its Subsidiaries including, but not limited to, matters relating or pertaining to the Net Sales, the Assigned Interests, and the Royalty Interest Payments, U.S. Licensing / Participation Payments and Ex-U.S. Licensing / Participation Payments payable hereunder with officers of such Obligor and with such Obligor's independent certified public accountants, in all cases solely to verify the accuracy of the Quarterly Reports provided under Section 5.01(f) and related payments due under this Agreement. Without limiting the foregoing, prior to any audit under this Section 5.01(d), the Purchasers Representative shall enter into a written confidentiality agreement with each Obligor that (A) limits the use of such Obligor's records to the verification purpose described in this Section 5.01(d); (B) limits the information that the Purchasers Representative may disclose to the Administrative Agent to information required for the Administrative Agent to understand the payments due and paid and any discrepancies; and (C) prohibits the disclosure of any information contained in such records to any other Third Party for any purpose. The Parties agree that all information subject to review under Section 5.01(d) or provided by the Purchasers Representative to Company is Company's Confidential Information, and neither the Administrative Agent nor the Purchasers shall use any such information for any purpose that is not germane to this Section 5.01(d).

(e) Resolution; Audit Costs. Any audit under Section 5.01(d) shall be at the Purchasers' expense, allocated to the Purchasers in accordance with their Proportionate Share; provided, however, that in the event that any such audit reveals that the amounts paid to the Purchasers hereunder for the period of such audit have been understated by more than five percent (5%) of the amounts determined to be due for the period subject to such audit, then the Company shall reimburse the Audit Costs for such audit. In the event that any audit of the books and records of any Obligor pursuant to Section 5.01(d) (i) reveals any underpayment by the Company of the amounts due hereunder, the amount of such underpayment shall be paid to the Administrative Agent for distribution to the Purchasers in accordance with their Proportionate Share within thirty (30) days of completion of such audit, or (ii) reveals any overpayment by the Company of amounts due hereunder, the amount of such overpayment shall be promptly refunded or fully creditable against amounts payable in subsequent payment periods, at the Company's election.

(f) Quarterly Reports. During the Term, the Company shall, promptly after the end of each Fiscal Quarter of the Company (but in no event later than forty-five (45) days following the end of each Fiscal Quarter), produce and deliver to the Administrative Agent (which shall, in turn, deliver to the Purchasers) a Quarterly Report for such quarter, together with a certificate of the Company, certifying that to the knowledge of the Company (i) such Quarterly Report is a true and complete copy and (ii) any statements and any data and information therein prepared by the Company are true, correct and accurate in all material respects. The Company shall use, and shall use Commercially Reasonable Efforts to ensure that each of its Affiliates shall use, Commercially Reasonable Efforts to include in each contract of the Obligors for the Development or

Commercialization of the Product entered into on or after the Effective Date, obligations reasonably appropriate to ensure that the counterparty to such contract shall furnish to the Company all information necessary for the Company to comply with this Section 5.01(f) and Section 5.01(a), and calculate the Royalty Interest Payments, U.S. Licensing / Participation Payments or Ex-U.S. Licensing / Participation Proceeds as set forth in this Agreement. In addition the Majority Purchasers may request a quarterly verbal update on material updates related to the Product Commercialization and Development Activities, including clinical trials, manufacturing and marketing related activities, whereby all Purchasers will be invited to such updates by the Company.

(g) Monthly Reports. During the Term, the Company shall, promptly after the end of each calendar month (but in no event later than fifteen (15) days following the end of each calendar month), produce and deliver to the Administrative Agent (which shall, in turn, deliver to the Purchasers) a flash report disclosing (i) the number of units of Products sold in the preceding calendar month and (ii) the Gross Sales for such calendar month, in each case of (i) and (ii) solely to enable the Purchasers to review the progress of the Commercialization of the Product and which shall be preliminary, unaudited, and subject to further verifications and modifications by the Company.

(h) Periodic Reports. The Company shall deliver to the Administrative Agent (which shall, in turn, deliver to the Purchasers) the following financial statements, provided that documents required to be furnished pursuant to this Section 5.01(h) shall be deemed furnished on the date that such documents are publicly available on "EDGAR":

(i) as soon as available and in any event within forty-five (45) days after the end of the first three (3) Fiscal Quarters of each fiscal year (commencing with the Fiscal Quarter ending June 30, 2024) (i) the consolidated balance sheets of Holdings and its Subsidiaries as of the end of such Fiscal Quarter and (ii) the related consolidated statements of income, shareholders' equity and cash flows of Holdings and its Subsidiaries for such quarter and the portion of the fiscal year through the end of such fiscal quarter, in each case prepared in all material respects in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the corresponding period in the preceding fiscal year, together with (iii) a certificate of the Company stating that (x) such financial statements fairly present in all material respects the financial condition of Holdings and its Subsidiaries as at such date and (y) the results of operations of Holdings and its Subsidiaries for the period ended on such date have been prepared in all material respects in accordance with GAAP consistently applied, subject to changes resulting from normal, year-end audit adjustments and except for the absence of notes; and

(ii) as soon as available and in any event within ninety (90) days after the end of each fiscal year (i) the consolidated balance sheets of Holdings and its Subsidiaries as of the end of such fiscal year and (ii) the related consolidated statements of income, shareholders' equity and cash flows of Holdings and its Subsidiaries for such fiscal year, in each case prepared in all material respects in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the previous fiscal year, accompanied by a report and opinion thereon of PricewaterhouseCoopers LLP, Ernst & Young LLP or another firm of independent certified public accountants of recognized national standing reasonably acceptable to the Administrative Agent, which report and opinion shall be prepared in accordance with generally

accepted auditing standards and such report and opinion shall not be subject to any "going concern" or like qualification or exception or emphasis of matter of going concern footnote or any qualification or exception as to the scope of such audit, and in the case of such consolidated financial statements, certified by an officer of the Company.

**Section 5.02 Product Agreements**. Each Obligor shall comply with all material terms and conditions of and fulfill all of its obligations under all the Product Agreements, except for such noncompliance which would not reasonably be expected to give rise to a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

**Section 5.03 Public Announcement**. Except as required by law or any Governmental Authority (including the Securities and Exchange Commission) or except with the prior written consent of the other party (which consent shall not be unreasonably withheld, conditioned or delayed), no party shall issue any press release or make any other public disclosure with respect to the transactions contemplated by this Agreement or any other Transaction Document; provided, however, that the Company and the Administrative Agent may jointly prepare a press release approved by the Purchasers for dissemination promptly following the Effective Date and each Applicable Funding Date and Holdings may file a current report on Form 8-K (or any other public announcement using substantially the same text as the press release or Form 8-K) with respect to the transactions contemplated by this Agreement.

**Section 5.04 Efforts; Further Assurance**.

(a) Subject to the terms and conditions of this Agreement, the Purchasers and the Company agree to execute and deliver such other documents, certificates, agreements and other writings (including any financing statement filings requested by the Purchasers) and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement and any other Transaction Document and to vest in the Purchasers good, valid and marketable rights and interests in and to the Assigned Interests free and clear of all Liens, except for Permitted Liens. Without limiting the generality of the foregoing, in the event any Obligor engages in Product Commercialization and Development Activities outside the United States and England, such Obligor shall promptly execute, acknowledge, deliver and cause to be filed all further instruments and documents and take all other actions as the Administrative Agent may from time to time reasonably request in order to assure, obtain, perfect, preserve and protect any security interest granted or purported to be granted with respect to such Product Intellectual Property in such jurisdiction or enable the Administrative Agent to exercise and enforce its rights and remedies with respect to the Product Intellectual Property in such jurisdiction.

(b) The Purchasers and the Company shall cooperate and provide assistance as reasonably requested by the other party in connection with any Third Party litigation, arbitration or other Third Party proceeding (whether threatened, existing, initiated, or contemplated prior to, on or after the date hereof) to which any party hereto or any of its officers, directors, shareholders, agents or employees is or may become a party or is or may become otherwise directly or indirectly affected or as to which any such Persons have a direct or indirect interests, in each case relating to

this Agreement, any other Transaction Document, the Assigned Interests or any other Collateral, the Back-Up Security Interest or the transactions described herein or therein.

**Section 5.05 Call Option**.

(a) Call Option. At any time after the Tranche A Funding Date, the Company shall have the right, but not the obligation (the "Call Option"), exercisable upon ten (10) days' written notice to the Administrative Agent, to repurchase the Assigned Interests from the Purchasers at a repurchase price equal to the Call Price. In order to exercise the Call Option, the Company shall deliver written notice to the Administrative Agent of its election to so repurchase the Assigned Interests not less than ten (10) days prior to the proposed closing date (the "Call Option Closing Date"); provided, however, that such notice may state that it is conditioned upon the effectiveness of any financing transaction or one or more other events specified therein (including the occurrence of a Change of Control), in which case such notice may be revoked by the Company (by notice to the Administrative Agent on or prior to the specified effective date) if such condition is not satisfied. On the Call Option Closing Date, the Company shall repurchase from each Purchaser its Assigned Interests at the Call Price in cash, the payment of which shall be made by wire transfer of immediately available funds to the Administrative Agent for the account of the Purchasers. Immediately upon exercise by the Company of the Call Option and the payment by the Company to the Purchasers of the Call Price, the Purchasers shall be deemed to have automatically assigned to the Company all right, title, and interest in and to the Assigned Interests.

(b) Obligations of the Purchasers. In connection with the consummation of a repurchase of the Assigned Interests pursuant to the Call Option, the Purchasers agree, at the expense of the Company, that they will (i) promptly but no later than five (5) Business Days after any request therefor execute and deliver to the Company such releases, discharges, UCC termination statements and other documents as may be necessary to release and/or discharge the Purchasers' Lien on the Collateral and otherwise give effect to such repurchases and (ii) take such other actions or provide such other assistance as may be necessary or as reasonably requested by the Company to give effect to such repurchase.

