

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K**

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

For the fiscal year ended December 31, 2022

or

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

For the transition period from _____ to _____

Commission File Number: 001-39724

LIQUIDIA CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware

85-1710962

(State or Other Jurisdiction of Incorporation or Organization)

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

419 Davis Drive, Suite 100, Morrisville, North Carolina

27560

(Address of Principal Executive Offices)

(Zip Code)

Registrant's telephone number, including area code: **(919) 328-4400**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value per share	LQDA	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

The aggregate market value of common stock held by non-affiliates of the registrant on June 30, 2022, which was the last business day of the registrant's most recently completed second fiscal quarter, was \$205,436,978 based on a \$4.36 closing price per share as reported on the Nasdaq Capital Market.

As of March 2, 2023, there were 64,688,314 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Liquidia Corporation Definitive Proxy Statement with respect to the 2023 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2022 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated therein. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, each document incorporated by reference herein is deemed not to be filed as part hereof.

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This Annual Report on Form 10-K, or this Annual Report, includes our trademarks, trade names and service marks, such as Liquidia, the Liquidia logo, YUTREPIA and PRINT, or Particle Replication In Non-wetting Templates, which are protected under applicable intellectual property laws and are the property of Liquidia Technologies, Inc. This Annual Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report on Form 10-K may appear without the ®, ™ or ℠ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report may be forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “would,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- those identified and disclosed in our public filings with the U.S. Securities and Exchange Commission (“SEC”) including, but not limited to (i) the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including YUTREPIA, the potential for, and timing regarding, eventual final approval by the United States Food and Drug Administration (the “FDA”) of and our ability to commercially launch YUTREPIA, including the potential impact of regulatory review, approval, and exclusivity developments which may occur for competitors; (ii) the timeline or outcome related to appeals or other motions arising in or from our patent litigation with United Therapeutics that was filed in the U.S. District Court for the District of Delaware or the inter partes reviews with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office; and (iii) the timing and our ability to obtain and maintain regulatory approval for the infusion pump that we are developing with Sandoz Inc. (“Sandoz”) and Mainbridge Health Partners, LLC (“Mainbridge”);
- our ability to predict, foresee, and effectively address or mitigate future developments resulting from the COVID-19 pandemic or other global shutdowns, which could include a negative impact on the availability of key personnel, the temporary closure of our facility or the facilities of our business partners, suppliers, third-party service providers or other vendors, or delays in payments or purchasing decisions, or the interruption of domestic and global supply chains, the economy and capital or financial markets;
- our expectations regarding the size of the patient populations for, market acceptance and opportunity for those drug products that we commercialize in collaboration with third parties, including Sandoz’s first-to-file fully substitutable generic treprostinil injection;
- the availability and market acceptance of medical devices and components of medical devices used to administer our drug products and drug products that we commercialize with third parties, including Smith Medical’s CADD-MS 3 infusion pump and the RG 3ml Medication Cartridge that we developed in collaboration with Chengdu Shifeng Medical Technologies LTD. used for the subcutaneous administration of Sandoz Inc.’s generic treprostinil injection, Smith Medical’s CADD Legacy infusion pump used for the intravenous administration of Sandoz Inc.’s generic treprostinil injection and Plastiaple’s RS00 Model 8 dry powder inhaler, which we plan to use for the administration of YUTREPIA;
- our ability to draw down on our financing facility with Healthcare Royalty Partners IV, L.P. (“HCR”) and our ability to satisfy the covenants contained in the Revenue Interest Financing Agreement with HCR (the “RIFA”);
- our ability to retain, attract and hire key personnel;
- prevailing economic, market and business conditions;
- the cost and availability of capital and any restrictions imposed by lenders or creditors;
- changes in the industry in which we operate;
- the failure to renew, or the revocation of, any license or other required permits;
- unexpected charges or unexpected liabilities arising from a change in accounting policies, including any such changes by third parties with whom we collaborate and from whom we receive a portion of their net profits, or the effects of acquisition accounting varying from our expectations;
- the risk that the credit ratings of our company or our subsidiaries may be different from what the companies expect, which may increase borrowing costs and/or make it more difficult for us to pay or refinance our debts and require us to borrow or divert cash flow from operations in order to service debt payments;
- fluctuations in interest rates;

- adverse outcomes of pending or threatened litigation or governmental investigations, including our patent litigation with United Therapeutics and the litigation arising from United Therapeutics' claim that we and a former employee misappropriated trade secrets from United Therapeutics;
- the effects on the companies of future regulatory or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we are subject;
- conduct of and changing circumstances related to third-party relationships on which we rely, including the level of credit worthiness of counterparties;
- the volatility and unpredictability of the stock market and credit market conditions;
- conditions beyond our control, such as natural disasters, global pandemics (including COVID-19), or acts of war or terrorism;
- variations between the stated assumptions on which forward-looking statements are based and our actual experience;
- other legislative, regulatory, economic, business, and/or competitive factors;
- our plans to develop and commercialize our product candidates;
- our planned clinical trials for our product candidates;
- the timing of the availability of data from our clinical trials;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our product candidates and their potential advantages compared to other treatments;
- our commercialization, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates and the sufficiency of our current manufacturing facilities to produce development and commercial quantities of our product candidates;
- our ability to establish and maintain collaborations;
- our estimates regarding the market opportunities for our product candidates;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and
- our expected use of proceeds from prior public offerings and the period over which such proceeds, together with our available cash, will be sufficient to meet our operating needs.

You should refer to the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements, including, but not limited to, the impact of the COVID-19 pandemic on our company and our financial condition and results of operations. The forward-looking statements in this Annual Report are only predictions, and we may not actually achieve the plans, intentions or expectations included in our forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

These forward-looking statements speak only as of the date of this Annual Report on Form 10-K. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Unless the context otherwise requires, references in this Annual Report on Form 10-K to "we," "us", "our", "Liquidia" and the "Company" refer to Liquidia Corporation, a Delaware corporation, and unless specified otherwise, include our wholly owned subsidiaries, Liquidia Technologies, Inc., a Delaware corporation, or Liquidia Technologies, and Liquidia PAH, LLC (formerly known as RareGen, LLC, or RareGen), a Delaware limited liability company, or Liquidia PAH.

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension (“PH”). We operate as a single entity through our two wholly owned operating subsidiaries, Liquidia Technologies and Liquidia PAH.

We currently generate revenue pursuant to a Promotion Agreement between Liquidia PAH and Sandoz Inc. (“Sandoz”) sharing profit derived from the sale of Sandoz’s substitutable generic treprostinil injection (“Treprostinil Injection”) in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. We employ a targeted sales force calling on physicians and hospital pharmacies in the treatment of pulmonary arterial hypertension (“PAH”), as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient base to expand from for the launch of YUTREPIA upon potential approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.

We conduct research, development, and manufacturing of novel products by applying our subject matter expertise in cardiopulmonary diseases and our proprietary PRINT® technology, a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy, and performance of a wide range of therapies. Through development of our own products and research with third parties, we have experience applying PRINT across multiple routes of administration and drug payloads including inhaled therapies, vaccines, biologics, nucleic acids and ophthalmic implants, among others.

Our lead product candidate is YUTREPIA for the treatment of PAH. YUTREPIA is an inhaled dry powder formulation of treprostinil designed with PRINT to improve the therapeutic profile of treprostinil by enhancing deep lung delivery while using a convenient, low resistance dry-powder inhaler (“DPI”) and by achieving higher dose levels than the labelled doses of current inhaled therapies. The United States Food and Drug Administration (“FDA”) tentatively approved our New Drug Application (“NDA”) for YUTREPIA for the treatment of PAH in November 2021. The FDA also confirmed that the clinical data in the NDA would support our pursuit of a supplemental NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity for the nebulized form of treprostinil in March 2024.

About Pulmonary Hypertension (PH)

Diseases

PH is divided into five groups based on the criteria of the World Health Organization (“WHO”) as defined at the 5th World Symposium on Pulmonary Hypertension in Nice, France. WHO Group I is comprised of individuals with PAH. WHO Group III includes patients with pulmonary hypertension caused by hypoxia and/or lung diseases, mostly interstitial lung disease (“ILD”), COPD and sleep-disordered breathing. Our current products seek to address unmet needs to treating patients diagnosed with PAH and PH-ILD.

PAH is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death, with an estimated diagnosed, treated prevalence in the United States of approximately 30,000 to 45,000 patients. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression and improve quality of life.

PH-ILD is the second most prevalent form of Group 3 PH (precapillary PH due to lung disease). ILD is a diverse collection of up to 150 different pulmonary diseases, including interstitial pulmonary fibrosis (IPF), chronic hypersensitivity pneumonitis, connective tissue disease related ILD, and sarcoidosis among others. Current estimates of diagnosed and undiagnosed prevalence of PH-ILD range between 30,000 to 70,000, depending on the growth on the underlying lung diseases. The prevalence of PH in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until recently.

Treatments

Drugs targeting the prostacyclin pathway are central to PAH and PH-ILD therapy. Prostacyclin analogs, like treprostinil, have been developed for continuous infusion, inhalation and oral administration. The maximal efficacy benefit of any one drug in the prostacyclin pathway is partially limited by its specific safety profile and the burden of administration.

Delivering prostacyclin analogs by inhalation has been effective and causes fewer systemic side effects than parenteral and oral formulations. Inhalation helps supplement the endogenous production of prostacyclin where it is normally synthesized, near the targeted pulmonary arteries. As a result, inhaled prostacyclin analogs help avoid side effects related to off-target tissues and takes advantage of binding key prostacyclin receptors that are preferentially expressed in the lung. The only inhaled prostacyclin analogs approved by the FDA are nebulized Ventavis[®] (iloprost), nebulized Tyvaso[®] (treprostinil), and Tyvaso DPI[®] (treprostinil), a dry powder inhaled formulation. With regard to PH-ILD, there is growing medical preference for inhaled therapies to avoid ventilation-perfusion mismatch resulting from systemic delivery of prostacyclins. In March 2021, the FDA approved Tyvaso[®] as the only treatment for PH-ILD, later adding Tyvaso DPI as a treatment option upon its approval by the FDA in May 2022.

Systemic delivery of prostacyclin has proven effective but challenging, especially in those patients who have progressed to more severe forms of PAH. Parenteral delivery of prostacyclin analogs by continuous infusion via intravenous or subcutaneous administration, like Remodulin[®] (treprostinil) and epoprostenol, are considered the most effective treatment for PAH; however, the burden of external pumps and side-effect profiles have limited their use to severely ill patients. Regardless, physicians have come to rely on these pump-delivered products to stabilize rapidly declining patients to slow disease progression and to ensure the mechanism of action is fully maximized.

Oral tablet delivery of prostacyclin analogs two or three times a day, like Orenitram[®] (treprostinil), or agonists of the prostacyclin signaling pathway, like Upravi[®] (selexipag), improve convenience compared to infusions, but does not address the off-target toxicities that limit optimal dosing. New patients to oral delivery may not be able to titrate to known therapeutic levels.

Market

In 2022, the total reported net revenue of branded therapies approved to treat PAH and PH-ILD in the United States exceeded \$4.6 billion, of which \$2.7 billion targeted the prostacyclin pathway. United Therapeutics reported that its class of branded treprostinil-based products generated net revenue of \$1.7 billion in 2022, of which Tyvaso[®] contributed \$873 million from predominately U.S. net sales, Orenitram contributed \$325 million and Remodulin[®] contributed \$500 million with \$93 million in net revenue coming from non-U.S. sales. The growth in United Therapeutics' total reported sales of 19% was primarily driven by the inhaled treprostinil products which grew 44% due to the addition of Tyvaso DPI and expansion into PH-ILD.

Our Products and Product Candidates

YUTREPIATM (treprostinil) Inhalation Powder to Treat PAH

Our lead investigational drug, YUTREPIATM (treprostinil) inhalation powder was tentatively approved by the FDA in November 2021. YUTREPIA is an inhaled dry powder formulation of treprostinil designed to improve the therapeutic profile of treprostinil by enhancing deep lung delivery and achieving higher dose levels than current inhaled therapies while using a convenient, easy-to-use dry-powder inhaler, the RS00 Model 8 DPI. This device and its variants have been

used in at least eight marketed products globally since 2001, including Novartis's Foradil Aerolizer® for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

We believe YUTREPIA can become the prostacyclin of first choice across the disease continuum in PAH and PH-ILD because of its convenience, low-resistance device and the ability to titrate to higher doses.

Each particle of YUTREPIA has been designed using our PRINT technology to have uniform size and shape to achieve enhanced aerosolization and deposition in the lungs. As a result, our PRINT formulation does not require deagglomeration by a patient actuated breath and can be effectively delivered using of a low-resistance, patient-friendly device and minimal inspiratory effort. The RS00 Model 8 DPI device used to deliver YUTREPIA is robust with regard to position and accidental movements and has been used globally to deliver drugs to patients with compromised lung function, like asthma, COPD, and cystic fibrosis. These beneficial product characteristics are in contrast to the recently approved Tyvaso DPI (May 2022), which uses a high resistance device and has only been used previously in patients with diabetes.

The different combinations of YUTREPIA's four proposed capsule-strengths, if approved, would allow customized dosing and easier titration based on a patient's disease progression. YUTREPIA can be safely titrated to doses far beyond the target dose of nebulized Tyvaso (9-12 breaths) and the doses described in the label for Tyvaso DPI (up to 80 mcg QID). YUTREPIA has been studied up to 238.5 mcg QID, which is comparable to 27 breaths of nebulized Tyvaso. By expanding the dose range of inhaled treprostinil, YUTREPIA may be able to keep patients on therapy longer before transitioning to parenteral therapies.

In clinical studies required for approval, YUTREPIA has proven to be safe, well-tolerated and effective regardless of a patient's previous exposure to treprostinil. Prostacyclin-naïve patients achieved comparable dosing to the transition patients within first two months of treatment. Patients on a stable dose of Tyvaso successfully transition to YUTREPIA while maintaining or improving clinical outcomes as measured by exploratory endpoints. The combination of data from both patient groups provide confidence that a physician may prescribe YUTREPIA across a continuum of PAH and PH-ILD patients.

We have developed YUTREPIA under the 505(b)(2) regulatory pathway using the nebulized form of treprostinil, Tyvaso, as the reference listed drug. This regulatory pathway allows us to rely in part on the FDA's previous findings of efficacy and safety of Tyvaso and the active ingredient treprostinil. We submitted the New Drug Application ("NDA") for YUTREPIA in January 2020. The FDA conducted on-site pre-approval inspections of two U.S. manufacturing facilities: the Company's Morrisville, North Carolina facility and the facility of the third-party provider of encapsulation and packaging services for YUTREPIA in August 2021 and October 2021, respectively. In November 2021, the FDA issued a tentative approval of YUTREPIA which indicated that the NDA had met all the requirements for final approval but cannot yet be marketed.

Final FDA approval and launch of YUTREPIA are directly impacted by the Hatch-Waxman litigation commenced by United Therapeutics on June 4, 2020. As a result, the FDA cannot issue a final approval for the YUTREPIA NDA until the resolution of the outstanding litigation described further in Item 3 *Legal Proceedings*. The FDA's tentative approval can be subject to change based on new information that may come to FDA's attention between such time as the tentative and final approval. A new drug product may not be marketed until the date of final approval.

Our NDA submission was based in part upon the results of our pivotal, open-label Phase 3 clinical trial, Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, for YUTREPIA ("INSPIRE"). The primary objective of the INSPIRE study was to evaluate the long-term safety of YUTREPIA with a primary endpoint to assess safety and tolerability through Month 2. The study enrolled patients who have either (a) been under stable treatment with Tyvaso (nebulizer-delivered treprostinil) for at least three months and transitioned to YUTREPIA under the protocol ("Transition patients"), or (b) patients who had been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and then had their treatment regimen supplemented with YUTREPIA under the protocol ("Prostacyclin Naïve patients"). Transition patients started at a dose comparable to their prior nebulized treprostinil dose and were titrated to higher doses as warranted by their clinical disease. Prostacyclin Naïve patients started on a dose of 26.5 mcg of YUTREPIA, with most (>80%) titrating to a 79.5 mcg dose or higher within the first

two months of treatment. Of the 121 patients enrolled in the study, 55 were Transition patients and 66 were Prostacyclin Naïve patients.

YUTREPIA was observed to be well-tolerated and treatment-emergent adverse events (“TEAEs”) were mostly mild to moderate in nature at Month 2 up to doses of 159 mcg, the highest dose studied for the primary endpoint. We continued to treat patients who chose to remain on YUTREPIA beyond the Month 2 timepoint. At the completion of the INSPIRE study, the patient with the longest duration of treatment had been on YUTREPIA therapy for 18 months and the highest dosing reached in the INSPIRE study was 212 mcg of treprostinil given four times per day. Patients from INSPIRE had the option of rolling into the LTI-302 extension study to remain on treatment. Patients in LTI-302 continued to titrate doses upwards as needed with no observed maximum tolerated dose and the highest dose delivered being 238 mcg.

Our NDA submission also includes results from pharmacokinetic (PK) studies in healthy volunteers indicating that the single-capsule dose of 79.5 mcg YUTREPIA provides comparable PK with nine breaths of Tyvaso (54 mcg). For reference, the target dose of Tyvaso is 9 to 12 breaths per treatment session, 4 times daily. Clinical results from the PK and pivotal studies of YUTREPIA have been presented at various international scientific meetings such as the American Thoracic Society (ATS), International Society of Heart Lung Transplantation (ISHLT), Pulmonary Vascular Research Institute (PVRI), American College of Chest Physicians (ACCP) in 2019 and 2020.

We are considering conducting other clinical trials to generate additional data to support the use of YUTREPIA, including a clinical trial in pediatric patients. We conducted a clinical study, known as LTI 201, at certain investigational sites in France and Germany to characterize the hemodynamic dose-response relationship to YUTREPIA. In December 2020, we decided to terminate the study earlier than planned due to challenges related to the COVID-19 pandemic; however, we did observe acute, hemodynamic responses as expected with inhaled treprostinil.

Treprostinil Injection, a Generic Version of Remodulin®

Remodulin® is treprostinil administered through continuous intravenous and subcutaneous infusion, as approved by the FDA in 2002 and 2004, and marketed by United Therapeutics. Patients must use external pumps manufactured by third parties to deliver Remodulin. Smiths Medical ASD, Inc. (“Smiths Medical”) manufactured the pumps used by most patients in the United States to administer Remodulin, including the CADD-MS® 3 pump used to deliver subcutaneous Remodulin, and the CADD-Legacy® pump to deliver intravenous Remodulin. An estimated 3,000 patients are treated annually with parenteral, infused treprostinil split between the two routes of administration. Branded Remodulin generated U.S. revenue of approximately \$408 million and \$423 million in 2022 and 2021, respectively.

In August 2018, Sandoz partnered with Liquidia PAH (then known as RareGen) on an exclusive basis to market and commercialize its generic Treprostinil Injection, which was subsequently launched as the first-to-file, fully-substitutable generic treprostinil for parenteral administration in March 2019. Liquidia PAH promotes the appropriate use of Treprostinil Injection for the treatment of PAH in the United States and works jointly with Sandoz on commercial strategy for the product. Sandoz retains all rights in and to Treprostinil Injection. As the Abbreviated New Drug Application (ANDA) holder, Sandoz maintains responsibility for compliance with FDA regulatory and healthcare laws including any regulatory communications with the FDA or any other regulatory authorities. In consideration for Liquidia PAH conducting certain responsibilities associated with the commercialization of Treprostinil Injection, Liquidia PAH receives a portion of the net profits generated from the sales of the product.

Treprostinil Injection contains the same active ingredient, same strength, same dosage forms and same inactive ingredient amounts as Remodulin, and at the same service and support, but at a lower price. The treprostinil is supplied in 20 mL multi-dose vials in four strengths — containing 20 mg, 50 mg, 100 mg, or 200 mg (1 mg/mL, 2.5 mg/mL, 5 mg/mL or 10 mg/mL) of treprostinil, respectively. Treprostinil Injection is available for intravenous and subcutaneous administration at the same specialty pharmacies that dispense the brand name medicine.

When first launched in April 2019, Treprostinil Injection was only available for intravenous administration. The cartridges required to operate the CADD-MS 3 pump for subcutaneous administration were not available to patients using Treprostinil Injection due to restrictions imposed by other companies. On May 21, 2021, Liquidia PAH’s manufacturing partner, Chengdu Shifeng Medical Technologies LTD (“Chengdu”) began selling the RG 3ml Medication

Cartridge, which now may be used to supply Treprostinil Injection to PAH patients with the CADD-MS 3 pump manufactured by Smiths Medical.

Smiths Medical no longer manufactures the CADD-MS 3 infusion pump and, under our Settlement Agreement with Smiths Medical, they are not obligated to support the existing inventory of CADD-MS 3 infusion pumps after January 1, 2025. We recently became aware of a shortage of a critical component of the CADD-MS 3 infusion pump that has caused the number of CADD-MS 3 infusion pumps available for the subcutaneous administration of Treprostinil Injection to be limited. Due to this limitation in the availability of pumps, specialty pharmacies are not currently placing new patients on to subcutaneous Treprostinil Injection therapy in order to preserve the available pumps for those patients already receiving subcutaneous administration of Treprostinil Injection. In March, 2023, we entered into an amendment to our agreement with Sandoz to attempt to alleviate the shortage of critical components for the CADD-MS 3 infusion pump. If successful, new components may be available in late 2023 or early 2024.

In addition, in December 2022, we entered a collaboration with Sandoz and Mainbridge Health Partners LLC (“Mainbridge”) to support the development of a new subcutaneous pump for infusion of Treprostinil Injection in order to alleviate the single-source dependence on the existing CADD-MS 3 system. Mainbridge will perform all development, validation and testing activities required for the pump and related consumables. We anticipate that Mainbridge will submit a 510(k) in 2023 for FDA clearance. Sandoz and Liquidia will split equally the development costs.

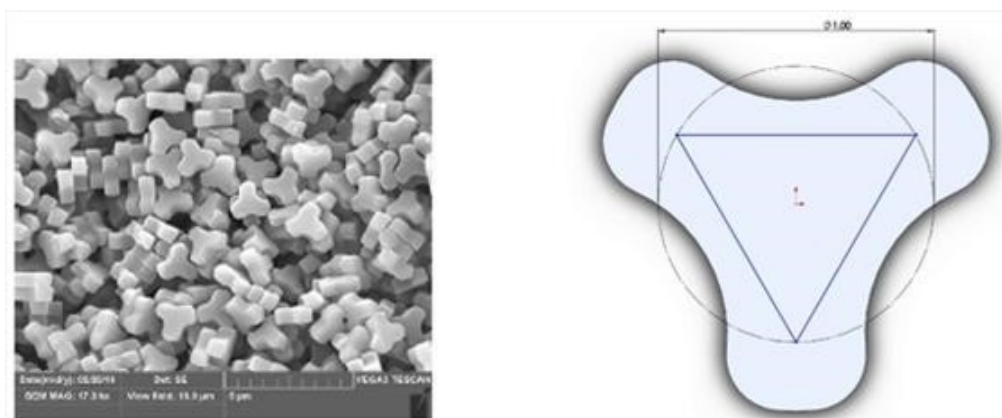
Separately, Smiths Medical has announced that it will discontinue support of the CADD Legacy pump, which is used to administer Treprostinil Injection intravenously, starting in 2028. We are working to identify alternative pumps that may be used for the intravenous administration of Treprostinil Injection.

PRINT Technology

Our proprietary PRINT particle engineering technology allows us to engineer and manufacture highly uniform drug particles with precise control over the size, three-dimensional geometric shape and chemical composition of the particles. By controlling these physical and chemical parameters of particles, PRINT enables us to engineer desirable pharmacological benefits into product candidates, including prolonged duration of drug release, increased drug loading, more convenient routes of administration, the ability to create novel combination products, enhanced storage and stability and the potential to reduce adverse side effects. Our manufacturing equipment and materials used in the production of our drug particles are proprietary and protected by our patent portfolio and trade secret know-how.

An example of the precise particle engineering enabled by PRINT is demonstrated in YUTREPIA. Each particle is designed to enhance delivery and deep-lung penetration with a precise size and highly uniform shape inspired by a naturally occurring pollen. YUTREPIA PRINT particles have a one micrometer trefoil-shape measured by an inscribed one micrometer circle as shown in the figure below. In vitro studies suggest that the uniformity of size and shape allow our inhaled particles to target delivery into the lungs with less deposition in the upper airways. The figures below depict

YUTREPIA, with the figure on the left showing size and shape consistency among particles and the figure on the right showing their trefoil shape:



Development, Regulatory and Commercial Strategy

We intend to develop and commercialize a pipeline of drugs by applying our expertise in the development of cardio-pulmonary medicines and leveraging the advantages of our proprietary PRINT technology. We believe that our PRINT technology can be applied to a wide range of therapeutic areas, molecule types, routes of administration and novel or generic products. To date, our internal pipeline has focused on the development of improved and differentiated drug products containing FDA-approved active pharmaceutical ingredients (“APIs”) with established efficacy and safety profiles, which we believe are eligible for the 505(b)(2) regulatory pathway to seek marketing approval in the U.S. The 505(b)(2) regulatory pathway can be capital efficient and potentially enable a shorter time to approval, subject to certain risks associated with this regulatory pathway. If our product candidates receive marketing approval, we plan to commercialize them in the U.S. either by ourselves or through partnership or licensing arrangements with other pharmaceutical companies. Outside of the U.S., we may pursue regulatory approval and commercialization of our product candidates in collaboration with pharmaceutical companies with regional expertise. We intend to manufacture our product candidates using in-house capabilities. Where appropriate, we will rely on contract manufacturing organizations (“CMOs”) to produce, package and distribute our approved drug products on a commercial scale.

We intend to focus our commercial efforts initially on the U.S. market in the treatment of PAH and PH-ILD. We currently employ a small, targeted sales force for Treprostinil Injection calling on physicians involved in the treatment of PAH in the U.S., as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient launch of YUTREPIA if and when we obtain final approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients. If we have success increasing the utilization of Treprostinil Injection and advancing YUTREPIA to FDA approval, we will increase our efforts to pursue the highly concentrated target market of PAH centers of excellence and high prescribers of PAH therapies. Our physician call points within these sites of care will include cardiologists, pulmonologists and their supporting staff. We believe that we can effectively commercialize YUTREPIA, if approved, with an expanded specialty field team. We also expect to further develop our internal resources and functional areas to support other types of communication. For example, we may utilize medical science liaisons and reimbursement specialists to support the proper conveying of scientific and medical information, and healthcare economic information regarding, and utilization of, YUTREPIA.

Manufacturing and Supply

We operate from a 45,000 square foot facility in Morrisville, North Carolina in which we design, formulate and manufacture engineered drug particles using PRINT particle fabrication lines as well as supportive activity including research and development, analytical development, quality control and production of mold templates that enable our

production processes. Our three operational PRINT particle fabrication lines are located within class ISO7 clean rooms that operate under applicable ISO and current good manufacturing practices (cGMP) air quality and environmental requirements. Our current operational fabrication lines are scaled and capable of producing the necessary materials to support our clinical trials and, if approved, commercial demand for our products.

In August 2021, the FDA completed an on-site Pre-Approval Inspection (PAI) of our Morrisville, North Carolina facility in connection with the review of the YUTREPIA NDA. The 5-day PAI concluded with no Form 483 Inspectional Observations issued. This was our first inspection of the Morrisville site by the FDA. We utilize contract manufacturers to finish production and package our drug product for clinical and commercial use.

We depend on third-party suppliers for commercial inventory and clinical supplies, including active pharmaceutical ingredients which are used in our product candidates. For example, we currently rely on a sole supplier, LGM Pharma, LLC, for tadalafil, the active pharmaceutical ingredient of YUTREPIA, and we currently rely on a sole supplier, Plastiaple S.p.A (“Plastiaple”), for RS00 Model 8 DPI, the device used to administer YUTREPIA. We also rely on a sole supplier, Lonza Tampa LLC, for encapsulation and packaging services. If and when we receive final marketing approval for our product candidates, we may, from time to time, rely on third-party CMOs to manufacture, package and distribute some or all of our approved drug products on a commercial scale.

Supply of Tadalafil Injection is managed directly by our partner Sandoz, who retains the ANDA, manages inventory and records gross revenue on product sales. Sandoz is either the manufacturer or contracted party for the entire supply chain. We collaborate with Sandoz on a regular basis to plan appropriate inventory production and management based on the demand for Tadalafil Injection and observations in the field. Additionally, we have contracted with our manufacturing partner Chengdu to supply the RG 3mL Medication Cartridge for use with CADD-MS® 3 (MS-3) ambulatory infusion pumps and enable subcutaneous administration of Tadalafil Injection.