**Section 5.06 Intellectual Property**.

(a) Each Obligor shall, at its sole expense, take such actions to prepare, execute, deliver and file any and all agreements, documents or instruments which are necessary to diligently prosecute (as applicable) and maintain all Product Intellectual Property, including Registered Product IP, owned or Controlled by such Obligor, consistent with prudent business practice. Each Obligor shall use reasonable efforts consistent with sound business judgment to seek and to apply for patent term extensions (to the extent it has the right to do so), pediatric data package exclusivity extension, supplementary protection certificates, any functional equivalents of any of the foregoing, or similar means of extending market exclusivity or patent protection for any Product Intellectual Property which it owns or Controls, and the Product in each territory that such Obligor obtains Governmental Approval for Commercialization, and where such items are permissible, as the case may be. No Obligor shall fail to take any action to prosecute and maintain the Product Intellectual Property that it owns or Controls, which would reasonably be expected to result in a Material Adverse Effect or Product Material Adverse Effect in the event at the time of

determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

(b) In the event that any Obligor or the Purchasers becomes aware of any actual or suspected infringement, misappropriation, violation or invalidity claims by a Third Party of or directed to, as applicable, any material Product Intellectual Property, including any Product Patents, then promptly following such Obligor or the Purchasers, respectively, becoming aware of such actual or suspected infringement, misappropriation, violation or invalidity claim, such Obligor or the Purchasers, respectively, shall inform the Purchasers of such actual or suspected infringement, misappropriation, violation or invalidity claim and shall, in addition to such notice, provide to the Purchasers any material information within such party's possession pertaining thereto (which may be subject to agreement necessary to protect privilege, confidentiality and the like with respect to such information). Each Obligor shall use Commercially Reasonable Efforts to defend or assert Product Intellectual Property owned or Controlled by such Obligor, including the Product Patents, against infringement, misappropriation, violation or claims and any interference by any other Person, and against any claims of invalidity or unenforceability of any Product Intellectual Property, including any Product Patents (including, by bringing any legal action for infringement or defending any counterclaim of invalidity or action of a Third Party for declaratory judgment of non-infringement or non-interference), in each case to the extent that the failure to do so would not reasonably be expected to result in a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products. The Company will keep the Purchasers reasonably informed with respect to the status of any such enforcement and/or defense of such Product Intellectual Property as the Purchasers may, from time to time, reasonably request. Each Obligor shall not, and shall use its Commercially Reasonable Efforts to cause any licensee not to, disclaim, abandon or otherwise dispose, or fail to take any action necessary to prevent the disclaimer, abandonment or disposal of, any Product Intellectual Property, including any of the Product Patents, except in accordance with reasonable and prudent business practice in a manner that would not reasonably be expected to result in a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

(c) In the event that any Obligor becomes aware that the Product (including any Product Commercialization and Development Activities) infringes, misappropriates or otherwise violates any Third Party Intellectual Property, such Obligor shall, in the exercise of its reasonable business discretion, use Commercially Reasonable Efforts to attempt to secure the right to use or otherwise exploit such Intellectual Property on behalf of itself and any affected licensee, as applicable, except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products, and all reasonable costs and amounts associated with obtaining any such license would be without any reduction in the Assigned Interests, if and as applicable.

(d) Without the prior written consent of the Majority Purchasers, each Obligor and each of its Subsidiaries shall not, and shall ensure that its Affiliates shall not, directly or indirectly, transfer, by means of contribution, sale, assignment, lease or sublease, license or sublicense (other

than pursuant to a Permitted Licensing Agreement), dispose of or otherwise encumber any of the Product Intellectual Property, other than Permitted Liens.

**Section 5.07 Protective Covenants**. Each Obligor shall not, and shall cause any of its Subsidiaries not to, without the prior written consent of the Purchasers:

(a) Forgive, release or compromise any amount owed to any Obligor or its Subsidiaries or its Affiliates and relating to the Assigned Interests outside the Ordinary Course;

(b) Waive, amend, cancel or terminate (other than expiration in accordance with its terms), exercise or fail to exercise, any of its material rights constituting or relating to the Net Sales outside the Ordinary Course; or

(c) Amend, modify, restate, cancel, supplement, terminate (other than expiration in accordance with its terms), waive any material provision, or enter into any Product Agreement, or grant any consent thereunder, or agree to do any of the foregoing, including, entering into any agreement with any Person under the provisions of such Product Agreement, in each case if such action would result in a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products; provided, that this clause (c) shall not apply to any Permitted Licensing Agreement (including any a co-distribution or co-promotion agreement for the Product entered into in connection with any Permitted Licensing Agreement);

(d) Incur or assume any Indebtedness, except for Permitted Indebtedness;

(e) Create, incur, assume or permit to exist (i) any Lien on the Assigned Interests, except for any Lien contemplated by clauses (a), (c), (d), (e), or (i) of the definition of Permitted Liens, or (ii) any Lien on any other Collateral other than the Permitted Liens;

(f) Sell, assign, convey, transfer, pledge or otherwise dispose of any right to receive any portion or component of Net Sales to any other Person, except pursuant to a Permitted Revenue Financing; or

(g) Enter into any contracts or arrangements or otherwise knowingly take any action or knowingly fail to act in a manner that would, individually or in the aggregate, reasonably be expected to materially and adversely affect the Purchasers' interest in the Assigned Interests, the Back-Up Security Interest or any other Collateral (the Parties agree that the entry into the Oaktree Term Facility shall be deemed to not materially adversely affect the Purchasers' interest in the Assigned Interests, the Back-Up Security Interest or any other Collateral).

**Section 5.08 Notice**.

(a) The Company shall provide the Administrative Agent (which shall, in turn, provide the Purchasers) with written notice as promptly as practicable (and in any event within ten (10) Business Days) after becoming aware of any of the following:

(i) any material breach or default by any Obligor of any covenant, agreement or other provision of this Agreement, or any other Transaction Document;

(ii) any representation or warranty made by any Obligor in any of the Transaction Documents or in any certificate delivered to the Administrative Agent pursuant hereto shall prove to be untrue, inaccurate or incomplete in any material respect on the date as of which made;

(iii) the occurrence of an Event of Default;

(iv) the occurrence of any material default or event of default under any Permitted Indebtedness;

(v) the termination of any Product Agreement other than upon its scheduled termination date;

(vi) the occurrence of any event(s) or the existence of any circumstance(s) that, individually or in the aggregate, would reasonably be expected to result in a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products;

(vii) the occurrence of any event or the existence of any circumstance that (with or without notice or lapse of time, or both) would result in or serve as a basis for any, action, suit or proceeding, or any investigation or claim, or the receipt of any written notice of the foregoing, that (a) claims that the manufacture, use, marketing, sale, offer for sale, importation or distribution of the Product as currently contemplated infringes, misappropriates or otherwise violates any Intellectual Property of any other Person, (b) otherwise materially involves the Product, or (c) involves the transactions contemplated by the Transaction Documents, the Assigned Interests or the Back-Up Security Interests;

(viii) (i) the filing by the Company or any ERISA Affiliate of any notice of intent to terminate any Title IV Plan, and a copy of such notice and (ii) the filing by the Company or any ERISA Affiliate of a request for a minimum funding waiver under Section 412 of the Code with respect to any Title IV Plan or Multiemployer Plan, in each case in writing and in reasonable detail (including a description of any action that it proposes to take with respect thereto, together with a copy of any notice filed with the PBGC or the IRS pertaining thereto);

(ix) any Contract entered into by any Obligor or any of its Subsidiaries in connection with any claim of actual or alleged infringement, misappropriation or other violation of any Intellectual Property by or against any Obligor or any of its Subsidiaries in connection with the Product Commercialization and Development Activities; or

(x) any claim of actual or alleged infringement, misappropriation or other violation of any Intellectual Property by or against any Obligor or any of its Subsidiaries in connection with the Product Commercialization and Development Activities that would reasonably be expected to result in a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

(b) The Company shall provide the Administrative Agent with written notice as promptly as practicable and in any event within ten (10) Business Days prior to the occurrence of a Change of Control.

**Section 5.09 Use of Proceeds**. The Company shall use proceeds received from the Purchasers in support of the Development and Commercialization of the Product and for other general corporate purposes.

**Section 5.10 Taxes**.

(a) Group Filings. Each of the Obligors and their Subsidiaries shall timely file (taking into account all extensions of due dates) all income Tax Returns and other material Tax Returns required to be filed by it and will pay all Taxes required to be paid with such returns, except (i) Taxes that are being contested in good faith by appropriate proceedings and for which the relevant Obligor or such Subsidiary, as applicable, has set aside on its books adequate reserves with respect thereto in accordance with GAAP or (ii) in each case, to the extent that the failure to so file or pay would not reasonably be expected to have an Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

(b) Withholding Forms. Each Purchaser shall deliver to the Company an IRS Form W-9 or applicable IRS Form W-8, or any successor form, as appropriate, properly completed and duly executed by such Purchaser, and such other documentation required under the Code or reasonably requested by the Company, establishing that such Purchaser is exempt from U.S. federal withholding and backup withholding tax with respect to payments under this Agreement. In addition, any Purchaser that is entitled to an exemption from or reduction of any other withholding Tax with respect to payments under this Agreement shall deliver to the Company such properly completed and executed documentation reasonably requested by the Company or the Administrative Agent as will permit any payments under this Agreement to be made without such withholding or at a reduced rate of such withholding. Each Purchaser will notify the Company reasonably in advance of any action or proposed action that would make any such form or documentation inaccurate and will replace the inaccurate form or documentation with an accurate one. The Company shall provide a Purchaser any reasonable assistance it may seek in obtaining an exemption or reduced rate from, or refund of, any withholding tax, if applicable. In addition, the Administrative Agent (or any successor Administrative Agent) shall, on or before the date on which it becomes a party hereto, provide to the Company duly completed and executed copies of (i) IRS Form W-9 or (ii) if the Administrative Agent is not a "United States person" within the meaning of Section 7701(a)(30) of the Code, IRS Form W-8IMY (with respect to amounts received on account of any Purchaser) and an appropriate IRS Form W-8 (with respect to amounts received on its own account), with the effect that, in either case, the Company will be entitled to make payments hereunder to the Administrative Agent (or any successor Administrative Agent) without withholding or deduction on account of United States federal taxes. The Administrative Agent and each Purchaser agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify the Company (and, with respect to any Purchaser, the Administrative Agent) in writing of its legal inability to do so.

(c) Payments Free of Taxes. Any and all payments by or on account of any Obligation shall be made without deduction or withholding for any Taxes, except as required by any Law. If any Law (as determined in the good faith discretion of the Company or the Administrative Agent, as applicable) requires the deduction or withholding of any Tax from any such payment by the Company or the Administrative Agent, then the Company or the Administrative Agent, as applicable, shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable Laws and, if such Tax is an Indemnified Tax, then the sum payable by the Company shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 5.10) the Purchasers receive an amount equal to the sum they would have received had no such deduction or withholding been made.

(d) Payment of Other Taxes by Company. The Company shall timely pay to the relevant Governmental Authority in accordance with applicable Law, or at the option of the Administrative Agent timely reimburse it for the payment of, any Other Taxes.

(e) Indemnification by the Company. The Company shall reimburse and indemnify each Purchaser, within ten (10) days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 5.10) payable or paid by such Purchaser or required to be withheld or deducted from a payment to such Purchaser and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to the Company by a Purchaser shall be conclusive absent manifest error.

(f) Evidence of Payments. As soon as practicable after any payment of Taxes by the Company to a Governmental Authority pursuant to this Section 5.10, the Company shall deliver to the Administrative Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment or other evidence of such payment reasonably satisfactory to the Administrative Agent.

(g) Treatment of Certain Tax Benefits. If any party to this Agreement determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this Section 5.10 (including by the payment of additional amounts pursuant to this Section 5.10), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under this Section 5.10 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this Section 5.10(g) (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this Section 5.10(g), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this Section 5.10(g)the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject

to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This Section 5.10(g)shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

(h) Survival. Each party's obligations under this Section 5.10 shall survive any assignment of rights by, or the replacement of, a Purchaser, the termination of the Obligations and the repayment, satisfaction or discharge of all Obligations under this Agreement.