Our Collaboration and Licensing Agreements

Sandoz Promotion Agreement

Liquidia PAH entered into a Promotion Agreement with Sandoz on August 1, 2018, as amended on May 8, 2020, September 4, 2020, November 18, 2022, and March 10, 2023, which engaged Liquidia PAH on an exclusive basis to promote the appropriate use of Sandoz’s tadalafil, Tadalafil Injection, referred to as the “Product” in the Promotion Agreement, for the treatment of PAH in the United States, including its commonwealths, territories, possessions and military bases. Liquidia PAH works jointly with Sandoz on commercial strategy for Tadalafil Injection and has responsibility for identifying, manufacturing and developing medical devices, including pumps and cartridges, that may be used to administer the Product. Sandoz retains all rights in and to the Product. Sandoz is the holder of the ANDA for the Product. As the ANDA holder, Sandoz maintains responsibility for compliance with FDA regulatory and healthcare laws including any regulatory communications with the FDA or any other regulatory authorities.

Under the Promotion Agreement, Sandoz retains responsibility for: the specifications, manufacture and supply, distribution and future development of tadalafil; regulatory submission and interactions with the FDA pertaining to tadalafil, including maintaining all necessary regulatory approvals; reporting to the FDA or other regulatory authorities on matters relating to manufacturing, sale or promotion, such as any safety events involving tadalafil; internally reviewing and, as it determines appropriate, approving promotional materials developed by Liquidia PAH, and making submissions to the FDA’s Office of Prescription Drug Promotion; handling safety activities including adverse event reporting, and initiating and managing any recalls of tadalafil.

Liquidia PAH’s activities and obligations related to regulatory matters conducted under the Promotion Agreement include: promotional and non-promotional activities, including sales and marketing activities for tadalafil, and engagement of healthcare professionals for advisory boards; developing, with prior written approval from Sandoz, marketing and educational materials consistent with FDA approved labeling and applicable laws; notifying Sandoz of notices from governmental authorities about adverse event reports or regulatory inquiries related to the safety of tadalafil, product complaints or alleged defects, unsolicited requests for off-label medical information; providing certain data and information to Sandoz in order to fulfill its transparency and reporting obligations under the Physician

Payment Sunshine Act; complying with applicable laws relevant to the activities conducted under the Promotion Agreement; establishing a compliance program and mechanism for disclosure of any violations of Liquidia PAH policies and procedures and submission of an annual report and certification to Sandoz of its compliance activities; and managing, with oversight and participation from Sandoz, negotiations and arrangements for managed care activities.

Under the Promotion Agreement, Sandoz and Liquidia PAH also agreed to enter into an agreement with Mainbridge for the development of a new pump for the subcutaneous administration of trestatinil and to enter into an agreement with a third party for the repair and servicing of CADD-MS 3 pumps. With respect to each of these agreements with third parties, Sandoz and Liquidia PAH have agreed to split all development costs and milestone payments evenly.

Liquidia PAH paid Sandoz an initial payment of \$10 million on August 1, 2018 and, upon the successful quality release by Sandoz of 9,000 units of the Product on August 3, 2018, Liquidia PAH paid Sandoz an additional \$10 million as further consideration for the right to conduct the activities as contemplated in the Promotion Agreement and to receive a portion of the “Net Profits” (as defined in the Promotion Agreement). The portion of Net Profits are allocated to Liquidia PAH currently through December 31, 2028 is as follows: (i) for that portion of aggregate Net Profits less than or equal to \$500 million, Liquidia PAH shall receive 50% of all such Net Profits; and (ii) for that portion of aggregate Net Profits greater than \$500 million, Liquidia PAH shall receive 75% of all such Net Profits. After December 31, 2028, the portion of Net Profits allocated to Liquidia PAH shall be as follows: (i) if aggregate Net Profits as of December 31, 2028 were less than \$500 million, Liquidia PAH shall receive 50% of all Net Profits; and (ii) if aggregate Net Profits as of December 31, 2028 were greater than or equal to \$500 million, Liquidia PAH shall receive 75% of all Net Profits.

The Promotion Agreement expires December 31, 2032, subject to certain renewal periods. Liquidia PAH and Sandoz may terminate the Promotion Agreement for cause upon a number of customary events, such as a material breach of the Promotion Agreement that remains uncured, complete withdrawal of marketing approval of the Product or upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings with respect to the other party. Further, either party may terminate the Promotion Agreement upon written notice to the other party at any time after the current term in the event Sandoz is then procuring 100% of its supply of Product from a single third party upon (a) expiration of the supply agreement with such third party and (b) Sandoz’s failure, after exercise of commercially reasonable efforts, to secure continued supply of the Product from such third party or other third parties within 12 months of the termination of such supply agreement. Liquidia PAH and Sandoz also each have a right to terminate the Promotion Agreement on not more than 90 days’ written notice in the event that Net Profits in the last calendar year are less than \$5 million.

Sandoz may terminate the Promotion Agreement on not more than 90 days’ written notice after the conclusion of any full 12-month calendar year in the event that Net Profits in such calendar year are less than or equal to 10% of the net sales in such calendar year; *provided, however*, that Sandoz may not terminate the Promotion Agreement in such instance if both (x) Net Profits or the profit margin were adversely affected in such calendar year by any temporary event or circumstance and (z) the joint steering committee makes a determination that such profit margin deficiency is not likely to continue in the subsequent calendar year. Sandoz may also terminate the Promotion Agreement upon a change of control of Liquidia PAH.

Liquidia PAH may terminate the Promotion Agreement on not more than 90 days’ written notice after the conclusion of any full 12-month calendar year in the event that Liquidia PAH’s share of the Net Profits in such calendar year are less than or equal to Liquidia PAH’s operating expenses relating to the Product for such calendar year; *provided, however*, that Liquidia PAH may not terminate the Promotion Agreement in such instance if both (x) Net Profits or its operating expenses relating to the Product were adversely affected in such calendar year by a temporary event or circumstance and (z) the joint steering committee makes a determination that Liquidia PAH’s share of the Net Profits is not likely to continue to be less than its operating expenses relating to the Product in the subsequent calendar year.

The University of North Carolina at Chapel Hill

In December 2008, we entered into the Amended and Restated License Agreement with The University of North Carolina at Chapel Hill (“UNC”) for the use of certain patent rights and technology relating to initial innovations of our PRINT technology (the “UNC License”). Under the terms of the UNC License, we have an exclusive license to such

patent rights and technology for our drug products. The UNC License grants us the right to grant sublicenses to the technology as well as control the litigation of any infringement claim instituted by or against us in respect of the licensed patent rights. We are also responsible for the costs of all expenses associated with the prosecution and maintenance of the patents and patent applications. Such filings and prosecution will be carried out by UNC and in UNC's name but under our control.

Under the UNC License, we are required to pay UNC royalties equal to a low single digit percentage of all net sales of our drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC License, as well as tiered royalty percentages ranging in the low single digits of sales by our sublicensees for any product covered by rights under a sublicense agreement granted pursuant to the UNC License. Under the UNC License, we are also required to pay UNC certain fees other than royalties that we collect and are attributable to UNC sublicensed intellectual property. We also reimburse UNC for its costs of procuring and maintaining the patents we license from UNC. Effective November 2017, we satisfied all substantive milestones associated with our UNC License other than semi-annual and annual reporting-based milestones that continue through the term of the UNC License. The UNC License expires (i) on the expiration of the last to expire patent included in the patent rights or (ii) if no patents mature from such patent rights, in December 2028.

We have the right to terminate the UNC License upon a specified period of prior written notice. UNC may terminate the UNC License in certain circumstances, including if we fail to pay royalty or other payments on time or if we fail to sublicense in accordance with the terms of the UNC License. Upon termination of the UNC License, we must pay any royalty obligations due upon termination.

Aerie Pharmaceuticals

We have exclusively licensed our PRINT technology to Aerie Pharmaceuticals, Inc., which in 2017 acquired most of the assets of Envisia Therapeutics, Inc., an entity which we formed in 2013, for broad usage in the design and commercialization of small molecule and biologic ophthalmic therapies. In November 2022, Alcon completed its acquisition of Aerie Pharmaceuticals to help bolster Alcon's presence in the ophthalmic pharmaceutical space and as a result, retains Aerie's direct license to the use of PRINT.

GlaxoSmithKline

Previously, we had collaborated with GlaxoSmithKline plc ("GSK") on the use of our PRINT technology in respiratory disease. In June 2012, we entered into an Inhaled Collaboration and Option Agreement (the "GSK ICO Agreement") with GSK to collaborate on research regarding the application of our PRINT technology to specified inhaled therapies. Pursuant to the GSK ICO Agreement, we granted GSK exclusive options and licenses to further develop and commercialize such inhaled therapies using our PRINT technology. In September 2015, GSK exercised its option to obtain an exclusive, worldwide license to certain of our know-how and patents relating to our PRINT technology for the purpose of developing inhaled therapeutics. In connection with the grant of this license, we received a one-time option exercise fee and were also entitled to continued research and development funding, certain milestone payments, and tiered royalties on the worldwide sales of the licensed products. In February 2016, we received a payment from GSK upon the achievement of a clinical development milestone related to the development of an inhaled antiviral for viral exacerbations in COPD. However, in July 2018, GSK notified us of its plans to discontinue development of this compound after completion of the related Phase 1 clinical trial.

In June 2019, we and GSK executed an amendment to the collaboration agreement providing us with rights to develop and commercialize three specified molecular entities for application in inhaled programs using our PRINT technology at our sole expense. This amendment also provides a mechanism for us to acquire rights to develop and commercialize further molecular entities for inhaled applications. New inhaled programs developed under this amendment would carry milestone and royalty payments due to GSK upon initiation of Phase 3 studies and subsequent commercialization, respectively.

In January 2020, we notified GSK of our intent to terminate the GSK ICO Agreement based upon GSK's lack of continued performance under the original agreement, which we believe constitutes a material breach of the agreement. In

February 2020, we received a letter from GSK disputing our basis for termination. The parties are currently attempting to resolve the dispute pursuant to the terms of the GSK ICO Agreement and are discussing a possible amendment to this agreement.

Intellectual Property

The proprietary nature and protection of our product candidates, their methods of use and our platform technology that enables our product candidates are an important part of our business strategy of rapidly developing and commercializing new medicines that address areas of significant unmet medical needs.

Our policy is to seek patent protection of our proprietary product candidates and technology by filing U.S., international and certain foreign patent applications covering certain of our proprietary technology, inventions, improvements and product candidates that are important to the growth and protection of our business. We also rely on a combination of trade secrets, know-how, trademarks and contractual restrictions to protect aspects of our business that are not amenable to patent protection or where we do not consider patent protection to be adequate or applicable.

Our success depends, in part, on our ability to obtain and maintain patent and other protection for our product candidates, enabling technology, inventions and know-how and our ability to defend and enforce these patents, preserve the proprietary nature of our trade secrets and trademarks and operate our business without infringing valid and enforceable patent and other proprietary rights of third parties. Where possible, we pursue both composition-of-matter patents and method-of-use patents for our product candidates. We are also pursuing patents covering our proprietary PRINT micro- and nano-particle fabrication technology.

We are the owner or exclusive licensee of patents and applications relating to our proprietary technology platform and our product candidates and are pursuing additional patent protection for these and for our other product candidates and technology developments.

We have a total of 145 patents and pending patent applications in our patent portfolio which protect our PRINT technology and drug products in development. As of December 31, 2022, we were the sole owner of 16 patents in the United States and 41 patents in foreign jurisdictions, as well as 12 additional pending patent applications, including provisional patent applications, in the United States, Europe, Japan and other jurisdictions. In addition to the patents and patent applications owned solely by us, our patent portfolio also includes 72 patents and 3 patent applications licensed from third parties. As of December 31, 2022, we had an exclusive, worldwide license from UNC to 19 U.S. patents and 52 foreign patents, as well as three additional patent applications in the United States or selected foreign jurisdictions. Five of the patents in the portfolio licensed from UNC are jointly owned by us. We also jointly own one patent application with Glaxosmithkline Intellectual Property (No. 2) Limited. YUTREPIA is specifically protected by 15 issued patents in the United States, the longest-lived of which will expire in 2037.

We hold multiple U.S. trademark registrations and have numerous pending trademark applications. Issuance of a federally registered trademark creates a rebuttable presumption of ownership of the mark; however, it is subject to challenge by others claiming first use in the mark in some or all the areas in which it is used. Federally registered trademarks have a perpetual life so long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We believe our patents and trademarks are valuable and would provide us certain benefits in marketing our products.

Competition

The pharmaceutical industry is intensely competitive, subject to rapid and significant technological change and places emphasis on the value of proprietary products. While we believe that our technologies and experience provide us with a competitive advantage, our competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies, biopharmaceutical companies and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies

may obtain marketing approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, technologies and drug products that are more effective or less costly than products that we are currently developing or that we may develop, which could render our products obsolete and non-competitive. We expect any products that we develop and commercialize to compete on the basis of, among others, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payors. We also expect to face competition in our efforts to recruit and retain qualified personnel, establish clinical trial sites and secure patient enrollment in our clinical trials, and identify appropriate collaborators to help commercialize any approved products in our target commercial markets.

Competition in PAH

Our products and development programs directed toward the treatment of PAH compete with several approved classes of drugs that target the prostacyclin pathway, the nitric oxide pathway and the endothelin pathway. We also expect continued development by competitors of new mechanisms of action that may be approved during the period of time that our products are being commercialized. Drugs targeting each of the clinically validated pathways may be used alone or in combination with each other to treat patients with PAH. Drugs targeted to the prostacyclin pathway, like Treprostinil Injection and YUTREPIA, are usually added to oral therapies targeting different mechanisms and their use could be impacted by changes in pricing or medical information. Specifically, PDE-5 inhibitors, such as tadalafil, marketed by United Therapeutics, and sildenafil, marketed by Pfizer Inc., now compete with generic versions of both tadalafil and sildenafil; endothelin receptor antagonists, such as bosentan and macitentan, both marketed by Actelion Pharmaceuticals Ltd (“Actelion”) and ambrisentan, marketed by Gilead Sciences, Inc, compete with generic version of bosentan and ambrisentan; and soluble guanylate cyclase (sGC) stimulator, such as riociguat marketed by Bayer, has seen increased sales since its U.S. approval in 2013.

Competition with prostacyclin-targeted treatments

Within the prostacyclin pathway, our products face competition from specific products and development programs described below.

The Treprostinil Injection product faces competition primarily from the continued use of the branded Remodulin® sold by United Therapeutics as well as additional generic treprostinil products offered by Teva, Par Pharmaceutical, Dr. Reddy’s and Alembic. Generic drug prices may decline dramatically as competitors seek to secure preferential utilization through the specialty pharmacy and hospital distribution channels in which parenteral prostacyclin products are sold. Other parenteral agents that utilize the prostacyclin pathway include parenteral epoprostenol, which is marketed by multiple companies as generic and branded products.

We expect United Therapeutics to continue to defend its leadership position vigorously through, among other actions, life cycle management, marketing agreements with third-party payors, and pharmacy benefits managers. In February 2021, United Therapeutics announced the commercial launch of the Remunity® pump for Remodulin®, which uses a small subcutaneous pump for patients starting or on a stable dose of Remodulin and can use prefilled Remodulin cassettes. The Remunity pump also has a water-resistant casing, which may be considered more convenient than the CADD-MS3 currently used to deliver treprostinil subcutaneously. United Therapeutics is also developing RemoPro™, a prodrug of treprostinil designed to be inactive in the subcutaneous tissue and activated once metabolized in the blood, decreasing site pain currently associated with subcutaneous Remodulin (treprostinil).

In addition to continuously infused treprostinil products, use of Treprostinil Injection may face competition from other orally delivered products in the prostacyclin pathway, including Orenitram®, sold by United Therapeutics, and Upravi®, a selective IP agonist sold by Janssen Pharmaceuticals/Actelion. These oral products are perceived to be more convenient than infused products, although their use is targeted earlier in a patient’s disease progression.

Systemically delivered treatments also compete with localized, inhaled treatments

In addition to oral and parenteral options, we expect that YUTREPIA will face competition from the following inhaled treprostinil therapies that are either currently marketed or in clinical development.

- Tyvaso, marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009. Tyvaso is the reference listed drug in our NDA for YUTREPIA. Following patent litigation, United Therapeutics and Watson Pharmaceuticals reached a settlement whereby Watson Pharmaceuticals will be permitted to enter the market with a generic version of Tyvaso beginning on January 1, 2026. In April 2021, United Therapeutics announced that Tyvaso was approved by FDA to include treatment of patients with PH-ILD.
- Ventavis[®], marketed by Actelion, a division of Johnson & Johnson, has been approved for the treatment of PAH in the United States since 2004.
- Tyvaso DPI, licensed from MannKind by United Therapeutics, is a dry-powder formulation of treprostinil that was approved for the treatment of PAH and PH-ILD in the United States in May 2022.
- Treprostinil Palmitil Inhalation Powder (TPIP), is a dry-powder formulation of a treprostinil prodrug being developed by Insmed. Insmed announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once-daily dosing. Insmed initiated Phase 2 trials studying patients diagnosed with PAH and PH-ILD in May 2021 and December 2022, respectively. If the TPIP clinical program is successful in demonstrating less frequent dosing with similar efficacy and safety to YUTREPIA and Tyvaso DPI, then TPIP has the potential to be viewed as a more attractive option and may take market share rapidly.
- L606 is a nebulized, liposomal formulation of treprostinil for treatment of PAH being developed by Pharmosa Biopharm Inc. (“Pharmosa”). In 2021, Pharmosa initiated a Phase 3 open-label study to evaluate the safety and tolerability of L606 in subjects with PAH that have been stabilized on Tyvaso. The intended product profile seeks reduce the daily dosing frequency of treprostinil.

There are also a variety of investigational PAH therapies in the later stages of development that target new or clinically-validated mechanism of actions (MOAs) that may benefit patients. The approval of some or any of these could change the treatment paradigm and impact the utilization of treprostinil products and the prostacyclin pathway at large. We believe that new MOAs may slow or reverse the disease progression of PAH having the net impact of increasing the diagnosed prevalent population by extending patient lives and increasing the potential addressable population for treprostinil-based therapies. For example, Merck & Co’s injectable sotatercept is an investigational, potential first-in-class molecule that targets the proliferation of cells in the pulmonary vasculature and is being reviewed by the FDA for approval in 2023. If approved, we currently expect that the drug will be used as it was studied: on-top of dual and triple background therapy that included prostacyclin analogs.

Human Capital

As of March 2, 2023, we employed 59 salaried and four hourly employees, all of whom are located in the United States. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. Much of our success is rooted in the diversity of our teams and our commitment to equity and inclusion. We value diversity at all levels.

Facilities

Our corporate headquarters is located in Morrisville, North Carolina, and consist of approximately 45,000 square feet of space under a lease that expires on October 31, 2026 and includes an option for us to renew the lease for an additional five years through October 31, 2031, as amended. The primary use of this location is general office, laboratory, research and development and light manufacturing. We believe that our facilities are adequate for our current needs, however, we will seek additional space as needed to accommodate our growth.

Corporate Information

We were incorporated in Delaware on June 17, 2020. Our principal executive offices are located at 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560 and our telephone number is (919) 328-4400. Our website is www.liquidia.com. The information on or that can be accessed through our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider any such information as part of this Annual Report on Form 10-K or in deciding whether to purchase our common stock. This Annual Report and all of our filings under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including copies of annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, are available free of charge through our website on the date we file those materials with, or furnish them to, the U.S. Securities and Exchange Commission (SEC). Such filings are also available to the public on the internet at the SEC's website at www.sec.gov.

Government Regulation

Government Regulation and Product Approval

Government authorities in the United States at the federal, state and local level and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, (including manufacturing changes), quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the United States Federal Food, Drug, and Cosmetic Act (FDCA) and the FDA's implementing regulations.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- submission to the FDA of an Investigational New Drug application (IND) which must become effective before human clinical studies may begin;
- approval by an independent IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical studies according to Good Clinical Practice (GCP), regulations, to establish the safety and efficacy of the proposed drug for its intended use;

- preparation and submission to the FDA of an NDA, containing the results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug product, proposed labeling and other relevant information, to request approval to market the drug product;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug product, or components thereof, are produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of clinical data;
- FDA review and approval of the NDA;
- payment of fees, including annual program fees for each drug product on the market; and
- ongoing compliance with any post approval requirements, including risk evaluation and mitigation strategy (REMS) and post approval studies required by the FDA.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. When a sponsor wants to proceed to test the product candidate in humans, it must submit an IND in order to conduct clinical trials.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical study lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical study and places the study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance, and may be imposed on all product candidates within a certain pharmaceutical class. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical studies of a certain duration or for a certain dose.

All clinical studies must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical study. Further, an IRB must review and approve the plan for any clinical study before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical study are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (NIH) for public dissemination on their ClinicalTrials.gov website.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- *Phase 2.* Involves clinical studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- *Phase 3.* Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

There are FDA-imposed limitations on communications about investigational drugs. The FDA prohibits companies from making promotional claims of safety or effectiveness of the drug for a use for which it is under investigation, and from "commercialization" of the drug before it is approved for commercial marketing and distribution, and otherwise regulates communications about products in clinical trials. FDA law prohibits "misbranding" of drugs and establishes related rules and policies on communications about promotional and non-promotional (educational, scientific) communications. Interactions with or communications directed to healthcare professionals (HCPs), patients or patient- or disease-advocates or advocacy groups, and payors, are subject to heightened scrutiny by the FDA. Relative to non-promotional communications, for example, there are specific and limited FDA accommodations for non-promotional, truthful and non-misleading sharing of information regarding products in development and off-label uses including dissemination of peer-reviewed reprints, support of independent continuing medical education (CME) and healthcare economic discussions with payors. In a competitive environment, a company's communications about products in development may also be subject to heightened scrutiny.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of the required clinical testing, the results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

The submission of an NDA is subject to the payment of a substantial application user fee although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review. The sponsor of an approved NDA is also subject to annual program user fees.

In addition, under the Pediatric Research Equity Act of 2003 (PREA) an NDA application (or a supplement to an application) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must contain a Pediatric Assessment. If so, the submission must contain data from pediatric studies that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the applicant has obtained a waiver or deferral. PREA applies only to products developed for diseases that occur in both adult and pediatric populations, and generally does not apply to products with Orphan Drug Designation or to ANDAs for generic drugs.

A sponsor who is planning to submit a marketing application for a drug product that is subject to the PREA requirements must submit an initial Pediatric Study Plan (PSP). The FDA encourages all applications to submit the PSP as soon as possible in the drug development process, and to discuss the plan with FDA at critical points in the development process. For products intended for life-threatening or severely debilitating illnesses, applicants are encouraged to discuss the PSP at the Pre-IND meeting and End-of-Phase 1 meeting. For products not intended for such illnesses, the FDA recommends that sponsors submit and discuss the PSP no later than the End-of-Phase 2 (EOP2) meeting. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical studies or other clinical development programs. The sponsor may submit a request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. It is critical that sponsors are in compliance with the PREA, as non-compliance may result in the FDA considering the drug product misbranded solely on that basis.

The FDA also may require submission of a REMS to mitigate any identified or suspected serious risks. The REMS could include medication guides, physician communication plans, assessment plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

The FDA reviews an NDA to determine whether a product is safe and effective for its intended use, which includes assessment of preclinical and clinical data; proposed labeling; CMC data; and an assessment of whether the manufacturing processes and facilities meet the appropriate requirements and comply with the applicable regulations (including cGMP requirements and adequate assurance for consistent commercial production of the product within required specifications). There are numerous FDA personnel assigned to review different aspects of an NDA, exercising judgment, discretion, and interpretation of data relative to the review process.

The FDA may approve an NDA only if, among other things, the methods used in, and the facilities and controls used for, the manufacture processing, packing and testing of the product are adequate to ensure and preserve its identity, strength, quality and purity.

Before approving an NDA, the FDA often will inspect the facility or facilities where the product is or will be manufactured.

The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts, including clinicians and other scientific experts, who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making decisions.

Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure clinical data supporting the submission were developed in compliance with GCP.

The approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied, or may require additional preclinical, clinical or CMC data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies, as well as other types of supporting data, are not always conclusive and the FDA may interpret data differently than an applicant interprets the same data.

After the FDA's evaluation of an application, the FDA may issue an approval letter or a complete response letter to indicate that the review cycle is complete and that the application is not ready for approval. A complete response letter generally contains a statement of specific conditions that must be met to secure final approval of the application and may require additional clinical or preclinical testing for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the application, addressing all of the deficiencies identified in the letter, or withdraw the application, or request an opportunity for a hearing.

Even with submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical studies, to further assess safety and effectiveness after approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA (described above) for innovator products, or an abbreviated new drug application, or ANDA, for generic products. Relevant to ANDAs, the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the "Hatch-Waxman Act"), amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are also referred to as listed drugs). Because the safety and efficacy of listed drugs have already been established by the brand company (sometimes referred to as the innovator), the FDA does not require new human clinical trials to establish safety and efficacy of generic products. Rather, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the active pharmaceutical ingredient is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. For some drugs, including locally acting drugs such as topical anti-fungals, other means of demonstrating bioequivalence may be required by the

FDA, especially where rate and/or extent of absorption are difficult or impossible to measure. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling and stability data.

A third alternative is a special type of NDA, commonly referred to as a 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing product, or published literature, in support of its application. 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings with respect to certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid, unenforceable or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below. Thus approval of a 505(b)(2) NDA or ANDA can be prevented until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

The FDA may issue tentative approval of an application if the application meets all conditions for approval but cannot receive effective approval because the listed patents, the 30-month stay or another period of regulatory exclusivity, as applicable, has not expired. If tentative approval is granted, then once such listed patents, 30-month stay or other regulatory exclusivity have expired or, in the case of patents that are subject to a patent infringement suit, been found to be invalid or not infringed, the applicant may seek final approval by submitting an amendment that, among other things, includes a safety update and any other changes, if any, in the conditions under which the product was tentatively approved. Prior to granting final approval, the FDA must review and approve any changes reflected in the amendment and may consider any other new information that has come to its attention. An amendment requesting final approval is generally subject to either a 2-month or 6-month review cycle, depending on the information submitted in the amendment.

Combination Products

Medical products containing a combination of new drugs, biological products, or medical devices are regulated as “combination products” in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories, such as drug/device, device/biologic or drug/biologic. The term combination product includes: (i) a product comprised of two or more regulated components (i.e., drug/device, biologic/device, drug/biologic or drug/device/biologic, that are physically, chemically or otherwise combined or mixed and produced as a single entity); (ii) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products or biological and drug products; (iii) a drug, device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, such as to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (iv) any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication or effect.

Each constituent part of a combination product is subject to the requirements established by the FDA for that type of constituent part, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by FDA of the primary mode of action of the combination product, and typically one application, such as for a drug/device combination product assigned to the FDA’s Center for Drug Evaluation and Research (CDER) an NDA, will be made.

A device with the primary purpose of delivering or aiding in the delivery of a drug and distributed containing a drug (i.e., a “prefilled delivery system”) is typically evaluated by CDER using drug authorities and device authorities, as necessary.

A device with the primary purpose of delivering or aiding in the delivery of a drug and that is distributed without the drug (i.e., unfilled) is typically evaluated by the FDA’s Center for Devices and Radiological Health and CDER, respectively, unless the intended use of the two products, through labeling, creates a combination product.

The FDA has indicated that dry powder inhalers, such as our lead product candidate, YUTREPIA, are drug/device combination products.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to extensive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping (including certain electronic record and signature requirements), periodic reporting, drug supply chain security surveillance and tracking requirements, product sampling and distribution, advertising and promotion and reporting of certain adverse experiences, deviations and other problems with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are also, under The Prescription Drug User Fee Act, continuing, annual FDA “program fee” requirements for products once they are approved, as well as new application fees for supplemental applications with clinical data.

The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and certain other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards and test each product batch or lot prior to its release. Combination products are subject to FDA regulation to ensure the quality of both the constituent parts and the finished product.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

The FDA may impose a number of post-approval requirements as a condition of approval of an application. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, problems with manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on the product or even complete withdrawal of the product from the market.

Potential implications include required revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. As a compliance best practice and risk mitigation measure, pharmaceutical companies typically train their sales force regarding the limitations on promotion of products relative to their approved indications for use and concerns regarding potential "off-label promotion." However, a physician may use products off-label when, in the physician's independent professional medical judgment, he or she deems it appropriate. Recent court decisions have impacted FDA's enforcement activity regarding off-label promotion in the light of First Amendment considerations; however, there are still significant risks in this area in part due to the potential for False Claims Act exposure. Further, the FDA has not materially changed its position on off-label promotion following legal setbacks on First Amendment grounds and the U.S. Department of Justice has consistently asserted in False Claims Act briefings that "speech serves as a conduit for violations of the law is not constitutionally protected."