**Section 5.11 Compliance with Laws and Other Obligations**. Each Obligor will, and will cause each of its Subsidiaries to, (i) comply with all Laws (including Anti-Terrorism Laws and Sanctions) applicable to it and its business activities, (ii) comply with all Healthcare Laws and Governmental Approval and Product Authorizations applicable to it and its business activities and (iii) maintain in full force and effect (other than termination of such agreement in accordance with its terms), remain in compliance, and perform all obligations under all Material Contracts to which it is a party, except in each case where the failure to so comply would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products. Each Obligor will, and will cause each of its Subsidiaries to maintain in effect and enforce policies and procedures reasonably designed to promote compliance by such Obligor, its Subsidiaries and their respective directors, officers, employees and agents with Anti-Terrorism Laws and Sanctions.

**Section 5.12 Maintenance of Properties, Etc.** Without limitation of any other covenants set forth in this Article V, each Obligor shall, and shall cause each of its Subsidiaries to, maintain and preserve all of its assets and properties relating to the Product or Product Commercialization and Development Activities, or that are otherwise necessary or useful in the conduct of its business in good working order and condition in accordance with the general practice of other Persons of similar character and size, ordinary wear and tear and damage from casualty or condemnation excepted.

**Section 5.13 Licenses**. Without limitation of any other covenants set forth in this Article V, each Obligor shall, and shall cause each of its Subsidiaries to, obtain and maintain all Governmental Approvals necessary for the execution, delivery and performance of the Transaction Documents, the consummation of the transactions thereunder or the operation and conduct of its business and ownership of its properties (including its Product Commercialization and Development Activities), except where the failure to do so would not reasonably be expected to have a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

**Section 5.14 Maintenance of Regulatory Approvals, Contracts, Etc.** With respect to the Product and all Product Commercialization and Development Activities, each Obligor will (directly or indirectly), and will cause each of its Subsidiaries (to the extent applicable) to, (i) use Commercially Reasonable Efforts to maintain in full force and effect, and pay all costs and expenses relating to, all Product Authorizations, Product Agreements and other rights, interests or

assets (whether tangible or intangible) reasonably necessary for the operations of such Person's business, except as would not reasonably be expected to have a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products, and (ii) promptly after obtaining knowledge thereof, notify the Purchasers of any claim by any Person that the conduct of the business of any Obligor or any of its Subsidiaries in connection with any Product Commercialization and Development Activities, has infringed, misappropriate or otherwise violated any Intellectual Property of such Person, where such claim could reasonably be expected to have a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

**Section 5.15 ERISA Compliance**. Each Obligor shall comply, and shall cause each of its Subsidiaries to comply, with the provisions of ERISA with respect to any Plans to which such Obligor or such Subsidiary is a party as an employer, except where the failure to do so would not reasonably be expected to have a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products.

**Section 5.16 Commercialization of the Product**.

(a) Each Obligor (itself or through one or more Subsidiaries or licensees) shall use Commercially Reasonable Efforts to (i) Develop and obtain Marketing Authorization for Product in the United States, and (ii) Commercialize the Product in each jurisdiction in which Marketing Authorization is obtained. Without limiting the foregoing, each Obligor will use Commercially Reasonable Efforts to prepare, execute, deliver and file any and all agreements, documents or instruments that are necessary to secure and maintain Marketing Authorization in the United States for the Product. No Obligor shall withdraw or abandon, or fail to take any action necessary to prevent the withdrawal or abandonment of, Marketing Authorization in any applicable jurisdiction for the Product once obtained, other than to the extent that such withdrawal is required for safety reasons or otherwise required under applicable Law, or where maintenance of such Marketing Authorization would not constitute Commercially Reasonable Efforts.

(b) Subject to Section 5.06(d), no Obligor shall enter into any Product Agreement unless such Obligor shall have performed reasonable and customary diligence in selecting the applicable counterparty to such Product Agreement and negotiating and agreeing to the terms of such Product Agreement (or any amendment, modification, restatement, cancellation, supplement, termination or waiver of any of the material terms thereof). In addition, if any Product Agreement that is necessary for the Product Commercialization and Development Activities terminates for any reason whatsoever, the applicable Obligor shall use Commercially Reasonable Efforts to enter into a replacement Product Agreement to the extent the relevant rights under such terminated Product Agreement are required for the ongoing Product Commercialization and Development Activities by such Obligor in accordance with its express obligations set forth in Section 5.16(a).

(c) Upon the occurrence of a breach of any Product Agreement by any other party thereto where such breach has (or is reasonably likely to have) a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of

its Affiliates is Developing or Commercializing one or more Other Products, the Company shall use Commercially Reasonable Efforts to seek to enforce all of its (or its Subsidiary's) rights and remedies thereunder.

**Section 5.17 Payment of Obligations**. Each of the Obligors and their Subsidiaries shall pay and discharge (a) all its obligations and liabilities prior to the date on which penalties attach thereto, with respect to all material Taxes imposed upon it or its properties or assets, unless the same are being contested in good faith by appropriate proceedings and adequate reserves in accordance with GAAP are being maintained by such Obligor or its Subsidiaries, except to the extent that the failure to do so would not reasonably be expected to have a Material Adverse Effect, or Product Material Adverse Effect in the event at the time of determination, the Company or any of its Affiliates is Developing or Commercializing one or more Other Products, and (b) as the same shall become due and payable, all lawful claims which, if unpaid, would by Law become a Lien upon any Collateral (other than (i) with respect to the Assigned Interests, any Lien contemplated by clauses (a), (c), (d), (e) or (i) of the definition of Permitted Liens, or (ii) with respect to any other Collateral, Permitted Liens).

**Section 5.18 RIPSA Account**.

(a) By no later than 30 days after the first commercial sale of the Product, the Company shall set up the RIPSA Account and shall thereafter at all times maintain the RIPSA Account pursuant to the terms of this Agreement.

(b) The Company shall cause the RIPSA Account to at all times be subject to an account control agreement (or any equivalent customary under any non-U.S. jurisdiction) among the Company, the Administrative Agent and the applicable depositary institution in favor of the Administrative Agent in form and substance reasonably acceptable to the Administrative Agent that (A) ensures, to the extent necessary under applicable Law and subject to the Intercreditor Agreement, the perfection of a first priority (subject to Liens permitted by clause (i) of the definition of "Permitted Liens") security interest in favor of the Administrative Agent on the RIPSA Account, (B) provides that, upon written notice from the Administrative Agent, such depositary institution shall comply with instructions originated by the Administrative Agent directing disposition of the funds in the RIPSA Account without further consent of the Company and (C) may not be terminated without the prior written consent of the Administrative Agent.

**Section 5.19 Sanctions; Anti-Corruption Use of Proceeds**.

(a) No Obligor nor any of its Subsidiaries or their respective agents shall (i) conduct any business or engage in any transaction or dealing with any Sanctioned Person, including the making or receiving any contribution of funds, goods or services to or for the benefit of any Sanctioned Person; (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to any Sanctions; or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in any Sanctions, the Patriot Act or any other Anti-Terrorism Law.

(b) The Company will not, directly or, to the knowledge of the Company, indirectly, use proceeds received from the Purchasers, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person, (i) in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any Person in violation of any applicable anti-corruption Law, or (ii) (A) for the purpose of funding any activities or business of or with any Person, or in any country or territory, that, at the time of such funding, is, or whose government is, the subject of country- or territory-wide Sanctions, in violation of Sanctions or (B) in any manner that would result in a violation of Sanctions by any party to this Agreement.

## ARTICLE VI

## TERMINATION

**Section 6.01 Term and Termination Date**. Except as provided in this Section 6.01 and in Section 6.02, this Agreement shall commence on the Effective Date and shall terminate upon the earliest of the following (the "Term"):

(a) If prior to the Tranche A Funding Date, the earliest to occur of the following:

(i) Pursuant Section 2.03(a), the occurrence of a Pre-Funding Change of Control and the upon payment of the Pre-Funding Event of Default Fee;

(ii) Pursuant Section 2.03(b), the occurrence of a Tranche A Funding Event of Default and upon payment of the Pre-Funding Event of Default Fee;

(iii) pursuant Section 2.03(c), the occurrence of a Bankruptcy Event of Default and upon payment of the Pre-Funding Event of Default Fee; and

(iv) pursuant to Section 2.03(d), the occurrence of an Event of Default, other than a Pre-Funding Change of Control, Tranche A Funding Event of Default and Bankruptcy Event of Default and the unanimous demand in writing by the Purchasers and upon payment of the Pre-Funding Event of Default Fee.

(b) If on or after the Tranche A Funding Date, the earliest to occur of the following:

(i) upon the receipt by the Purchasers of the Hard Cap;

(ii) upon the Call Option Closing Date and upon the payment of the applicable Call Price;

(iii) pursuant Section 2.03(c), the occurrence of a Bankruptcy Event of Default and upon payment of the Event of Default Fee; and

(iv) pursuant to Section 2.03(d), the occurrence of an Event of Default, other than a Bankruptcy Event of Default and the unanimous demand in writing by the Purchasers and upon payment of the Event of Default Fee.

(c) Notwithstanding anything to the contrary herein, either Party may terminate this Agreement in the event Ensifentrine Approval is not obtained on or prior to September 30, 2024.

(d) In addition, notwithstanding anything to the contrary herein, the Company may terminate this Agreement by written notice immediately upon the Purchasers' failure to pay the Tranche A Purchase Price on the date that it is due in accordance with Section 2.05(b)unless such failure is caused by an error or omission of an administrative or operational nature and such payment is made within two (2) Business Days of the original due date.

(e) Upon expiration or termination of this Agreement in accordance with its terms and upon payment of all amounts due to the Purchasers hereunder, all right, title, and interest in and to the Assigned Interest and the Collateral shall automatically revert to Company, and the Purchasers will have no further rights, title, or interest in the Assigned Interests or the Collateral.

**Section 6.02 Effect of Termination**. In the event of the termination of this Agreement pursuant to Section 6.01, (a) this Agreement shall forthwith become void and have no effect without any liability on the part of any party hereto or its Affiliates, directors, officers, stockholders, partners, managers or members other than the provisions of this Section 6.02, Section 7.05 and Section 7.19 hereof, which shall survive any termination as set forth in Section 6.01, (b) upon the payment and performance in full of all Obligations hereunder (other than contingent indemnification claims for which no claim has been made), the Back-Up Security Interest created by any Transaction Document shall be automatically released and (c) the Collateral and, to the extent that any transfer of the Assigned Interests to the Purchasers contemplated by this Agreement is held not to be a true sale, the Assigned Interests, shall revert back to the Company. In the event of a sale, transfer or any other disposition of any Collateral in a transaction permitted under this Agreement or subject to the terms of the Intercreditor Agreement or any Permitted First Lien Intercreditor Agreement or Permitted Pari Passu Intercreditor Agreement, the security interests in such Collateral created by any Transaction Document shall automatically be released. In connection with any such termination and release, the Administrative Agent and the Purchasers shall, at the expense of the Company, execute and deliver to and authorize the filing by any Obligor all documents such Obligor shall reasonably request to evidence such termination and release. Nothing contained in this Section 6.02 shall relieve any party from liability for any breach of this Agreement.