The distribution of commercial prescription drugs is subject to the Drug Supply Chain Security Act (DSCSA), which regulates the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain and regulation of manufacturers and repackagers, wholesale distributors, third-party logistics providers, and dispensers. The DSCSA preempts certain previously enacted state pedigree laws and upon taking effect superseded the pedigree requirements of the Prescription Drug Marketing Act (PDMA). Trading partners within the drug supply chain must now ensure certain product tracing requirements are met, and are required to exchange transaction information, transaction history, and transaction statements. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system of product tracing have been and will continue to be phased in over a period of years through 2023, and subject companies will need to continue their implementation efforts. Many states still have in place licensure and other requirements for manufacturers and distributors of drug products. The distribution of product samples continues to be regulated under the PDMA, and some states also impose regulations on drug sample distribution.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited PTE under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term effectively lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension. Extensions are not granted as a matter of right and the extension must be applied for prior to expiration of the patent and within a sixty-day period from the date the product is first approved for commercial marketing. The USPTO, in consultation with the FDA, reviews and approves the application for any PTE or restoration. In the future, we may apply for PTEs, defined as the length of the regulatory review of products covered by our granted patents, for some of our currently owned or licensed applications and patents to add patent life beyond their current expiration dates. Such extensions will depend on the length of the regulatory review; however, there can be no assurance that any such extension will be granted to us.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The specific scope varies, but fundamentally the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving applications for drugs containing the original active agent. This three-year exclusivity does not preclude submission of the ANDA or Section 505(b)(2) NDA for such a product but prevents the FDA from giving final approval to such product. Five-year and three-year exclusivity will not

delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical studies necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to the term of any existing regulatory exclusivity, including the non-patent exclusivity periods described above. This six-month exclusivity may be granted based on the voluntary completion of a pediatric clinical study that “fairly responds” to an FDA-issued “Written Request” for such a clinical study.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. Some of the additional requirements and restrictions on coverage and reimbursement levels imposed by third-party payors influence the purchase of healthcare services and products. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific drugs on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication, or place drugs at certain formulary levels that result in lower reimbursement levels. Moreover, a payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, one payor’s determination to provide coverage does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement may differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors.

Reimbursement may also impact the demand for drug products that obtain marketing approval. If coverage for a drug product is obtained by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Further, third party payors require onerous prior approvals or implement other forms of restricted access that make it difficult for patients to utilize our drug products. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Prescribing physicians are unlikely to use or prescribe drug products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of those drug products. If reimbursement is not available, or is available only to limited levels, a drug product which has obtained marketing approval may not be successfully commercialized.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, U.S. federal prosecutors have issued subpoenas to pharmaceutical companies seeking information about pricing practices in connection with an investigation into pricing practices being conducted by the DOJ. Several state attorneys general also

have commenced drug pricing investigations and filed lawsuits against pharmaceutical companies, and the U.S. Senate has publicly investigated a number of pharmaceutical companies relating to price increases and pricing practices. Proposed legislation has been designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Federal budget proposals have included measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. It is possible that President Biden may issue Executive Orders with the potential to change a number of prior executive branch actions on drug pricing. At the state level, legislatures have increasingly passed legislation and implemented 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. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drugs and product candidates from coverage and limit payments for pharmaceuticals. We continue to monitor the potential impact of proposals to lower prescription drug costs at the federal and state level, and anticipate that current and future U.S. federal and state legislative proposals may result in additional downward pressure on drug pricing and reimbursement, which could have a significant impact on our business.

The Inflation Reduction Act of 2022 (the “IRA”), which includes certain new tax measures, was signed into law in August 2022. The IRA contains two main tax provisions, a new corporate alternative minimum tax imposed on certain corporations meeting average annual financial statement income of more than \$1 billion during a three-year tax period, and an excise tax imposed upon share repurchases by certain publicly traded corporations. The IRA is effective for tax years beginning after December 31, 2022; we are evaluating the provisions of the IRA but currently do not believe these provisions will have a material impact on our consolidated financial statements. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). Failure to comply with requirements under the drug price negotiation program or pay the identified rebates is subject to an excise tax and/or a civil monetary penalty. The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated and the impact of the IRA on the pharmaceutical industry and on generic drug pricing cannot yet be fully determined.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians and third-party payors often play a primary role in the recommendation and prescription of any drug products for which we may obtain marketing approval, or for which we may provide contracted promotional services to third parties. Our current and future arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell, or distribute drug products.

Among the laws and regulations that may affect our ability to operate and may present risk to our business are those, at the federal and state level, on topics including: anti-kickback, false claims, and other healthcare fraud, waste, and abuse matters; drug pricing and price reporting; advertising, promotion, and other types of communications regarding pharmaceutical products; limitations on and transparency regarding financial relationships with healthcare professionals; and data privacy and security. *See Item 1A. Risk Factors – General Risks Related to Healthcare Regulation.*

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States including the Patient Protection and Affordable Care Act (ACA).

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we will be able to charge for our product candidates, or the amounts of reimbursement available for our product candidates. If future legislation were to impose direct governmental price controls or access restrictions, it could have a significant adverse impact on our business. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, measures to reduce costs of the Medicaid program, and some states are considering implementing measures that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on our profitability.

These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Foreign Regulation of Drugs

In order to market any product outside of the United States, we will need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding development, approval, commercial sales and distribution of our products, and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products, if approved. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes thereto, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the information contained under the heading "Cautionary Note Regarding Forward-Looking Statements" before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock 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. We may update these risk factors in our periodic and other filings with the SEC.

The following is a summary of the principal risk factors described in this section:

- We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any

approved product candidates. The future viability of our company is dependent on our ability to raise additional capital to finance our future operations.

- We have a history of losses and our future profitability remains uncertain.
- We are primarily dependent on the success of our product candidate, YUTREPIA, for which we received tentative approval from the FDA in November 2021, and this product candidate may fail to receive final marketing approval (in a timely manner or at all) or may not be commercialized successfully.
- United Therapeutics has initiated a lawsuit against us in which it has claimed that YUTREPIA is infringing three of its patents and a separate lawsuit against us that we and a former United Therapeutics employee, who later joined us as an employee, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. The judge in the patent lawsuit entered a final judgment finding that one of the three asserted United Therapeutics' patents is both valid and infringed and ordering that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the infringed patent, which will be in 2027. While the PTAB found that this same patent was unpatentable, the PTAB's decision with respect to the patent will not override the court's order unless and until the decision of the PTAB is affirmed on appeal. These lawsuits may result in our company being delayed in its efforts to commercialize YUTREPIA.
- Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection or the RG Cartridge and is dependent on Sandoz and Chengdu to manufacture and supply Treprostinil Injection and the RG Cartridge, respectively, in compliance with FDA requirements, and is more broadly dependent on Sandoz's and Chengdu's FDA and healthcare compliance relative to Treprostinil Injection and the RG Cartridge, respectively.
- Treprostinil Injection is presently administered intravenously via Smith Medical's CADD Legacy infusion pump and subcutaneously via Smith Medical's CADD-MS 3 infusion pump. Smith Medical no longer manufactures the CADD-MS 3 infusion pump and has no obligation to service or maintain CADD-MS 3 infusion pumps after January 1, 2025. In addition, Smith Medical has issued a notice of its intent to discontinue the CADD Legacy infusion pump, although it has indicated that it has sufficient parts to support the CADD Legacy infusion pump until 2028. Should components of such pumps become unavailable, Smith Medical's ability to service and maintain such pumps may terminate earlier than anticipated. For instance, we recently became aware of a potential shortage of a critical component of the CADD-MS 3 infusion pump that may cause the number of CADD-MS 3 infusion pumps available for the administration of Treprostinil Injection to be depleted prior to January 1, 2025. In the event the specialty pharmacies are unable to access sufficient quantities of operable pumps or in the event we are unable to identify or develop a new pump prior to the current pumps becoming unavailable, the commercial success of Treprostinil Injection may be adversely affected.
- Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration and the medical devices used for administration of Treprostinil Injection, including the Smiths Medical infusion pumps, any future pumps that we develop and the RG Cartridge, by patients, health care providers and by third-party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection.
- We expect that we will need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA or for which there may be a greater likelihood of success.
- We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively, including if one or more such products have a superior product profile to YUTREPIA.

- Our financing facility with HCR contains milestones that must be achieved in order to draw down on the facility, and failure to achieve these milestones may result in our having insufficient financing for our existing business plan. Our financing facility with HCR also contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in HCR taking possession and disposing of any collateral.
- Our products may not achieve market acceptance.
- Our product candidates are based on our proprietary, novel technology, PRINT, which has not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining final regulatory approval.
- Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.
- We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or enter into agreements with third parties to market and sell our drug products.
- We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA. In the event of any disruption in these supplies, our ability to develop and commercialize, and the timeline for commercialization of, YUTREPIA may be adversely affected.
- We rely on third parties to conduct our preclinical studies and clinical trials.
- We may become involved in litigation to protect our intellectual property, to enforce our intellectual property rights or to defend against claims of intellectual property infringement by third parties, which could be expensive, time-consuming and may not be successful.
- We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel.
- We expect that the market price of our common stock may be volatile, and you may lose all or part of your investment.
- As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to do so may adversely affect investor confidence in us and, as a result, the trading price of our shares.

Risks Related to our Financial Position and Need for Additional Capital

We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company may depend on our ability to raise additional capital to finance our future operations.

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the impact of the COVID-19 pandemic, and the ability to secure additional capital to fund operations. We expect to incur significant expenses and may incur significant operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. In addition, if we obtain marketing approval for any of our product candidates, we would incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. The future viability of our company may depend on our ability to raise additional capital to finance our future operations. We may seek additional funding through public or private financings, debt financing or collaboration. Our inability to obtain funding, if and when needed, would have a negative impact on our financial condition and ability to pursue our business strategies.

We have a history of losses and our future profitability remains uncertain.

We have incurred net losses of \$41.0 million during the year ended December 31, 2022 and \$34.6 million during the year ended December 31, 2021. We also had negative operating cash flows for each of these periods. As of December 31, 2022, we had an accumulated deficit of \$350.6 million.

Since our incorporation, we have invested heavily in the development of our product candidates and technologies, as well as in recruiting management and scientific personnel. To date, we have not commenced the commercialization of our product candidates and all of our revenue has been derived from up-front fees and milestone payments made to us in connection with licensing and collaboration arrangements we have entered into and the Promotion Agreement, under which we share in the profit derived from the sale of Treprostinil Injection in the United States. These up-front fees and milestone payments have been, and combined with revenue generated from Treprostinil Injection may continue to be, insufficient to match our operating expenses. We expect to continue to devote substantial financial and other resources to the clinical development of our product candidates and, as a result, must generate significant revenue to achieve and maintain profitability or raise additional capital to fund clinical development. We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow.

We may need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA or for which there may be a greater likelihood of success.

We may need to raise additional funds to meet our future funding requirements for the continued research, development and commercialization of our product candidates and technology. In the event that funds generated from our operations are insufficient to fund our future growth, we may raise additional funds through the issuance of equity or debt securities or by borrowing from banks or other financial institutions. We cannot assure you that we will be able to obtain such additional financing on terms that are acceptable to us, or at all. Global and local economic conditions could negatively affect our ability to raise funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing, even if obtained, may be accompanied by restrictive covenants that may, among others, limit our ability to pay dividends or require us to seek consent for payment of dividends, or restrict our freedom to operate our business by requiring consent for certain actions.

If we conclude that we require additional financing and fail to obtain it on terms that are favorable to us, we will not be able to implement our growth plans, and we may be required to significantly curtail, delay or discontinue one or more of our research, development or manufacturing programs or the commercialization of any approved product. Furthermore, if we fail to obtain additional financing on terms that are acceptable to us, we may forgo or delay the pursuit of opportunities presented by other potential product candidates or indications that may later prove to have greater commercial potential than the product candidates and indications that we have chosen to pursue.

Our financing facility with HCR contains milestones that must be achieved in order to draw down on our financing facility and operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in HCR taking possession and disposing of any collateral.

Our financing facility with HCR contains restrictions that limit our flexibility in operating our business. Under the terms of the RIFA, HCR has agreed to pay us an aggregate investment amount of up to \$100.0 million (the "Investment Amount"). Under the terms of the RIFA, \$32.5 million of the Investment Amount was funded at the initial closing, an additional \$7.5 million of the Investment Amount will be funded fifteen business days after a request made by the us to HCR to fund our acquisition of rights, whether in the form of an acquisition, license, joint venture or similar transaction, to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension, an additional \$35.0 million of the Investment Amount will be funded fifteen business days after the earlier of regulatory approval of YUTREPIA or a favorable determination relating to the asserted patents in the ongoing patent litigation with United Therapeutics Corporation, and the remaining \$25.0 million of the Investment Amount will be funded fifteen

business days after the mutual agreement of HCR and us to fund such amount. In the event we do not achieve the milestones necessary to trigger the second or third tranches of the Investment Amount or in the event we and HCR do not mutually agree to the funding of the fourth tranche of the Investment Amount, we will be unable to draw the full amount of the Investment Amount. In addition, under the terms of the RIFA, we may not, among other actions, without the prior written consent of HCR, (a) pay any dividends or make any other distribution or payment or redeem, retire or purchase any capital stock, except in certain prescribed circumstances, (b) create, incur, assume, or be liable with respect to any indebtedness except certain permitted indebtedness, or make or permit any payment on any indebtedness, except under certain limited circumstances, or (c) make any sale, transfer, out-license, lease or other disposition of any property or any economic interest, other than certain limited exceptions. Additionally, we are required (i) during the period from January 1, 2024 through December 31, 2024, to maintain at all times a minimum cash balance of \$7.5 million, and (ii) during all periods after December 31, 2024, to maintain at all times a minimum cash balance of \$15.0 million. Our obligations under the RIFA are collateralized by all of our assets and property, subject to limited exceptions.

If we breach certain of our covenants in the RIFA and are unable to cure such breach within the prescribed period or are not granted waivers in relation to such breach, it may constitute an event of default under the RIFA, giving HCR the right to require us to repay the then outstanding obligations immediately, and HCR could, among other things, foreclose on the collateral granted to them to collateralize such indebtedness, which includes our intellectual property, if we are unable to pay the outstanding debt immediately.

Our management has broad discretion in using the net proceeds from our financing facility with HCR and prior equity offerings and may not use them effectively.

We are using the net proceeds of our financing facility with HCR, our April 2022 public equity offering, our April 2021 private equity offering and prior public and private equity offerings to support the development and commercialization of YUTREPIA, including the potential commercial launch of YUTREPIA in the event of final FDA approval, the commercialization of Treprostinil Injection, the development of a pump for the administration of Treprostinil Injection, one or more strategic transactions, preclinical pipeline activities, the development and commercialization of any products acquired or developed and for general corporate purposes. Our management has broad discretion in the application of such proceeds and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our equity. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, diminish cash flows available to service our obligations to HCR, cause the value of our equity to decline and delay the development of our product candidates. Pending their use, we may invest such proceeds in short-term, investment-grade, interest-bearing securities, which may not yield favorable returns.

Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change”, generally defined as a greater than 50.0% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. With our April 2022 public equity offering, the closing of the RareGen acquisition in November 2020, our July 2020 equity offering, our December 2019 private placement, issuances under our prior at-the-market facility, our March 2019 follow-on equity offering and our July 2018 initial public offering, as well as other past transactions, we may have already triggered an “ownership change” limitation. We have not completed a formal study to determine if any “ownership changes” within the meaning of IRC Section 382 have occurred. If “ownership changes” within the meaning of Section 382 of the Code have occurred, and if we earn net taxable income, our ability to use our net operating loss carryforwards and research and development tax credits generated since inception to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

Recently enacted tax reform legislation in the U.S., changes to existing tax laws, or challenges to our tax positions could adversely affect our business and financial condition.

In recent years, various tax legislations were signed into law. On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law, making significant changes to the Internal Revenue Code.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted in response to the COVID-19 pandemic. Certain provisions of the CARES Act amend or suspend certain provisions of the Tax Act. For example, the tax relief measures under the CARES Act for businesses include a five-year net operating loss carryback, suspension of annual deduction limitation of 80% of taxable income from net operating losses generated in a tax year beginning after December 31, 2017, changes in the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property. On June 15, 2020, Assembly Bill 85 was passed in California which suspended the use of net operating losses and limited the use of credits for certain corporations. Changes to existing federal and state tax laws could adversely impact our business, results of operations and financial position as the impact of recent tax legislation is uncertain.

In addition, U.S. federal, state and local tax laws are extremely complex and subject to various interpretations. Although we believe that our tax estimates and positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities. If the relevant tax authorities assess additional taxes on us, this could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position.

We are a late-stage clinical biopharmaceutical company with no approved products and no historical revenue from the sale of our own products, which may make it difficult for you to evaluate our business, financial condition and prospects.

We are a late-stage clinical biopharmaceutical company with no history of commercial operations upon which you can evaluate our prospects other than the activities we have undertaken with respect to the Promotion Agreement with Sandoz. Drug product development involves a substantial degree of uncertainty. Our operations to date have been limited to engaging in promotional and nonpromotional activities under the Promotion Agreement with Sandoz, developing our PRINT technology, undertaking preclinical studies and clinical trials for our product candidates and collaborating with pharmaceutical companies, including GSK, to expand the applications for our PRINT technology through licensing as well as joint product development arrangements. We have not obtained final marketing approval for any of our product candidates and, accordingly, have not demonstrated an ability to generate revenue from our own pharmaceutical products or successfully overcome the risks and uncertainties frequently encountered by companies undertaking drug product development. Consequently, your ability to assess our business, financial condition and prospects may be significantly limited. Further, the net losses that we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Other unanticipated costs may also arise.

Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection and is dependent on Sandoz to manufacture and supply Treprostinil Injection in compliance with FDA requirements, and is more broadly dependent on Sandoz's FDA and healthcare compliance relative to Treprostinil Injection.

Sandoz holds the FDA approval (the ANDA) for and controls Treprostinil Injection and is responsible among other things for the compliant manufacture, distribution, labeling, and advertising of Treprostinil Injection. Our role is one of a specialized service provider to Sandoz. As a result, we are dependent on Sandoz to manufacture and supply Treprostinil Injection, and dependent on Sandoz for the continued FDA compliance of Treprostinil Injection. We do not have control over Sandoz's compliance with laws and regulations applicable to drug manufacturers and ANDA holders (for example, applicable current good manufacturing practices (GMPs); FDA labeling, promotional labeling, and advertising requirements; pharmacovigilance and adverse event reporting; and other ongoing FDA reporting and submission requirements), nor over its compliance with healthcare compliance and fraud, waste, and abuse laws, or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. In addition, we have no control over the ability of Sandoz to maintain adequate quality control, quality assurance and

qualified personnel, or other personnel with roles related to the regulatory compliance of Treprostinil Injection and its labeling, promotion, and advertising or of Sandoz's activities in relation to government healthcare programs. If the FDA or a comparable foreign regulatory authority finds deficiencies with the manufacture or quality assurance of Treprostinil Injection or identifies safety or efficacy concerns related to Treprostinil Injection, or if Sandoz otherwise is unable to comply with applicable laws, regulations and standards, Sandoz's ability to manufacture, sell and supply Treprostinil Injection could be limited.

Sandoz's ability to consistently manufacture and supply Treprostinil Injection in a timely manner may also be interrupted by production shortages or other supply interruptions, including as a result of the ongoing COVID-19 pandemic. Our share of net profits under the Promotion Agreement is reduced by certain manufacturing costs and other write-offs related to Sandoz's inability to sell Treprostinil Injection, including in the event that Treprostinil Injection expires prior to sale. Currently, Treprostinil Injection expires 24 months after the date of manufacture.

Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third-party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection.

Our ability to sell Treprostinil Injection is dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third-party payors. If Treprostinil Injection does not achieve an adequate level of acceptance, we may not generate sufficient revenue to offset our cost of revenue.

At the same time, arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business or financial arrangements and relationships.

The degree of market acceptance of Treprostinil Injection will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer Treprostinil Injection for sale at competitive prices (generic drug prices, after initial generic entry, have been observed to decline with the entrance of additional generic competition);
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning;
- the willingness of the target patient population to try new treatments, including the generic version of a brand, and of physicians to prescribe such treatments;
- our ability to hire and retain sales and marketing personnel and their ability to support Sandoz under the Promotion Agreement;
- the strength of Sandoz's manufacturing and distribution support;
- the requirement by third-party payors to use generic treprostinil for parenteral administration in place of Remodulin;
- the availability of third-party coverage and adequate reimbursement for Treprostinil Injection;
- the prevalence and severity of any side effects;
- any restrictions on the use of Treprostinil Injection together with other medications;
- our and Sandoz's ability to maintain relationships with the specialty pharmacies; and
- the services provided by specialty pharmacies related to use of Treprostinil Injection.

Our business may also be impacted by the need to maintain compliant operations (including oversight and monitoring of personnel and our activities) in relation to interactions with the persons and parties noted above, relative to FDA and healthcare law requirements, and with consideration of government and industry compliance best practices.

Medical devices, which we do not control, are necessary for the administration of Treprostinil Injection.

In order for Treprostinil Injection to be administered to patients, patients must use certain other medical equipment, including pumps, cartridges and infusion sets. We do not manufacture or control such medical equipment, which is manufactured by third parties and owned and dispensed by specialty pharmacies, hospitals or other third parties. Our ability to serve patients is dependent upon the ability of specialty pharmacies to maintain sufficient inventory of such medical equipment to provide to patients. If manufacturers cease to manufacture or support medical equipment or if specialty pharmacies are unable to obtain or maintain sufficient inventories of such medical equipment, our sales may be adversely impacted.

We have worked with Chengdu to develop the RG Cartridge, which received FDA 510(k) clearance in March 2021. The ability of patients to administer Treprostinil Injection through subcutaneous injection is dependent on the continued availability of the RG Cartridge. Our ability to sell the Treprostinil Injection for subcutaneous administration is dependent on market acceptance of the RG Cartridge by patients, health care providers and by third-party payors. If the RG Cartridge does not achieve an adequate level of acceptance or if the RG Cartridge experiences any quality problems, recalls or other adverse events, our ability to provide Treprostinil Injection to patients who receive Treprostinil through subcutaneous injection will be limited. The degree of market acceptance of the RG Cartridge will depend on a number of factors, including:

- the efficacy, safety, quality and potential advantages or disadvantages compared to alternative cartridges;
- Chengdu's ability to offer the RG Cartridge for sale at competitive prices;
- the strength of Chengdu's manufacturing and distribution support; and
- Chengdu's ability to maintain regulatory approvals necessary to manufacture and sell the RG Cartridge in the United States.

In addition, to administer Treprostinil Injection through subcutaneous injection, patients currently must use the CADD-MS 3 infusion pump manufactured by Smiths Medical. Smiths Medical no longer manufactures the CADD-MS 3 infusion pump and, under our Settlement Agreement with Smiths Medical, they are no longer obligated to support the CADD-MS 3 infusion pump after January 1, 2025. Moreover, in the event components of the CADD-MS 3 infusion pump become unavailable prior to January 1, 2025, Smiths Medical may be unable to service pumps that require a replacement of such components. For instance, we recently became aware of a shortage of a critical component of the CADD-MS 3 infusion pump that has caused the number of CADD-MS 3 infusion pumps available for the administration of Treprostinil Injection to be limited. Due to this limitation in the availability of pumps, specialty pharmacies are not currently placing new patients on to subcutaneous Treprostinil Injection therapy in order to preserve the available pumps for those patients already receiving subcutaneous administration of Treprostinil Injection. If we are unable to identify a solution to this shortage, the number of patients that can receive subcutaneous administration of Treprostinil Injection will continue to be constrained, which would continue to adversely affect sales of Treprostinil Injection. Also, to administer Treprostinil Injection intravenously, patients currently use the CADD Legacy infusion pump manufactured by Smiths Medical. Smiths Medical has announced that it will discontinue support of the CADD Legacy pump starting in 2028.

We are seeking to work with third parties to develop or procure other pumps that can be used to administer Treprostinil Injection in the future. For example, we have entered into an agreement with Sandoz and Mainbridge to develop a new pump that can be used to administer Treprostinil Injection in the future. Such pumps will require FDA 510(k) clearance before they can be sold. There is no guarantee that we or our partners will receive FDA 510(k) clearance for any such pumps. If we are unable to identify, develop and obtain any required FDA clearance for new pumps for the subcutaneous and intravenous administration of Treprostinil Injection prior to the unavailability of the CADD-MS 3 and CADD Legacy pumps, respectively, we may no longer be able to serve patients with Treprostinil Injection through the applicable route of administration.

Failure by us or third parties to successfully develop or supply the medical equipment or to obtain or maintain regulatory approval or clearance of such medical equipment could negatively impact the market acceptance of and sales of Treprostinil Injection.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

Our cash is held in non-interest-bearing and interest-bearing accounts may exceed the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank (“SVB”), where we previously held all of our cash and cash equivalents, on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole, and we were able to move substantially all of our cash and cash equivalents to another financial institution. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders’ access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

Risks Related to the Commercialization of our Product Candidates and Generic Trepstinil Injection

United Therapeutics has initiated lawsuits against us in which it claims that YUTREPIA is infringing three of its patents and that we have misappropriated United Therapeutics’ trade secrets, which may result in our company being delayed in its efforts to commercialize YUTREPIA.

We are developing YUTREPIA under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. Accordingly, under the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act, we were required to, in the NDA for YUTREPIA, certify that patents listed in the Orange Book for Tyvaso are invalid, unenforceable or will not be infringed by the manufacture, use or sale of YUTREPIA. Two of these patents are U.S. Patent No. 9,604,901 (the “’901 Patent”), entitled “Process to Prepare Trepstinil, the Active Ingredient in Remodulin®”, and U.S. Patent No. 9,593,066 (the “’066 Patent”), entitled “Process to Prepare Trepstinil, the Active Ingredient in Remodulin®”, both of which are owned by United Therapeutics. A notice of the paragraph IV certification was required to be provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. In June 2020, United Therapeutics, as the holder of such patents, asserted a patent challenge directed to the ‘901 Patent and the ‘066 Patent by filing a complaint against us in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA) (the “Hatch-Waxman Litigation”).

In July 2020, the U.S. Patent and Trademark Office (the USPTO) issued U.S. Patent No. 10,716,793 (the “’793 Patent”), entitled “Trepstinil Administration by Inhalation”, to United Therapeutics. In July 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the ‘793 Patent by the practice of YUTREPIA.

In June 2021, the Court held a claim construction hearing. Based on the Court’s construction of the claim terms, United Therapeutics filed a stipulation of partial judgment with respect to the ‘901 Patent in December 2021 under which United Therapeutics agreed to the entry of judgment of our non-infringement of the ‘901 Patent. United Therapeutics did not appeal the Court’s construction of the claim terms of the ‘901 Patent.

Trial proceedings in the Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the ‘066 Patent were invalid, that the remaining asserted claims of the ‘066 Patent were not infringed by us, and that all of the asserted claims of the ‘793 Patent were both valid and infringed by us, based on the arguments we presented in the Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the ‘793 Patent, which will be in 2027. Both we and United Therapeutics have appealed Judge Andrews’ decision to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In September of 2022, following entry of final judgment, we filed a motion requesting that Judge Andrews stay enforcement of the order delaying the effective date of any final approval by the FDA of YUTREPIA until the expiration

of the '793 Patent. Briefing on the motion for stay of enforcement is complete, and the motion remains pending with the Court.

In March 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (PTAB) of the USPTO. One petition was for *inter partes* review of the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid, and a second petition is for *inter partes* review of the '066 Patent, seeking a determination that the claims in the '066 Patent are invalid. In October 2020, the PTAB instituted an *inter partes* review of the '901 Patent and concurrently denied institution on the '066 Patent, stating that the '066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of trestatinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '901 patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the '901 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In January 2021, we filed a petition with the PTAB for *inter partes* review of the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. In August 2021, the PTAB instituted an *inter partes* review of the '793 Patent, finding that we had demonstrated a reasonable likelihood that we would prevail with respect to showing that at least one challenged claim of the '793 Patent is unpatentable as obvious over the combination of certain prior art cited by us in our petition to the PTAB. In July 2022, the PTAB ruled in our favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '793 Patent. The rehearing request was denied in February 2023. United Therapeutics has publicly stated that it will appeal the PTAB's decision with respect to the '793 Patent. The PTAB's decision with respect to the '793 Patent will not override Judge Andrews' order in the Hatch-Waxman Litigation that YUTREPIA may not be approved due to infringement of the '793 Patent unless and until the decision of the PTAB is affirmed on appeal.