**Section 6.03 Reinstatement**. The Obligations under this Agreement shall be automatically reinstated if and to the extent that for any reason any payment by the Company is at any time rescinded, annulled, avoided, set aside, invalidated, declared to be fraudulent transfer or must be otherwise restored or repaid by any Purchasers, whether as a result of any proceedings in bankruptcy or reorganization, equitable cause or otherwise.

## ARTICLE VII

## MISCELLANEOUS

**Section 7.01 Survival**. All representations and warranties made herein and in any other Transaction Document, any certificates or in any other writing delivered pursuant hereto or thereto

shall survive the execution and delivery of this Agreement and shall continue to survive until the termination of this Agreement in accordance with Article VII.

**Section 7.02 Limitations on Damages**. Notwithstanding anything to the contrary in this Agreement, in no event shall either party be liable for special, indirect, incidental, punitive or consequential damages of the other party, whether or not caused by or resulting from the actions of such party or the breach of its covenants, agreements, representations or warranties hereunder, even if such party has been advised of the possibility of such damages.

**Section 7.03 Notices**. All notices, requests, instructions, directions and other communications provided for herein (including any modifications of, or waivers, requests or consents under, this Agreement) or in the other Transaction Documents shall be given or made in writing (including by telecopy or email) delivered, if to the Company, Holdings, the Administrative Agent or any Purchaser, to its address specified on the signature pages hereto, or at such other address as shall be designated by such party in a written notice to the other parties. Except as otherwise provided in this Agreement or therein, all such communications shall be deemed to have been duly given upon receipt of a legible copy thereof, in each case given or addressed as aforesaid. All such communications provided for herein by telecopy shall be confirmed in writing promptly after the delivery of such communication (it being understood that non-receipt of written confirmation of such communication shall not invalidate such communication).

**Section 7.04 Successors and Assigns**. The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns. No Obligor shall be entitled to assign the Transaction Documents or any of its obligations and rights under the Transaction Documents without the prior written consent of each Purchaser, and any such assignment in violation of this Section 7.04 shall be null and void; provided that the foregoing shall not apply to any assignment by merger or operation of law provided that the successor or surviving entity, if not the Obligor, shall agree in writing to be bound by all the provisions of this Agreement. The consent of the Company (such consent not to be unreasonably withheld, conditioned or delayed) shall be required for any transfer or assignment of Assigned Interests by a Purchaser unless (x) an Event of Default arising from a violation of any of Section 2.02 or Section 2.03 or a Bankruptcy Event of Default has occurred and is continuing at the time of such assignment or (y) such assignment is to an Eligible Transferee; provided that the Company shall be deemed to have consented to any such assignment unless it shall object thereto by written notice to the Administrative Agent within ten (10) Business Days after having received written notice thereof; provided, further, that, the consent of the Company shall not be required for any assignment to (x) Oaktree Capital Management, L.P. or any of its managed funds or accounts, (y) any Affiliate of the foregoing or (z) any OMERS Purchaser. Any assignment made in violation or breach of this Section 7.04 shall be null and void.

**Section 7.05 Indemnification**.

(a) Each Obligor, jointly and severally, hereby indemnifies and holds the Administrative Agent, the Purchasers and their respective Affiliates and any of their respective limited partners, general partners, partners, directors, managers, members, officers, employees and agents (each, a "Purchasers Indemnified Party") harmless from and against any and all Losses

(including all Losses in connection with any product liability claims or claims of infringement, violation or misappropriation of any Intellectual Property rights of any Third Parties) incurred or suffered by any Purchasers Indemnified Party arising out of any breach of any representation, warranty or certification made by any Obligor in any of the Transaction Documents or any breach of or default under any covenant or agreement by any Obligor pursuant to any Transaction Document, including any failure by any Obligor to satisfy any of the Excluded Liabilities and Obligations; provided, however, that the foregoing shall exclude any indemnification to any Purchasers Indemnified Party (i) that results from the gross negligence, bad faith or willful misconduct, or violation of applicable Law of such the Purchasers Indemnified Party, (ii) to the extent resulting from acts or omissions of any Obligor based upon and in compliance with the written instructions from any Purchasers Indemnified Party or (iii) for any matter in respect of which any Company Indemnified Party would be entitled to indemnification under Section 7.05(b). This Section 7.05(a) shall not apply to Taxes other than Taxes relating to a non-Tax claim or Loss governed by this Section 7.05(a).

(b) The Purchasers, severally but not jointly, hereby indemnify and hold the Company, its Affiliates and any of their respective partners, directors, managers, officers, employees and agents (each, a "Company Indemnified Party") harmless from and against any and all Losses incurred or suffered by a Company Indemnified Party arising out of any breach of any representation, warranty or certification made by the Purchasers in any of the Transaction Documents or any breach of or default under any covenant or agreement by the Purchasers pursuant to any Transaction Document; provided, however, that the foregoing shall exclude any indemnification to any Company Indemnified Party (i) that results from the gross negligence, bad faith or willful misconduct or violation of applicable Law of such Company Indemnified Party, (ii) to the extent resulting from acts or omissions of the Purchasers based upon and in compliance with the written instructions from any Company Indemnified Party or (iii) for any matter in respect of which any Purchasers Indemnified Party would be entitled to indemnification under Section 7.05(a). This Section 7.05(b) shall not apply to Taxes other than Taxes relating to a non-Tax claim or Loss governed by this Section 7.05(b).

(c) If any claim, demand, action or proceeding (including any investigation by any Governmental Authority) shall be brought or alleged against an indemnified party in respect of which indemnity is to be sought against an indemnifying party pursuant to the preceding paragraphs, the indemnified party shall, promptly after receipt of notice of the commencement of any such claim, demand, action or proceeding, notify the indemnifying party in writing of the commencement of such claim, demand, action or proceeding, enclosing a copy of all papers served, if any; provided, that the omission to so notify such indemnifying party will not relieve the indemnifying party from any liability that it may have to any indemnified party under the foregoing provisions of this Section 7.05 unless, and only to the extent that, such omission results in the forfeiture of, or has a material adverse effect on the exercise or prosecution of, substantive rights or defenses by the indemnifying party. In case any such action is brought against an indemnified party and it notifies the indemnifying party of the commencement thereof, the indemnifying party will be entitled to participate therein and, to the extent that it may wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party (who shall not, except with the consent of the indemnified party, be counsel to the indemnifying party), and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party will not

be liable to such indemnified party under this Section 7.05 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation. In any such proceeding, an indemnified party shall have the right to retain its own counsel, but the reasonable fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel, (ii) the indemnifying party has assumed the defense of such proceeding and has failed within a reasonable time to retain counsel reasonably satisfactory to such indemnified party or (iii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential conflicts of interests between them based on the advice of such counsel. It is agreed that the indemnifying party shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate law firm in each relevant jurisdiction for all such indemnified parties. The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding.

(d) The indemnification afforded by this Section 7.05 shall be the sole and exclusive remedy for any and all Losses awarded against or incurred or suffered by the Purchasers Indemnified Parties against the Obligors in connection with the Obligors' indemnification obligations hereunder and the Company Indemnified Parties against the Purchasers in connection with the Purchasers' indemnification obligations hereunder, in each case other than any indemnification obligations resulting from (A) the gross negligence, the bad faith or willful misconduct or violation of applicable Law of the other Party or (B) acts or omissions based upon and in compliance with the written instructions from the other Party; provided that nothing in this Section 7.05 shall alter or affect the rights of the Purchasers to exercise remedies under the Transaction Documents in accordance with their terms or other rights of creditors under the UCC or any other applicable Law.

(e) Notwithstanding anything in this Agreement to the contrary, no Obligor shall have any liability under this Section 7.05 on any day on which such indemnity claim under this Section 7.05 is paid by such Obligor, in excess of the Cap Amount for such day. "Cap Amount" means, for any day on which an indemnity claim under this Section 7.05 is paid by any Obligor, the excess of (x) the Hard Cap over (y) the sum of (A) the aggregate amount of Royalty Interest Payments, U.S. Licensing / Participation Payments and Ex-U.S. Licensing / Participation Payments received by the Purchasers on or prior to such day and (B) the aggregate amount of payments made under this Section 7.05 by any Obligor on or prior to such day. Notwithstanding anything in this Agreement to the contrary, the Purchasers shall not have any liability under this Section 7.05 in excess of the Purchase Price, in the aggregate.

**Section 7.06 No Implied Representations and Warranties**. Each party acknowledges and agrees that, other than the representations and warranties specifically contained in any of the Transaction Documents, there are no representations or warranties of either party or any other

Person either expressed or implied with respect to the Assigned Interests or the transactions contemplated hereby. Without limiting the foregoing, each of the Purchasers acknowledges and agrees that (a) such Purchaser and its Affiliates, together with its and its Affiliates' representatives, have made their own investigation of the Product (including the Product Intellectual Property) and are not relying on any implied warranties or upon any representation or warranty whatsoever as to the future amount or potential amount of the Assigned Interests or as to the creditworthiness of the Obligors and (b) except as expressly set forth in any representation or warranty in a Transaction Document, such Purchaser shall have no claim or right to indemnification pursuant to Section 7.05 (or otherwise) with respect to any information, documents or materials furnished to such Purchaser, any of its Affiliates, or any of its or its Affiliates' representatives, including any information, documents or material made available to such Purchaser and its Affiliates and its Affiliates' representatives in any data room, presentation, interview or any other form relating to the transactions contemplated hereby.

**Section 7.07 Independent Nature of Relationship**.

(a) The relationship between each Obligor and its Subsidiaries, on the one hand, and the Purchasers, on the other, is solely that of seller and purchaser, and neither the Purchasers, on the one hand, nor any Obligor and its Subsidiaries, on the other, has any fiduciary, employment, franchise, agency or other special relationship with the other or any of their respective Affiliates. Nothing contained herein or in any other Transaction Document shall be deemed to constitute any Obligor and its Subsidiaries and the Purchasers as a partnership, an association, a joint venture or other kind of entity or legal form for any purposes. The Parties agree that they shall not take any inconsistent position with respect to such treatment in a filing with any Governmental Authority.

(b) The Company and/or any of its Affiliates shall not at any time obligate the Purchasers, or impose on the Purchasers any obligation, in any manner or with respect to any Person not a party hereto.

**Section 7.08 Tax Treatment**. For all U.S. federal, state and local and non-U.S. tax purposes, unless otherwise required by applicable Law, each Obligor and its Subsidiaries, on the one hand, and the Purchasers, on the other, shall treat this Agreement as effecting a sale of a contractual right to receive payments in respect of the Assigned Interests. The Parties do not intend that the Assigned Interests be treated as an equity, profit-participating or ownership interest in the Company or any other Obligor or Subsidiary or as creating an actual or constructive partnership, joint venture, association, or similar relationship or arrangement between or among the Parties for tax purposes. The Parties agree not to take any position that is inconsistent with the provisions of this Section 7.08 on any Tax Return or in any audit or other administrative or judicial proceeding unless (i) all the Parties have consented in writing to take such an inconsistent position, (ii) the Party that contemplates taking such an inconsistent position has been advised by a nationally recognized counsel or accounting firm in writing that it is more likely than not that the inconsistent position is required by applicable Law, or (iii) to the extent required pursuant to a "determination" within the meaning of Section 1313(a) of the Code, or a comparable provision of applicable state, local or non-U.S. Law. Notwithstanding anything to the contrary in this Agreement, this Section 7.08 shall govern with respect to the tax treatment of the transactions hereunder.