In December 2021, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, alleging that we and a former United Therapeutics employee, who later joined us as an employee many years after terminating his employment with United Therapeutics, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2022, our co-defendant in the lawsuit removed the lawsuit to the United States District Court for the Middle District of North Carolina. Subsequently, in January 2022, United Therapeutics filed an amended complaint eliminating their claim under the federal Defend Trade Secrets Act and a motion seeking to have the case remanded to North Carolina state court. In April 2022, the Court granted United Therapeutics' motion to have the case remanded to North Carolina state court. In May 2022, we filed a motion to dismiss all of the claims made by United Therapeutics in the trade secret lawsuit. The motion was denied by the Court in October 2022. Discovery in the case is ongoing.

As a result of this litigation and the order by Judge Andrews in the Hatch-Waxman Litigation, we may be subject to significant delay and incur substantial additional costs in litigation before we are able to commercialize YUTREPIA, if at all. If we are unable to either have Judge Andrews' decision with respect to the '793 Patent overturned on appeal or obtain an affirmance of Judge Andrews' decision with respect to the '066 Patent or the PTAB's decision with respect to the '793 Patent upon appeal, we may be unable to commercialize YUTREPIA until the expiration of those patents, which could materially harm our business.

Success in the lawsuits or *inter partes* review proceedings with respect to some patents or some claims in a given patent does not mean that we will be similarly successful upon appeal of those decisions. In addition, success with respect to a given patent or patent claim in one proceeding does not mean we will be similarly successful with respect to that same patent or patent claim in another proceeding.

If, after the appeals process has been completed, we are found to infringe, misappropriate or otherwise violate any United Therapeutics' intellectual property rights, we could be required to obtain a license from United Therapeutics to continue developing and marketing YUTREPIA. However, we may not be able to obtain any required license on

commercially reasonable terms or at all. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or to have misappropriated a trade secret of United Therapeutics. In addition, we may be forced to redesign YUTREPIA to avoid infringement.

We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively.

We face significant competition from industry players worldwide, including large multi-national pharmaceutical companies, other emerging or smaller pharmaceutical companies, as well as universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as a larger research and development staff and more experience in manufacturing and marketing, than we do. As a result, these companies may obtain marketing approval for their product candidates more quickly than we are able to and/or be more successful in commercializing their products, including generic treprostinil products, than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies. We may also face competition as a result of advances in the commercial applicability of new technologies and greater availability of capital for investment in such technologies. Our competitors may also invest heavily in the discovery and development of novel drug products that could make our product candidates less competitive or may file FDA citizen petitions which may delay the approval process for our product candidates. Furthermore, our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. Our competitors may also succeed in asserting existing patents or developing new patents, including patents that may issue from patent applications that are currently being pursued by United Therapeutics, to which we do not have a license in an attempt to prevent us from marketing our products. These competitors may also compete with us in recruiting and retaining qualified sales personnel.

Any new drug product that competes with a prior approved drug product must demonstrate advantages in safety, efficacy, tolerability or convenience in order to overcome price competition and to be commercially successful. Our products, if and when approved, are expected to face competition from drug products that are already on the market, as well as those in our competitors' development pipelines. We expect that our lead program, YUTREPIA, an inhaled treprostinil therapy for the treatment of PAH, will face competition from the following inhaled treprostinil therapies that are either currently marketed or in clinical development:

- Tyvaso, marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009. Tyvaso is the reference listed drug in our NDA for YUTREPIA. Following patent litigation, United Therapeutics and Watson Pharmaceuticals reached a settlement whereby Watson Pharmaceuticals will be permitted to enter the market with a generic version of Tyvaso beginning on January 1, 2026. In April 2021, United Therapeutics announced that Tyvaso was approved by FDA to include treatment of patients with PH-ILD.
- Ventavis®, marketed by Actelion, a division of Johnson & Johnson, has been approved for the treatment of PAH in the United States since 2004.
- Tyvaso DPI, licensed from MannKind by United Therapeutics, is a dry-powder formulation of treprostinil that was approved for the treatment of PAH and PH-ILD in the United States in May 2022. There is a possibility that the FDA could grant three years of market exclusivity to Tyvaso DPI as an inhaled dry-powder formulation of treprostinil that could delay the final approval of YUTREPIA until said exclusivity expires.
- Treprostinil Palmitil Inhalation Powder (TPIP), is a dry-powder formulation of a treprostinil prodrug being developed by Insmed. Insmed announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once-daily dosing. Insmed initiated a Phase 2 trials studying patients diagnosed with PAH and PH-ILD in May 2021 and December 2022, respectively. If the TPIP clinical program is successful in demonstrating less

frequent dosing with similar efficacy and safety to YUTREPIA and Tyvaso DPI, then TPIP has the potential to be viewed as a more attractive option and may take market share rapidly.

- L606 is a nebulized, liposomal formulation of treprostinil for treatment of PAH being developed by Pharmosa Biopharm Inc. (“Pharmosa”). In 2021, Pharmosa initiated a Phase 3 open-label study to evaluate the safety and tolerability of L606 in subjects with PAH that have been stabilized on Tyvaso. The intended product profile seeks reduce the daily dosing frequency of treprostinil.

In addition to these other inhaled treprostinil therapies, we expect that YUTREPIA will also face competition from other treprostinil-based drugs, including Orenitram, which is administered orally, and Remodulin, which is administered parenterally, both of which are marketed by United Therapeutics. Branded pharmaceutical companies such as United Therapeutics continue to defend their products vigorously through, among other actions, life cycle management, marketing agreements with third-party payors, pharmacy benefits managers and generic manufacturers. These actions add increased competition in the generic pharmaceutical industry, including competition for Treprostinil Injection.

Additionally, even though Sandoz launched the first-to-file fully substitutable generic treprostinil for parenteral administration in March 2019 that is sold primarily through the specialty pharmacies, Teva Pharmaceutical Industries Ltd. launched a generic treprostinil for parenteral administration in October 2019 that is sold primarily through a specialty pharmacy and to hospitals, Par Pharmaceutical, Inc. launched a generic treprostinil for parenteral administration after receiving approval in September 2019 that is sold primarily to hospitals, Dr. Reddy’s Laboratories Inc. received approval in May 2020 for generic treprostinil for parenteral administration, and Alembic received approval in February 2021 for generic treprostinil for parenteral administration. Such increased competition may result in a smaller than expected commercial opportunity for us.

Generic drug prices may, and often do, decline, sometimes dramatically, especially as additional generic pharmaceutical companies (including low-cost generic producers outside of the United States) receive approvals and enter the market for a given product. The goals established under the Generic Drug User Fee Act, and increased funding of the FDA’s Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for generic products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. The FDA’s changes may benefit our competitors. Our ability to sell Treprostinil Injection and earn revenue is affected by the number of companies selling competitive products, including new market entrants, and the timing of their approvals.

In addition to treprostinil-based therapies, other classes of therapeutic agents for the treatment of PAH include the following:

- ***IP-agonists***, such as selexipag, marketed by Actelion, and ralinepeg, licensed from Arena Pharmaceuticals, Inc. by United Therapeutics, which is currently in clinical development;
- ***Endothelin receptor antagonists***, such as bosentan and macitentan, both marketed by Actelion, and ambrisentan, marketed by Gilead. Generic version of bosentan and ambrisentan are currently available.
- ***PDE-5 inhibitors***, such as tadalafil, marketed by United Therapeutics, and sildenafil, marketed by Pfizer Inc. Generic versions of both tadalafil and sildenafil are currently available.
- ***Soluble guanylate cyclase (sGC) stimulator***, such as riociguat marketed by Bayer.

We are also aware of several other agents in clinical development that are exploring mechanisms of action which, if approved, could impact the standard of care for treating PAH in the United States, including programs from Merck & Co. Inc., Gossamer Bio, Inc., Aerovate Therapeutics, Inc., Aerami Therapeutics Inc., Tenax Therapeutics, Inc. and Sumitovant Biopharma Ltd, among others. For example, Merck & Co’s injectable sotatercept is an investigational, potential first-in-class molecule that targets the proliferation of cells in the pulmonary arterial wall and is being reviewed

by the FDA for approval in 2023. If approved, it is possible that it may be used prior to prostacyclin therapies, which may have an adverse effect on the market potential for YUTREPIA.

There are a number of competitors seeking marketing approval and/or regulatory exclusivity with respect to products that are or would be competitive to our product candidate. Thus, we face the risk that one of our competitors will be granted marketing approval and/or regulatory exclusivity before we are able to obtain FDA approval for our product candidate. In that case, as stated above, there is the possibility that such a competitor would be able to prevent us from obtaining approval of and marketing our product candidate until the expiration of the competitor's term of FDA regulatory exclusivity, which could be a term of three years for so-called New Clinical Study exclusivity, or could conceivably be for longer periods of time if the competitor is successful in being granted other forms of FDA regulatory exclusivity which might include, for example, Orphan Disease Designation exclusivity (seven years), New Chemical Entity exclusivity (five years), or Pediatric exclusivity (six months beyond other existing exclusivities or patent terms). In addition, if one of our competitors is granted marketing approval before we are able to obtain FDA approval for our product candidate, as was the case with respect to the approval of United Therapeutics' Tyvaso DPI product, such competitors will be able to detail and market their products before we are able to do so, which may place us at a competitive disadvantage in the marketplace.

United Therapeutics has been granted New Clinical Study exclusivity for Tyvaso through March 31, 2024 for the indication of treatment of PH-ILD to improve exercise ability. Until the expiration of this exclusivity, we will be unable to receive FDA approval for YUTREPIA for the indication of treatment of PH-ILD to improve exercise ability. Because United Therapeutics is also the sponsor of the NDA for Tyvaso DPI, the regulatory exclusivity granted to United Therapeutics with respect to Tyvaso did not limit the indications for which the FDA approved Tyvaso DPI. Thus, even if YUTREPIA is approved, Tyvaso DPI will have a broader label than the initial label for YUTREPIA. If YUTREPIA has a narrower label than other competitive products, it may affect our ability to compete with such products.

The ability of competitors to utilize other regulatory incentive programs could also expedite their FDA review and approval timeline, which could result in their products reaching the market before our product candidate, and which could create further potential implications on exclusivity as noted above. For example, when a Priority Review Voucher (PRV) is redeemed in connection with an NDA, the FDA's goal review period would generally be expedited to six months, although this timeframe is not guaranteed.

If we are unable to maintain our competitive position, our business and prospects will be materially and adversely affected.

Our products may not achieve market acceptance.

We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505(b)(2) regulatory pathway, which allows us to rely on existing knowledge of the safety and efficacy of the relevant reference listed drugs to support our applications for approval in the United States. While we believe that it will be less difficult for us to convince physicians, patients and other members of the medical community to accept and use our drug products as compared to entirely new drugs, our drug products may nonetheless fail to gain sufficient market acceptance by physicians, patients, other healthcare providers and third-party payors. If any of our drug products fail to achieve sufficient market acceptance, we may not be able to generate sufficient revenue to become profitable. The degree of market acceptance of our drug products, if and when they are approved for commercial sale, will depend on a number of factors, including but not limited to:

- the timing of our receipt of marketing approvals, the terms of such approvals and the countries in which such approvals are obtained;
- the safety, efficacy, reliability and ease of administration of our drug products;
- the prevalence and severity of undesirable side effects and adverse events;
- the extent of the limitations or warnings required by the FDA or comparable regulatory authorities in other countries to be contained in the labeling of our drug products;
- the clinical indications for which our drug products are approved;

- the availability and perceived advantages of alternative therapies;
- any publicity related to our drug products or those of our competitors;
- the quality and price of competing drug products;
- our ability to obtain third-party payor coverage and sufficient reimbursement;
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage; and
- the selling efforts and commitment of our commercialization collaborators.

If our drug products, if and when approved, fail to receive a sufficient level of market acceptance, our ability to generate revenue from sales of our drug products will be limited, and our business and results of operations may be materially and adversely affected.

We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or enter into agreements with third parties to market and sell our drug products.

In order to market and sell any of our drug products, if and when approved, we will be required to build our marketing and sales capabilities with respect to such products. With the acquisition of Liquidia PAH, we acquired a sales force to market generic tadalafil in accordance with the Promotion Agreement. We cannot assure you that we will be successful in further building our marketing and sales capabilities or be able to do so in a cost-effective manner. In addition, we may enter into collaboration arrangements with third parties to market our drug products. We may face significant competition for collaborators. In addition, collaboration arrangements may be time-consuming to negotiate and document. We cannot assure you that we will be able to negotiate collaborations for the marketing and sales of our drug products on acceptable terms, or at all. Even if we do enter into such collaborations, we cannot assure you that our collaborators will be successful in commercializing our products. If we or our collaborators are unable to successfully commercialize our drug products, whether in the United States or elsewhere, our business and results of operations may be materially and adversely affected.

As we seek to establish a commercial operation with respect to YUTREPIA in anticipation of potential approval from the FDA, we also continue to evaluate additional drug candidates. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our commercial activities. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which include problems relating to managing manufacturing and supply, reimbursement, marketing problems, and other additional costs.

There are risks involved with building and expanding our sales, marketing, and other commercialization capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any drug launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may impact our efforts to commercialize our drug candidates on our own and generate product revenues include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel over a large geographic area;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- understanding and training relevant personnel on the limitations on, and the transparency and reporting requirements applicable to, remuneration provided to actual and potential referral sources;
- the clinical indications for which the products are approved and the claims that we may make for the products;

- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- the inability of sales personnel to obtain access to physicians or to effectively promote any future drugs;
- our ability to appropriately market, detail and distribute products in light of healthcare provider facility closures, quarantine, travel restrictions and other governmental restrictions caused by COVID-19;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- any distribution and use restrictions imposed by the FDA or to which we agree;
- liability for sales and marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- our ability to maintain a healthcare compliance program including effective mechanisms for compliance monitoring; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

In the future, we may choose to participate in sales activities with collaborators for some of our drug candidates. However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any drug candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

We may be exposed to claims and may not be able to obtain or maintain adequate product liability insurance.

Our business is exposed to the risk of product liability and other liability risks that are inherent in the development, manufacture, clinical testing and marketing of pharmaceutical products. These risks exist even if a product is approved for commercial sale by the FDA or comparable regulatory authorities in other countries and manufactured in licensed facilities. Our current product candidate, YUTREPIA, and Treprostinil Injection are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products could result in injury to a patient or even death.

Claims that are successfully brought against us could have a material and adverse effect on our financial condition and results of operations. Further, even if we are successful in defending claims brought against us, our reputation could suffer. Regardless of merit or eventual outcome, product liability claims may also result in, among others:

- a decreased demand for our products;
- a withdrawal or recall of our products from the market;
- a withdrawal of participants from our ongoing clinical trials;
- the distraction of our management's attention from our core business activities to defend such claims;
- additional costs to us; and
- a loss of revenue.