**Section 7.09 Entire Agreement**. This Agreement, together with the Exhibits and Schedules hereto (which are incorporated herein by reference), and the other Transaction Documents constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements (including the Term Sheet), understandings and negotiations, both written and oral, between the parties with respect to the subject matter of this Agreement. No representation, inducement, promise, understanding, condition or warranty not set forth herein (or in the Exhibits, Schedules or other Transaction Documents) has been made or relied upon by either party hereto. None of this Agreement, nor any provision hereof, is intended to confer upon any Person other than the parties hereto any rights or remedies hereunder.

**Section 7.10 Amendments; No Waivers**.

(a) This Agreement or any term or provision hereof may not be amended, changed or modified except with the written consent of the parties hereto. No waiver of any right hereunder shall be effective unless such waiver is signed in writing by the party against whom such waiver is sought to be enforced.

(b) No failure or delay by either party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by law.

**Section 7.11 Interpretation**. When a reference is made in this Agreement to Articles, Sections, Schedules or Exhibits, such reference shall be to an Article, Section, Schedule or Exhibit to this Agreement unless otherwise indicated. The words "include", "includes" and "including" when used herein shall be deemed in each case to be followed by the words "without limitation". Neither party hereto shall be or be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one party or the other. Unless otherwise expressly provided herein, references to organizational documents, agreements (including the Transaction Documents) and other contractual instruments shall be deemed to include all subsequent amendments, restatements, extensions, supplements and other modifications thereto permitted by the Transaction Documents.

**Section 7.12 Headings and Captions**. The headings and captions in this Agreement are for convenience and reference purposes only and shall not be considered a part of or affect the construction or interpretation of any provision of this Agreement.

**Section 7.13 Counterparts; Effectiveness**. This Agreement may be executed in two or more counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other parties hereto. Any counterpart may be executed by facsimile or pdf signature and such facsimile or pdf signature shall be deemed an original.

**Section 7.14 Severability**. If any provision of this Agreement is held to be invalid or unenforceable, the remaining provisions shall nevertheless be given full force and effect.

**Section 7.15 Expenses**. Each Obligor, jointly and severally, agrees to pay or reimburse (i) each Purchaser and the Administrative Agent for each of their reasonable and documented out-of-pocket costs and expenses (including the reasonable and documented out of pocket fees, expenses, charges and disbursements of counsel of Sullivan & Cromwell LLP and counsel of Hogan Lovells US LLP, each counsel to the Administrative Agent and the Purchasers, and (if necessary) of a single local counsel to the Administrative Agent and the Purchasers, taken as a whole, in each relevant material jurisdiction and one regulatory counsel for the Administrative and the Purchasers taken as a whole, and any sales, goods and services or other similar Taxes applicable thereto, and reasonable and documented printing, reproduction, document delivery, communication and travel costs) in connection with (x) the negotiation, preparation, execution and delivery of this Agreement and the other Transaction Documents and the making of the purchases (exclusive of post-closing costs); provided that, notwithstanding the foregoing, (A) the Obligors shall only be required to pay or reimburse legal and Intellectual Property diligence expenses (collectively, "Legal & IP Expenses") pursuant to this clause (i)(x) in an amount equal to (1) 100% of any Legal and IP Expenses up to $500,000 (in the aggregate with any due diligence expenses required to be paid or reimbursed by the obligors under the Oaktree Term Loan Facility) and (2) 50% of any Legal and IP Expenses in excess thereof and (B) the Obligors shall only be required to pay or reimburse due diligence expenses (other than Intellectual Property diligence expenses constituting Legal and IP Expenses) pursuant to this clause (i)(x) in an amount equal to (1) 100% of any such due diligence expenses up to $125,000 (in the aggregate with any due diligence expenses (other than intellectual property diligence expenses) required to be paid or reimbursed by the obligors under the Oaktree Term Loan Facility) and (2) 50% of any such due diligence expenses in excess thereof; provided, further, that the amount of all Legal and IP Expenses, due diligence expenses and all other fees, costs and expenses payable pursuant to this clause (i) shall be net of any amounts previously paid by any Obligor to the Administrative Agent or any Purchaser as a deposit against such fees, costs and expenses, (y) post-closing costs (including costs of the administration of this Agreement and the other Transaction Documents) and (z) the negotiation or preparation of any modification, supplement or waiver of any of the terms of this Agreement or any of the other Transaction Documents (whether or not consummated) and (ii) each of the Administrative Agent and the Purchasers for all of their documented out-of-pocket costs and expenses (including the reasonable and documented fees and expenses of any legal counsel, provided, that such documentation shall not include legal time entries, but may include aggregate hours) in connection with the enforcement, exercise or protection of their rights in connection with this Agreement and the other Transaction Documents, including their rights under this Section 7.15 , or in connection with the purchases made hereunder, including such out-of-pocket expenses incurred during any workout, restructuring or negotiations in respect of such purchases.

**Section 7.16 Governing Law; Jurisdiction**.

(a) This Agreement shall be governed by, and construed, interpreted and enforced in accordance with, the laws of the state of New York, without giving effect to the principles of conflicts of law thereof.

(b) Any legal action or proceeding with respect to this Agreement or any other Transaction Document may be brought in any state or federal court of competent jurisdiction in the State of New York, County of New York. By execution and delivery of this Agreement, each party hereto hereby irrevocably consents to and accepts, for itself and in respect of its property,

generally and unconditionally the exclusive jurisdiction of such courts. Each party hereto hereby further irrevocably waives any objection, including any objection to the laying of venue or based on the grounds of forum non conveniens, which it may now or hereafter have to the bringing of any action or proceeding in such jurisdiction in respect of any Transaction Document.

(c) Each party hereto hereby irrevocably consents to the service of process out of any of the courts referred to in subsection (b) of this Section 7.16 in any such suit, action or proceeding by the mailing of copies thereof by registered or certified mail, postage prepaid, to it at its address set forth in this Agreement. Each party hereto hereby irrevocably waives any objection to such service of process and further irrevocably waives and agrees not to plead or claim in any suit, action or proceeding commenced hereunder or under any other Transaction Document that service of process was in any way invalid or ineffective. Nothing herein shall affect the right of a party to serve process on the other party in any other manner permitted by law.

**Section 7.17 Waiver of Jury Trial**. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any action, proceeding, claim or counterclaim arising out of or relating to any Transaction Document or the transactions contemplated under any Transaction Document. This waiver shall apply to any subsequent amendments, renewals, supplements or modifications to any Transaction Document.

**Section 7.18 Release of Liens upon Certain Permitted Financings; Non-Disturbance; Permitted First Lien Intercreditor Agreement; Permitted Pari Passu Intercreditor Agreement**.

(a) In connection with the incurrence by any Obligor or any of its Subsidiaries of any Permitted Priority Debt (other than the Oaktree Term Loan Facility), the Administrative Agent and the Purchasers (upon request of the Company) shall enter into an intercreditor agreement with the lenders under such Permitted Priority Debt (or the agent to such lenders), which intercreditor agreement shall contain substantially similar terms as those in the Intercreditor Agreement, or such other terms as are reasonably acceptable to the Company, the Administrative Agent and the Purchasers (a "Permitted First Lien Intercreditor Agreement"). In connection with the incurrence or entry into by any Obligor or any of its Subsidiaries of any Permitted Revenue Financing, the Administrative Agent and the Purchasers (upon request of the Company) shall enter into a customary pari passu intercreditor agreement with the lenders or purchasers under such Permitted Revenue Financing (or the agent to such lenders or purchasers), in form and substance reasonably acceptable to the Company, the Administrative Agent and the Purchasers (any such intercreditor agreement, an "Permitted Pari Passu Intercreditor Agreement").

(b) Upon the request of any licensee party (or prospective licensee to be a party) to a Permitted Licensing Agreement, the Administrative Agent and the Purchasers shall, at the reasonable request of the Company, enter into non-disturbance and similar agreements in connection with the licensing of any Product Intellectual Property and other general intangibles covering the Product permitted under this Agreement to the extent reasonably requested by licensee thereof and on terms reasonably satisfactory to the Majority Purchasers. In connection with any licensing or sub-licensing transactions permitted pursuant to this Agreement, each of the Administrative Agent and the Purchasers agree, at the request of the Company, to execute and

deliver such documents as the Company may reasonably request to evidence such non-disturbance or similar agreement which shall be on terms reasonably satisfactory to the Majority Purchasers.

(c) Any Lien held by the Purchasers or by the Administrative Agent for the benefit of the Purchasers against (i) any Collateral that is disposed of by any Obligor or its Subsidiaries (including pursuant to a valid waiver or consent) in any transaction not prohibited by this Agreement or (ii) any property subject to a Lien described in clause (b) of the definition of "Permitted Liens" shall, in each case, be automatically released without further action by the Administrative Agent, any Purchaser or any Obligor or its Subsidiary, and each Purchaser hereby directs the Administrative Agent to, and the Administrative Agent hereby agrees, upon receipt of reasonable advance notice from the Company and at the expense of the Company, to execute and deliver or file such documents and to perform other actions reasonably necessary to release the guarantees and Liens when and as directed pursuant to this Section 7.18 and deliver to the Company, at the expense of the Company, any portion of such Collateral so released pursuant to this Section 7.18 that is in possession of the Administrative Agent.

**Section 7.19 Confidentiality**. The Administrative Agent and the Purchasers agree to keep confidential all non-public information provided to it by any Obligor pursuant to this Agreement; provided that nothing herein shall prevent the Administrative Agent or the Purchasers from disclosing any such information (i) to the Purchasers, any Affiliate of the Purchasers or any other assignee permitted under Section 7.04, (ii) to their employees, officers, directors, agents, attorneys, accountants, trustees and other professional advisors, potential or actual lenders or investors or those of any of its Affiliates (collectively, its "Affiliated Parties"), (iii) upon the request or demand of any Governmental Authority purporting to have jurisdiction over such Person or its Affiliates (including any self-regulatory authority, such as the National Association of Insurance Commissioners), (iv) in response to any order of any court or other Governmental Authority or as may otherwise be required pursuant to any Law, (v) if required to do so in connection with any litigation or similar proceeding, (vi) that has been publicly disclosed (other than as a result of a disclosure in violation of this Section 7.19) or (vii) to the extent necessary in connection with the exercise of any remedy hereunder or under any other Transaction Document; provided that, in the case of disclosure pursuant to clause (iii), (iv) and (v) above, the Purchasers shall promptly provide notice to the Company to the extent reasonable and not prohibited by Law or any applicable Governmental Authority; provided, further, that the Administrative Agent and the Purchasers shall be permitted to disclose a general description of transactions arising under the Transaction Documents for advertising, marketing or other similar purposes (including, so-called "tombstone" advertisements and notices).

## ARTICLE VIII

## THE ADMINISTRATIVE AGENT

**Section 8.01 Appointments and Duties**.

(a) Appointment of the Administrative Agent. Each of the Purchasers hereby irrevocably appoints Oaktree Fund Administration, LLC (together with any successor Administrative Agent) as the Administrative Agent hereunder and authorizes the Administrative Agent to (i) execute and deliver the Transaction Documents and accept delivery thereof on its

behalf from any Obligor or any of its Subsidiaries, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to the Administrative Agent under such Transaction Documents and (iii) exercise such powers as are reasonably incidental thereto. Except as expressly set forth herein, the provisions of this Article VIII are solely for the benefit of the Administrative Agent and the Purchasers, and neither the Company nor its Affiliates shall have rights as a third-party beneficiary of any such provisions.

(b) Duties as Agent. Without limiting the generality of Section 8.01(a), the Administrative Agent shall have the sole and exclusive right and authority (to the exclusion of the Purchasers), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Purchasers with respect to all payments and collections arising in connection with the Transaction Documents, and each Person making any payment in connection with any Transaction Document to any Secured Party is hereby authorized to make such payment to the Administrative Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of the Secured Parties with respect to any Obligation in any bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Secured Party), (iii) act as collateral agent for each Secured Party for purposes of acquiring, holding, enforcing and perfecting all Liens created by the Transaction Documents and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Transaction Documents, (vi) except as may be otherwise specified in any Transaction Document, exercise all remedies given to the Administrative Agent and the other Secured Parties with respect to the Collateral, whether under the Transaction Documents, applicable Laws or otherwise and (vii) execute any amendment, consent or waiver under the Transaction Documents on behalf of any Purchaser that has consented in writing to such amendment, consent or waiver; provided that the Administrative Agent hereby appoints, authorizes and directs each Purchaser to act as collateral sub-agent for the Administrative Agent and the Purchasers for purposes of the perfection of all Liens with respect to the Collateral, including any deposit account maintained by any Obligor, and cash and cash equivalents held by, such Purchaser, and may further authorize and direct the Purchasers to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to the Administrative Agent, and each Purchaser hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed.

(c) Limited Duties. The Purchasers and the Company hereby each acknowledge and agree that the Administrative Agent (i) has undertaken its role hereunder purely as an accommodation to the parties hereto and the transactions contemplated hereby, (ii) is receiving no compensation for undertaking such role and (iii) subject only to the notice provisions set forth in Section 8.09, may resign from such role at any time for any reason or no reason whatsoever. Without limiting the foregoing, the parties hereto further acknowledge and agree that under the Transaction Documents, the Administrative Agent (i) is acting solely on behalf of the Purchasers (except to the limited extent provided in Section 8.11) with duties that are entirely administrative in nature, notwithstanding the use of the defined term "the Administrative Agent", the terms "agent", "administrative agent" and "collateral agent" and similar terms in any Transaction Document to refer to the Administrative Agent, which terms are used for title purposes only, (ii) is not assuming any duty or obligation under any Transaction Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Purchaser or any other Secured

Party and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Transaction Document (fiduciary or otherwise), in each case, regardless of whether a Default, breach or Event of Default under this Agreement has occurred and is continuing, and each Purchaser hereby waives and agrees not to assert any claim against the Administrative Agent based on the roles, duties and legal relationships expressly disclaimed in this clause (c). Without in any way limiting the foregoing, the Administrative Agent shall not, except as expressly set forth in this Agreement and in the other Transaction Documents, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to the Company or any of its Affiliates that is communicated to or obtained by the Person serving as the Administrative Agent or any of its Affiliates in any capacity.

**Section 8.02 Binding Effect**. Each Purchaser agrees that (i) any action taken by the Administrative Agent in accordance with the provisions of the Transaction Documents, (ii) any action taken by the Administrative Agent in reliance upon the instructions of the Purchasers and (iii) the exercise by the Administrative Agent of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Secured Parties.

**Section 8.03 Use of Discretion**.

(a) No Action without Instructions. The Administrative Agent shall not be required to exercise any discretion or take, or to omit to take, any action, including with respect to enforcement or collection, except (subject to clause (b) below) any action it is required to take or omit to take (i) under any Transaction Document or (ii) pursuant to written instructions from the Majority Purchasers (or, where expressly required or permitted by the terms of this Agreement, any number of the Purchasers).

(b) Right Not to Follow Certain Instructions. Notwithstanding Section 8.03(a) or any other term or provision of this Article VIII, the Administrative Agent shall not be required to take, or to omit to take, any action (i) unless, upon demand, the Administrative Agent receives an indemnification satisfactory to it from the Purchasers (or, to the extent applicable and acceptable to the Administrative Agent, any other Secured Party) against all liabilities that, by reason of such action or omission, may be imposed on, incurred by or asserted against the Administrative Agent or any Affiliate thereof or (ii) that is, in the opinion of the Administrative Agent, in its sole and absolute discretion, contrary to any Transaction Document, Law or the best interests of the Administrative Agent or any of its Affiliates, including, for the avoidance of doubt, any action that may be in violation of the automatic stay in connection with any insolvency or similar proceeding.

**Section 8.04 Delegation of Rights and Duties**. The Administrative Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Transaction Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any Secured Party). The Administrative Agent and any such Person may perform any and all of its duties and exercise its rights and powers by or through their respective Affiliates. Any such Person and its Affiliates shall benefit from this Article VIII to the extent provided by the Administrative Agent; provided, however, that the exculpatory provisions of this Article VIII shall apply to any such sub-agent and to the Affiliates of the Administrative Agent and of any such sub-

agent, and shall apply to their respective activities in connection with their activities as Administrative Agent. The Administrative Agent shall not be responsible for the negligence or misconduct of any sub-agents except to the extent that a court of competent jurisdiction determines in a final and non-appealable judgment that the Administrative Agent acted with gross negligence or willful misconduct in the selection of such sub-agents.

**Section 8.05 Liability**.

(a) The Administrative Agent may, without incurring any liability hereunder, (i) consult with any of its Affiliates and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, any Obligor) and (ii) rely and act upon any notice, request, certificate, consent, statement, instrument, document or other writing (including and electronic message, Internet or intranet website posting or other distribution), telephone message or conversation or oral conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. In determining compliance with any condition hereunder to the making of a Purchase Price payment that by its terms must be fulfilled to the satisfaction of a Purchaser, the Administrative Agent may presume that such condition is satisfactory to such Purchaser unless the Administrative Agent shall have received written notice to the contrary from such Purchaser prior to the making of such purchase.

(b) Neither the Administrative Agent nor any of its Affiliates shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Transaction Document, and the Purchasers and the Company hereby waive and shall not assert (and the Company shall cause each other Obligor to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting primarily from the fraudulent conduct or behavior of the Administrative Agent or, as the case may be, such Affiliate (each as determined in a final, non-appealable judgment or order by a court of competent jurisdiction) in connection with the duties expressly set forth herein. Without limiting the foregoing, the Administrative Agent:

(i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of, or with the consent of, the Purchasers or for the actions or omissions of any of its Affiliates selected with reasonable care (other than employees, officers and directors of the Administrative Agent, when acting on behalf of the Administrative Agent);

(ii) shall not be responsible to any Secured Party for the (a) validity, enforceability, effectiveness or genuineness of this Agreement, any other Transaction Document or any other agreement, instrument or document, or (b) due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Transaction Document;

(iii) makes no warranty or representation, and shall not be responsible, to any Secured Party for, and shall not have any duty to ascertain or inquire into, any statement, document, information, certificate, report, representation or warranty made or furnished by or on behalf of

any Affiliate, in or in connection with any Transaction Document or any transaction contemplated therein, whether or not transmitted by the Administrative Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by the Administrative Agent in connection with the Transaction Documents (other than to confirm receipt of items expressly required to be delivered to the Administrative Agent); and

(iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Transaction Document or whether any condition set forth in any Transaction Document is satisfied or waived, including, without limiting the generality of the foregoing, as to the financial condition of any Obligor or as to the existence or continuation or possible occurrence or continuation of any Default or Event of Default and shall not be deemed to have notice or knowledge of such occurrence or continuation unless it has received a notice from the Company or any Purchaser describing such Event of Default clearly labeled "put option event" (in which case the Administrative Agent shall promptly give notice of such receipt to all Purchasers);

and, for each of the items set forth in clauses (i) through (iv) above, each Purchaser and the Company hereby waives and agrees not to assert (and the Company shall cause each other Obligor to waive and agree not to assert) any right, claim or cause of action it might have against the Administrative Agent based thereon.

**Section 8.06 Administrative Agent Individually**. The Administrative Agent and its Affiliates may make loans and other extensions of credit to, acquire stock and stock equivalents of, accept deposits from, act as the financial advisor for or in any other advisory capacity for, or engage in any kind of business with, any Obligor or its Subsidiaries as though it were not acting as the Administrative Agent and may receive separate fees and other payments therefor. To the extent the Administrative Agent or any of its Affiliates becomes a Purchaser hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Purchaser and the term "Purchaser" and any similar terms shall, except where otherwise expressly provided in any Transaction Document, include, without limitation, the Administrative Agent or such Affiliate, as the case may be, in its individual capacity as Purchaser.

**Section 8.07 Purchaser Investment Decision**. Each Purchaser acknowledges that it has, independently and without reliance upon the Administrative Agent, any Purchaser or any of their Affiliates or upon any document solely or in part because such document was transmitted by the Administrative Agent or any of its Affiliates, conducted its own independent investigation of the financial condition and affairs of each Obligor and has made and continues to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Transaction Document or with respect to any transaction contemplated in any Transaction Document, in each case based on such documents and information as it shall deem appropriate.

**Section 8.08 Expenses; Indemnities**.

(a) Each Purchaser agrees to reimburse the Administrative Agent and each of its Affiliates (to the extent not reimbursed by any Obligor) promptly upon demand for such Purchaser's Proportionate Share of any costs and expenses (including fees, charges and

disbursements of financial, legal and other advisors and Other Taxes paid in the name of, or on behalf of, the Company or any of its Subsidiaries or Affiliates) that may be incurred by the Administrative Agent or any of its Affiliates in connection with the preparation, syndication, execution, delivery, administration, modification, consent, waiver or enforcement (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding or otherwise) of, or legal advice in respect of its rights or responsibilities under, any Transaction Document.

(b) Each Purchaser agrees to indemnify the Administrative Agent (or any sub-agent thereof) and any Affiliates of the Administrative Agent (or any such sub-agent) (to the extent not indefeasibly paid by any Obligor), from and against such Purchaser's aggregate Proportionate Share of the liabilities (including taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to on or for the account of any Purchaser) that may be imposed on, incurred by or asserted against the Administrative Agent (or any sub-agent thereof) or any Affiliates of the Administrative Agent (or any such sub-agent) in any matter relating to or arising out of, in connection with or as a result of any Transaction Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by the Administrative Agent (or any sub-agent thereof) or any Affiliates of the Administrative Agent (or any such sub-agent) under or with respect to any of the foregoing; provided that no Purchaser shall be liable to the Administrative Agent (or any sub-agent thereof) or any Affiliates of the Administrative Agent (or any such sub-agent) to the extent such liability has resulted primarily from the gross negligence or willful misconduct of the Administrative Agent (or any sub-agent thereof) or, as the case may be, such Affiliate of the Administrative Agent (or any sub-agent thereof), as determined by a court of competent jurisdiction in a final non-appealable judgment or order.

**Section 8.09 Resignation of the Administrative Agent**.

(a) At any time upon not less than thirty (30) days' prior written notice to the Purchasers, the Administrative Agent may resign as the "the Administrative Agent" hereunder, in whole or in part (in the sole and absolute discretion of the Administrative Agent). If the Administrative Agent delivers any such notice, the Majority Purchasers shall have the right, in consultation with the Company, to appoint a successor, which shall be (i) a Purchaser holding at least thirty percent (30%) of the outstanding Commitments or any Affiliate thereof or (ii) any other financial institution consented to by the Company (provided that the consent of the Company shall not be required to the extent an Event of Default has occurred and is continuing). If a successor Administrative Agent has not been appointed on or before the effectiveness of the resignation of the resigning Administrative Agent (or such earlier date as shall be agreed by the Majority Purchasers) (the "Resignation Effective Date"), then the resigning Administrative Agent may (but shall not be obligated to), on behalf of the Purchasers, appoint any Person reasonably chosen by it as the successor Administrative Agent, notwithstanding whether the Majority Purchasers have appointed a successor or the Company has consented to such successor. Whether or not a successor has been appointed, such resignation shall become effective on the Resignation Effective Date.

(b) Effective from the Resignation Effective Date, (i) the resigning Administrative Agent shall be discharged from its duties and obligations under the Transaction Documents to the extent set forth in the applicable resignation notice, (ii) the Purchasers shall assume and perform

all of the duties of the Administrative Agent until a successor Administrative Agent shall have accepted a valid appointment hereunder, (iii) the resigning Administrative Agent and its Affiliates shall no longer have the benefit of any provision of any Transaction Document other than with respect to (x) any actions taken or omitted to be taken while such resigning Administrative Agent was, or because the Administrative Agent had been, validly acting as the Administrative Agent under the Transaction Documents or (y) any continuing duties such resigning Administrative Agent will continue to perform, and (iv) subject to its rights under Section 8.04, the resigning Administrative Agent shall take such action as may be reasonably necessary to assign to the successor Administrative Agent its rights as the Administrative Agent under the Transaction Documents. Effective immediately upon its acceptance of a valid appointment as the Administrative Agent, a successor Administrative Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the resigning Administrative Agent under the Transaction Documents.

**Section 8.10 [Reserved]**.

**Section 8.11 Additional Secured Parties**. The benefit of the provisions of the Transaction Documents directly relating to the Collateral or any Lien granted thereunder shall extend to and be available to any Secured Party that is not a Purchaser as long as, by accepting such benefits, such Secured Party agrees, as among the Administrative Agent and all other Secured Parties, that such Secured Party is bound by (and, if requested by the Administrative Agent, shall confirm such agreement in a writing in form and substance acceptable to the Administrative Agent) this Article VIII and the decisions and actions of the Administrative Agent and the Purchasers to the same extent a Purchaser is bound; provided that, notwithstanding the foregoing, (i) such Secured Party shall be bound by Section 8.08 only to the extent of liabilities, costs and expenses with respect to or otherwise relating to the Collateral held for the benefit of such Secured Party, in which case the obligations of such Secured Party thereunder shall not be limited by any concept of pro rata share or similar concept, (ii) each of the Administrative Agent and each Purchaser shall be entitled to act at its sole discretion, without regard to the interest of such Secured Party, regardless of whether any Obligation to such Secured Party thereafter remains outstanding, is deprived of the benefit of the Collateral, becomes unsecured or is otherwise affected or put in jeopardy thereby, and without any duty or liability to such Secured Party or any such Obligation and (iii) such Secured Party shall not have any right to be notified of, consent to, direct, require or be heard with respect to, any action taken or omitted in respect of the Collateral or under any Transaction Document.

**Section 8.12 Agent May File Proofs of Claim**. In case of the pendency of any insolvency or similar proceeding or any other judicial proceeding relating to any Obligor, the Administrative Agent (irrespective of whether any payments under this Agreement shall then be due and payable as herein expressed or by declaration or otherwise and irrespective of whether the Administrative Agent shall have made any demand on any other Obligor) shall be entitled and empowered (but not obligated) by intervention or such proceeding or otherwise:

(a) to file and prove a claim for the whole amount of all Obligations that are owing and unpaid under this Agreement and to file such other documents as may be necessary or advisable in order to have the claims of the Purchasers and the Administrative Agent (including any claim

for the reasonable compensation, expenses, disbursements and advances of the Purchasers and the Administrative Agent and their respective agents and counsel); and

(b) to collect and receive any monies or other property payable or deliverable on any such claims and to distribute the same;

and any custodian, receiver, assignee, trustee, liquidator, sequestrator or other similar official in any such judicial proceeding is hereby authorized by each Purchaser to make such payments to the Administrative Agent and, in the event that the Administrative Agent shall consent to the making of such payments directly to the Purchasers, to pay to the Administrative Agent any amount due for the reasonable compensation, expenses, disbursements and advances of the Administrative Agent and its agents and counsel.

**Section 8.13 [Reserved].**

**Section 8.14 Acknowledgements of Purchasers.**

(a) If the Administrative Agent notifies a Purchaser, or any Person who has received funds on behalf of a Purchaser (any such Purchaser or other recipient, a "Payment Recipient"), that the Administrative Agent has determined in its sole discretion (whether or not after receipt of any notice under immediately succeeding clause (b)) that any funds (as set forth in such notice from the Administrative Agent) received by such Payment Recipient from the Administrative Agent or any of its Affiliates were erroneously transmitted to, or otherwise erroneously or mistakenly received by, such Payment Recipient (whether or not known to such Purchaser or other Payment Recipient on its behalf) (any such funds, whether transmitted or received as a payment, prepayment or repayment of Royalty Interest Payments, U.S. Licensing / Participation Payments or Ex-U.S. Licensing / Participation Payments, fees, distribution or otherwise, individually and collectively, an "Erroneous Payment") and demands in writing the return of such Erroneous Payment (or a portion thereof), such Erroneous Payment shall at all times remain the property of the Administrative Agent pending its return or repayment as contemplated below in this Section 8.14, and held in trust for the benefit of the Administrative Agent, and such Payment Recipient shall (or, with respect to any Payment Recipient who received such funds on its behalf, shall cause such Payment Recipient to) promptly, but in no event later than two (2) Business Days thereafter (or such later date as the Administrative Agent may, in its sole discretion, specify in writing), return to the Administrative Agent the amount of any such Erroneous Payment (or portion thereof) as to which such a demand was made, in same day funds (in the currency so received), together with interest thereon (except to the extent waived in writing by the Administrative Agent) in respect of each day from the date such Erroneous Payment (or portion thereof) was received by such Payment Recipient to the date such amount is repaid to the Administrative Agent in same day funds at the greater of the Federal Funds Effective Rate and a rate determined by the Administrative Agent in accordance with banking industry rules on interbank compensation from time to time in effect. A notice of the Administrative Agent to any Payment Recipient under this clause (i) shall be conclusive, absent manifest error.

(b) Without limiting immediately preceding clause (a), each Payment Recipient hereby further agrees that if it receives a payment, prepayment or repayment (whether received as a payment, prepayment or repayment of Royalty Interest Payments, U.S. Licensing / Participation

Payments or Ex-U.S. Licensing / Participation Payments, fees, distribution or otherwise) from the Administrative Agent (or any of its Affiliates) (x) that is in a different amount than, or on a different date from, that specified in this Agreement or in a notice of payment, prepayment or repayment (a "Payment Notice") sent by the Administrative Agent (or any of its Affiliates) with respect to such payment, prepayment or repayment, (y) that was not preceded or accompanied by a Payment Notice, or (z) that such Payment Recipient otherwise becomes aware was transmitted, or received, in error or by mistake (in whole or in part), then, in each such case: (i) such Payment Recipient acknowledges and agrees that (A) in the case of immediately preceding clauses (x) or (y), an error and mistake shall be presumed to have been made (absent written confirmation from the Administrative Agent to the contrary) or (B) an error and mistake has been made (in the case of immediately preceding clause (z)), in each case, with respect to such payment, prepayment or repayment; and (ii) such Payment Recipient shall promptly (and, in all events, within one (1) Business Day of its knowledge of the occurrence of any of the circumstances described in immediately preceding clauses (x), (y) or (z)) use commercially reasonable efforts to notify the Administrative Agent of its receipt of such payment, prepayment or repayment, the details thereof (in reasonable detail) and that it is so notifying the Administrative Agent pursuant to this Section 8.14(b)(ii).

(c) Each Purchaser hereby authorizes the Administrative Agent to set off, net and apply any and all amounts at any time owing to such Purchaser under any Transaction Document, or otherwise payable or distributable by the Administrative Agent to such Purchaser from any source, against any amount that the Administrative Agent has demanded to be returned pursuant to immediately preceding clause (a).

(d) In the event that an Erroneous Payment (or portion thereof) is not recovered by the Administrative Agent for any reason, after demand therefor by the Administrative Agent in accordance with immediately preceding clause (a), from any Purchaser that has received such Erroneous Payment (or portion thereof) (and/or from any Payment Recipient who received such Erroneous Payment (or portion thereof) on its respective behalf) (such unrecovered amount, an "Erroneous Payment Return Deficiency"), upon the Administrative Agent's notice to such Purchaser at any time, then effective immediately (with the consideration therefor being acknowledged by the parties hereto), (i) such Purchaser shall be deemed to have assigned its Assigned Interests (but not its Commitments) with respect to which such Erroneous Payment was made (the "Erroneous Payment Impacted Assigned Interests") in an amount equal to the Erroneous Payment Return Deficiency (or such lesser amount as the Administrative Agent may specify) (such assignment of the Assigned Interests (but not Commitments) of the Erroneous Payment Impacted Assigned Interests, the "Erroneous Payment Deficiency Assignment") (on a cashless basis) (with the assignment fee to be waived by the Administrative Agent in such instance), and is hereby (together with the Company) deemed to execute and deliver an assignment and assumption agreement with respect to such Erroneous Payment Deficiency Assignment, and such Purchaser shall deliver any notes or other instruments evidencing such Assigned Interests to the Company or the Administrative Agent (but the failure of such Person to deliver any such notes shall not affect the effectiveness of the foregoing assignment), (ii) the Administrative Agent as the assignee Purchaser shall be deemed to have acquired the Erroneous Payment Deficiency Assignment, (iii) upon such deemed acquisition, the Administrative Agent as the assignee Purchaser shall become a Purchaser, as applicable, hereunder with respect to such Erroneous Payment Deficiency Assignment and the assigning Purchaser shall cease to be a Purchaser, as applicable, hereunder

with respect to such Erroneous Payment Deficiency Assignment, excluding, for the avoidance of doubt, its obligations under the indemnification provisions of this Agreement and its applicable Commitments which shall survive as to such assigning Purchaser, (iv) the Administrative Agent and the Company shall each be deemed to have waived any consents required under this Agreement to any such Erroneous Payment Deficiency Assignment, and (iv) the Administrative Agent may reflect in the Register its ownership interest in the Assigned Interests subject to the Erroneous Payment Deficiency Assignment. Subject to Section 7.04, the Administrative Agent may, in its discretion, sell any Assigned Interests acquired pursuant to an Erroneous Payment Deficiency Assignment and upon receipt of the proceeds of such sale, the Erroneous Payment Return Deficiency owing by the applicable Purchaser shall be reduced by the net proceeds of the sale of such Assigned Interests (or portion thereof), and the Administrative Agent shall retain all other rights, remedies and claims against such Purchaser (and/or against any recipient that receives funds on its respective behalf). For the avoidance of doubt, no Erroneous Payment Deficiency Assignment shall reduce the Commitments of any Purchaser and such Commitments shall remain available in accordance with the terms of this Agreement. In addition, each party hereto agrees that, except to the extent that the Administrative Agent has sold an Assigned Interests (or portion thereof) acquired pursuant to an Erroneous Payment Deficiency Assignment, and irrespective of whether the Administrative Agent may be equitably subrogated, the Administrative Agent shall be contractually subrogated to all the rights and interests of the applicable Purchaser under the Transaction Documents with respect to each Erroneous Payment Return Deficiency (the "Erroneous Payment Subrogation Rights") (provided that the Obligors' Obligations under the Transaction Documents in respect of the Erroneous Payment Subrogation Rights shall not be duplicative of such Obligations in respect of the Assigned Interests that have been assigned to the Administrative Agent under an Erroneous Payment Deficiency Assignment).

(e) The parties hereto agree that an Erroneous Payment shall not pay, prepay, repay, discharge or otherwise satisfy any Obligations owed by any Obligor, provided that this Section 8.14 shall not be interpreted to increase (or accelerate the due date for), or have the effect of increasing (or accelerating the due date for), the Obligations of the Company relative to the amount (and/or timing for payment) of the Obligations that would have been payable had such Erroneous Payment not been made by the Administrative Agent; provided, further, that for the avoidance of doubt, the last sentence of immediately preceding clause (d) and this clause (e) shall not apply to the extent such Erroneous Payment is, and solely with respect to the amount of such Erroneous Payment that is, comprised of funds received by the Administrative Agent from any Obligor for the purpose of making such Erroneous Payment.

(f) To the extent permitted by applicable law, no Payment Recipient shall assert any right or claim to an Erroneous Payment, and hereby waives, and is deemed to waive, any claim, counterclaim, defense or right of set-off or recoupment with respect to any demand, claim or counterclaim by the Administrative Agent for the return of any Erroneous Payment received, including without limitation waiver of any defense based on "discharge for value" or any similar doctrine.

(g) Each party's obligations, agreements and waivers under this Section 8.14 shall survive the resignation or replacement of the Administrative Agent, any transfer of rights or obligations by, or the replacement of, a Purchaser, the termination of the Commitments and/or the

repayment, satisfaction or discharge of all Obligations (or any portion thereof) under any Transaction Document.

[SIGNATURE PAGE FOLLOWS]

**IN WITNESS WHEREOF,** the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the date first above written.

**COMPANY:**

**VERONA PHARMA, INC.**

By: /s/ Mark W. Hahn
Name: Mark W. Hahn
Title: Treasurer, Secretary and Chief Financial Officer

**VERONA PHARMA PLC**

By: /s/ Mark W. Hahn
Name: Mark W. Hahn
Title: Chief Financial Officer

**ADMINISTRATIVE AGENT:**

**OAKTREE FUND ADMINISTRATION, LLC**

By: Oaktree Capital Management, L.P.
Its: Managing Member

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

Address for Notices:
Oaktree Fund Administration, LLC
333 S. Grand Avenue, 28th Fl.
Los Angeles, CA 90071
Attn: Oaktree Agency
Email: Oaktreeagency@alterdomus.com

With a copy to:
Oaktree Capital Management, L.P.
333 S. Grand Avenue, 28th Fl.
Los Angeles, CA 90071
Attn: [ ● ]
Email: [ ● ]

With a copy (which shall not constitute notice) to:
Sullivan & Cromwell LLP
125 Broad Street
New York, NY 10004
Attn: [ ● ]
Email: [ ● ]

**PURCHASER:**

**OAKTREE-TCDRS STRATEGIC CREDIT, LLC**

By: Oaktree Capital Management, L.P.
Its: Managing Member

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**SC INVESTMENTS UBTI BLOCKER, LLC**

By: Oaktree Fund GP IIA, LLC
Its: Manager

By: Oaktree Fund GP II, L.P.
Its: Managing Member

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**OAKTREE-TSE 16 STRATEGIC CREDIT, LLC**

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**INPRS STRATEGIC CREDIT HOLDINGS, LLC**

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**FSFC HOLDINGS, INC.**

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Chief Operating Officer

**OSCF BLOCKER HOLDINGS, INC.**

By: Oaktree Strategic Credit Fund
Its: Director

By: Oaktree Fund Advisors, LLC
Its: Investment Advisor

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**OAKTREE AZ STRATEGIC LENDING FUND, L.P.**

By: Oaktree AZ Strategic Lending Fund GP, L.P.
Its: General Partner

By: Oaktree Fund GP IIA, LLC
Its: General Partner

By: Oaktree Fund GP II, L.P.
Its: Managing Member

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**OAKTREE LSL FUND DELAWARE HOLDINGS EURRC, L.P.**

By: Oaktree Life Sciences Lending Fund GP, L.P.
Its: General Partner

By: Oaktree Life Sciences Lending Fund GP Ltd.
Its: General Partner

By: Oaktree Capital Management, L.P.
Its: Director

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**OAKTREE DIRECT LENDING FUND DELAWARE HOLDINGS NON-EURRC, L.P.**

By: Oaktree Direct Lending Fund GP, L.P.
Its: General Partner

By: Oaktree Direct Lending Fund GP Ltd.
Its: General Partner

By: Oaktree Capital Management, L.P.
Its: Director

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**OAKTREE DIRECT LENDING FUND UNLEVERED DELAWARE HOLDINGS NON-EURRC, L.P.**

By: Oaktree Direct Lending Fund GP, L.P.
Its: General Partner

By: Oaktree Direct Lending Fund GP Ltd.
Its: General Partner

By: Oaktree Capital Management, L.P.
Its: Director

By: Oaktree Capital Management, L.P.
Its: Director

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**OAKTREE DIRECT LENDING FUND VCOC DELAWARE HOLDINGS NON-EURRC, L.P.**

By: Oaktree Direct Lending Fund VCOC (Parallel), L.P.
Its: General Partner

By: Oaktree Direct Lending Fund GP, L.P.
Its: General Partner

By: Oaktree Direct Lending Fund GP Ltd.
Its: General Partner

By: Oaktree Capital Management, L.P.
Its: Director

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

**OAKTREE LOAN ACQUISITION FUND, L.P.**

By: Oaktree Fund GP IIA, LLC
Its: General Partner

By: Oaktree Fund GP II, L.P.
Its: Managing Member

By: /s/ Matthew Stewart
Name: Matthew Stewart
Title: Managing Director

By: /s/ Mary Gallegly
Name: Mary Gallegly
Title: Managing Director

Address for Notices:
Oaktree Fund Administration, LLC
333 S. Grand Avenue, 28th Fl.
Los Angeles, CA 90071
Attn: Oaktree Agency
Email: Oaktreeagency@alterdomus.com

With a copy to:
Oaktree Capital Management, L.P.
333 S. Grand Avenue, 28th Fl.
Los Angeles, CA 90071
Attn: [ ● ]
Email: [ ● ]

With a copy (which shall not constitute notice) to:
Sullivan & Cromwell LLP
125 Broad Street
New York, NY 10004
Attn: [ ● ]
Email: [ ● ]

**PURCHASER:**

**OCM Life Sciences Portfolio LP**

By: OCM Life Sciences Portfolio G.P. Inc.
Its: General Partner

By: /s/ Rob Miserre
Name: Rob Missere
Title: President

By: /s/ Bernhard Wu
Name: Bernhard Wu
Title: Vice President

Address for Notices:
OCM Life Sciences Portfolio LP
c/o OCM Life Sciences Portfolio G.P. Inc.
100 Adelaide St. W, Suite 900
Toronto, ON M5H 0E2 Canada
Attn: [ ● ]
Email: [ ● ]

With a copy to:
OMERS Capital Solutions LP
100 Adelaide St. W, Suite 900
Toronto, ON M5H 0E2 Canada
Attn: [ ● ]
Email: [ ● ]

With a copy (which shall not constitute notice) to:
Sidley Austin LLP
2850 Quarry Lake Dr., Suite 280
Baltimore, MD 21209
Attn: [ ● ]
Email: [ ● ]

## SCHEDULE 1

## PURCHASERS AND ALLOCATIONS

| Purchasers | Tranche A | Tranche B |
|---|---|---|
| Oaktree-TCDRS Strategic Credit, LLC | [***] | [***] |
| SC Investments UBTI Blocker, LLC | [***] | [***] |
| Oaktree-TSE 16 Strategic Credit, LLC | [***] | [***] |
| INPRS Strategic Credit Holdings, LLC | [***] | [***] |
| FSFC Holdings, Inc. | [***] | [***] |
| OSCF Blocker Holdings, Inc. | [***] | [***] |
| Oaktree AZ Strategic Lending Fund, L.P. | [***] | [***] |
| Oaktree LSL Fund Delaware Holdings EURRC, L.P. | [***] | [***] |
| Oaktree Direct Lending Fund Delaware Holdings Non-EURRC, L.P | [***] | [***] |
| Oaktree Direct Lending Fund Unlevered Delaware Holdings Non-EURRC, L.P. | [***] | [***] |
| Oaktree Direct Lending Fund VCOC Delaware Holdings Non-EURRC, L.P. | [***] | [***] |
| Oaktree Loan Acquisition Fund, L.P. | [***] | [***] |
| OCM Life Sciences Portfolio LP | [***] | [***] |
| **Total** | **$100,000,000.00** | **$150,000,000.00** |

**Exhibit 31.1**

**CERTIFICATION**

I, David Zaccardelli, Pharm.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verona Pharma plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 08, 2024

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

David Zaccardelli, Pharm.D.

Chief Executive Officer

*(principal executive officer)*

**Exhibit 31.2**

**CERTIFICATION**

I, Mark W. Hahn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verona Pharma plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 08, 2024 By: /s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (*principal financial officer*)

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Verona Pharma plc (the "Company") for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 08, 2024

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

David Zaccardelli, Pharm.D.
Chief Executive Officer
(*principal executive officer*)

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Verona Pharma plc (the "Company") for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 08, 2024 By: /s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (*principal financial officer)*