Our insurance may not provide adequate coverage against our potential liabilities. Furthermore, we, our collaborators or our licensees may not be able to obtain or maintain insurance on acceptable terms, or at all. In addition, our collaborators or licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. To the extent that they are uninsured or uninsurable, claims or losses that may be suffered by us, our collaborators or our licensees may have a material and adverse effect on our financial condition and results of operations.

Risks Related to the Development and Regulatory Approval of our Product Candidates

We are primarily dependent on the success of our product candidate, YUTREPIA, for which we received tentative approval from the FDA in November 2021, and this product candidate may fail to receive final marketing approval (in a timely manner or at all) or may not be commercialized successfully.

We do not have any products approved for marketing in any jurisdiction and we have never generated any revenue from sales of our own products. Our ability to generate revenue from sales of our own products and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We expect that a substantial portion of our efforts and expenditure over the next few years will be devoted to our product candidate, YUTREPIA, a proprietary inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension (PAH).

We received tentative approval of our NDA for YUTREPIA in November 2021. However, our receipt of tentative approval does not mean that we will receive final approval of our NDA for YUTREPIA in a timely manner or at all. Expectations related to final FDA approval and projected product launch timelines are impacted by ongoing Hatch-Waxman Litigation following a lawsuit filed by United Therapeutics in June 2020. As a result of Judge Andrews' order in the Hatch-Waxman Litigation, the FDA may not issue a final approval for the YUTREPIA NDA until 2027 unless either Judge Andrews' decision with respect to the '793 Patent is reversed on appeal or the PTAB's decision with respect to the '793 Patent is affirmed on appeal. In addition, a drug product that is granted tentative approval, like YUTREPIA, may be subject to additional review before final approval, particularly if tentative approval was granted more than three years before the earliest lawful approval date. The FDA's tentative approval of YUTREPIA was based on information available to FDA at the time of the tentative approval letter (i.e., information in the application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention. A new drug product may not be marketed until the date of final approval.

Expectations for YUTREPIA also may be impacted by competing products, including Tyvaso® DPI. *See Item 1A. Risk Factors - We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively.*

We cannot assure you that we will receive final marketing approval for YUTREPIA. The FDA or comparable regulatory authorities in other countries may delay, limit or deny final approval of our product candidate for various reasons. For example, such authorities may disagree with the design, scope or implementation of our clinical trials, or with our interpretation of data from our preclinical studies or clinical trials. Further, there are numerous FDA personnel assigned to review different aspects of an NDA, and uncertainties can be presented by their ability to exercise judgment and discretion during the review process. During the course of review prior to final approval, the FDA may request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC) or other data and information, and the development and information may be time-consuming and expensive. Status as a combination product, as is the case for YUTREPIA, may complicate or delay the FDA review process. Product candidates that the FDA deems to be combination products, such as YUTREPIA, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process. Additionally, the FDA could delay approval of YUTREPIA even if approvable after completing its review. For example, if a competing product comprised of an inhaled dry-powder formulation of treprostinil, such as Tyvaso DPI, is granted three years of market exclusivity, that could delay the final approval of YUTREPIA until said exclusivity expires. Moreover, the applicable requirements for approval may differ from country to country.

If we successfully obtain marketing approval for YUTREPIA, we cannot assure you that it will be commercialized in a timely manner or successfully, or at all. For example, YUTREPIA may not achieve a sufficient level of market acceptance, or we may not be able to effectively build our marketing and sales capabilities or scale our manufacturing operations to meet commercial demand. The successful commercialization of YUTREPIA will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such product,

even if approved. Any delay or setback we face in the commercialization of YUTREPIA may have a material and adverse effect on our business and prospects, which will adversely affect your investment in our company.

Our preclinical studies and clinical trials may not be successful and delays in such preclinical studies or clinical trials may cause our costs to increase and significantly impair our ability to commercialize our product candidates. Results of previous clinical trials or interim results of ongoing clinical trials may not be predictive of future results.

Before we are able to commercialize our drug products, we are required to undertake extensive preclinical studies and clinical trials to demonstrate that our drug products are safe and effective for their intended uses. However, we cannot assure you that our drug products will, in preclinical studies and clinical trials, demonstrate safety and efficacy as necessary to obtain marketing approval. Due to the nature of drug product development, many product candidates, especially those in early stages of development, may be terminated during development. Although we believe we have completed clinical development for YUTREPIA, we have not yet obtained final approval for or commercialized any of our own product candidates and as a result do not have a track record of successfully bringing our own product candidates to market. Furthermore, YUTREPIA has, to date, been tested only in relatively small study populations and, accordingly, the results from our earlier clinical trials may be less reliable than results achieved in larger clinical trials, if required. Additionally, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary and interim results of a clinical trial do not necessarily predict final results.

Preclinical studies and clinical trials may fail due to factors such as flaws in trial design, dose selection and patient enrollment criteria. The results of preclinical studies and early clinical trials may not be indicative of the results of subsequent clinical trials. Product candidates may, in later stages of clinical testing, fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and earlier clinical trials. Moreover, there may be significant variability in safety or efficacy results between different trials of the same product candidate due to factors including, but not limited to, changes in trial protocols, differences in the composition of the patient population, adherence to the dosing regimen and other trial protocols and amendments to protocols and the rate of drop-out among patients in a clinical trial. If our preclinical studies or clinical trials are not successful and we are unable to bring our product candidates to market as a result, our business and prospects may be materially and adversely affected.

Furthermore, conducting preclinical studies and clinical trials is a costly and time-consuming process. The length of time required to conduct the required studies and trials may vary substantially according to the type, complexity, novelty and intended use of the product candidate. A single clinical trial may take up to several years to complete. Moreover, our preclinical studies and clinical trials may be delayed or halted due to various factors, including, among others:

- delays in raising the funding necessary to initiate or continue a clinical trial;
- delays in manufacturing sufficient quantities of product candidates for clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining institutional review board approval at clinical trial sites;
- delays in recruiting suitable patients to participate in a clinical trial;
- delays in patients' completion of clinical trials or their post-treatment follow-up;
- regulatory authorities' interpretation of our preclinical and clinical data; and
- unforeseen safety issues, including a high and unacceptable severity, or prevalence, of undesirable side effects or adverse events caused by our product candidates or similar drug products or product candidates.

If our preclinical studies or clinical trials are delayed, the commercialization of our product candidates will be delayed and, as a result, we may incur substantial additional costs or not be able to recoup our investment in the development of our product candidates, which would have a material and adverse effect on our business.

Clinical trials and data analysis can be expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for our products, or any required clinical studies of our products do not provide positive results, we may be required to delay or abandon development of such products, which would have a material adverse impact on our business.

Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We cannot provide any assurance or certainty regarding when we might receive regulatory approval for our products, including YUTREPIA. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon an NDA filed with the FDA or repeat clinical trials. The commencement and completion of clinical trials for any current or future development product candidate may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols or amendments to our protocols.

In addition, the FDA or an independent institutional review board (IRB) may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. Although clinical data is an essential part of NDA filings, NDAs must also contain a range of additional data including CMC data to meet FDA standards for approval. In the event we do not ultimately receive final regulatory approval for YUTREPIA, we may be required to terminate development of our only product candidate.

The marketing approval processes of the FDA and comparable regulatory authorities in other countries are unpredictable and our product candidates may be subject to multiple rounds of review or may not receive marketing approval.

Pursuing marketing approval for a pharmaceutical product candidate (for example, through the NDA process) is an extensive, lengthy, expensive and inherently uncertain process. We cannot assure you that any of our product candidates will receive marketing approval. Regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including, but not limited to, the following:

- the FDA or comparable regulatory authorities may, for a variety of reasons, take the view that the data collected from our preclinical and clinical trials and human factors testing, or data that we otherwise submit or reference to support an application, are not sufficient to support approval of a product candidate;
- the FDA or comparable regulatory authorities in other countries may ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers do not sufficiently demonstrate compliance with cGMP to support approval of a product candidate, or that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable regulatory authorities in other countries that our product candidate is safe and effective for its proposed indication, or that its clinical and other benefits outweigh its safety risks;
- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval.

Even if we obtain marketing approval, the FDA or comparable regulatory authorities in other countries may approve our product candidates for fewer or more limited indications than those for which we requested approval or may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates. Likewise, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or other studies or the conduct of an expensive REMS, which could significantly reduce the potential for commercial success or viability of our product candidates. We also may not be able to find acceptable collaborators to manufacture our drug products, if and when approved, in commercial quantities and at acceptable prices, or at all.

We may encounter difficulties in enrolling patients in our clinical trials.

We may not be able to commence or complete clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials.

Patient enrollment may be affected by, among others:

- the severity of the disease under investigation;
- the design of the clinical trial protocol and amendments to a protocol;
- the size and nature of the patient population;
- eligibility criteria for the clinical trial in question;
- the perceived risks and benefits of the product candidate under clinical testing, including a high and unacceptable severity, or prevalence, of undesirable side effects or adverse events caused by our product candidates or similar products or product candidates;
- the existing body of safety and efficacy data in respect of the product candidate under clinical testing;
- the proximity of patients to clinical trial sites;
- the number and nature of competing therapies and clinical trials; and
- other environmental factors such as the ongoing COVID-19 pandemic or other natural or unforeseen disasters.

Any negative results we may report in clinical trials of our product candidates may also make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate.

We expect that if we initiate, as we are currently contemplating, a clinical trial of YUTREPIA in pediatric patients, we may encounter difficulties enrolling patients in such a trial because of the limited number of pediatric patients with this disease. Furthermore, we are aware of a number of therapies for PAH that are being developed or that are already available on the market, and we expect to face competition from these investigational drugs or approved drugs for potential subjects in our clinical trials, which may delay enrollment in our planned clinical trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays, or both. We may, as a result of such delays or failures, be unable to carry out our clinical trials as planned or within the timeframe that we expect or at all, and our business and prospects may be materially and adversely affected as a result.

Product candidates that the FDA deems to be combination products, such as YUTREPIA, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process.

The FDA has indicated that it considers YUTREPIA, which is delivered by a DPI, to be a drug-device combination product. Accordingly, the DPI was evaluated as part of our NDA filing. When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable interactions between the drug and the delivery system, including the potential to negatively impact the safety or effectiveness of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. We rely on third parties for the design and manufacture of the delivery systems for our products, including the DPI for YUTREPIA, and

in some cases for the right to refer to their data on file with the FDA or other regulators. Quality or design concerns with the delivery system, or commercial disputes with these third parties, could delay or prevent regulatory approval and commercialization of our product candidates.

We are pursuing the FDA 505(b)(2) pathway for our current product candidates. If we are unable to rely on the 505(b)(2) regulatory pathway to apply for marketing approval of our product candidates in the United States, seeking approval of these product candidates through the 505(b)(1) NDA pathway would require full reports of investigations of safety and effectiveness, and the process of obtaining marketing approval for our product candidates would likely be significantly longer and more costly.

We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505(b)(2) regulatory pathway, which permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us for a particular product candidate, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We have pursued this pathway for our current product candidate, YUTREPIA. Even if the FDA allows us to rely on the 505(b)(2) regulatory pathway for a given product candidate, we cannot assure you that marketing approval will be obtained in a timely manner, or at all.

The FDA may require us to perform additional clinical trials to support any change from the reference listed drug, which could be time-consuming and substantially delay our receipt of marketing approval. Also, as has been the experience of others in our industry, our competitors may file citizens' petitions with the FDA to contest approval of our NDA, which may delay or even prevent the FDA from approving any NDA that we submit under the 505(b)(2) regulatory pathway. If an FDA decision or action relative to our product candidate, or the FDA's interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for our product candidates. Even if we are able to utilize the 505(b)(2) regulatory pathway, a drug approved via this pathway may be subject to the same post-approval limitations, conditions and requirements as any other drug.

In addition, we may face Hatch-Waxman litigation in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the approval of our product candidates. The pharmaceutical industry is highly competitive, and 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505(b)(2) NDA. If the previously approved drugs referenced in an applicant's 505(b)(2) NDA are protected by patent(s) listed in the Orange Book, the 505(b)(2) applicant is required to make a claim after filing its NDA that each such patent is invalid, unenforceable or will not be infringed. The patent holder may thereafter bring suit for patent infringement, which will trigger a mandatory 30-month delay (or the shorter of dismissal of the lawsuit or expiration of the patent(s)) in approval of the 505(b)(2) NDA application. In addition, in the event the court in any such lawsuit finds that any claims of any of the asserted patents are both valid and infringed, the court would likely issue an injunction prohibiting approval of the product at issue until the expiration of the patent(s) found to have been infringed. For example, the YUTREPIA NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. Under the Hatch-Waxman Act, as a result of the litigation commenced by United Therapeutics in June 2020, the FDA was automatically precluded from approving the YUTREPIA NDA for up to 30 months. In August 2022, prior to the expiration of the 30-month stay, the Court found that the asserted claims of one of the patents, the '793 Patent, were both valid and infringed by the Company and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent. As a result of the Court's order, the FDA may not issue a final approval for the YUTREPIA NDA until the expiration of the '793 Patent unless either the Court's decision with respect to the '793 Patent is reversed on appeal or the PTAB's decision, invalidating the '793 Patent, is affirmed on appeal.

It is also not uncommon for a manufacturer of an approved product, such as United Therapeutics, to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product.

However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

If the FDA determines that any of our product candidates do not qualify for the 505(b)(2) regulatory pathway, we would need to reconsider our plans and might not be able to commercialize our product candidates in a cost-efficient manner, or at all. If we were to pursue approval under the 505(b)(1) NDA pathway, we would be subject to more extensive requirements and risks such as conducting additional clinical trials, providing additional data and information or meeting additional standards for marketing approval. As a result, the time and financial resources required to obtain marketing approval for our product candidates would likely increase substantially and further complications and risks associated with our product candidates may arise. Also, new competing products may reach the market faster than ours, which may materially and adversely affect our competitive position, business and prospects.

We may be unable to continually develop a pipeline of product candidates, which could affect our business and prospects.

A key element of our long-term strategy is to continually develop a pipeline of product candidates by developing proprietary innovations to FDA-approved drug products using our PRINT technology. If we are unable to identify off-patent drug products for which we can develop proprietary innovations using our PRINT technology or otherwise expand our product candidate pipeline, whether through licensed or co-development opportunities, and obtain marketing approval for such product candidates within the timeframes that we anticipate, or at all, our business and prospects may be materially and adversely affected.

We have conducted, and may in the future conduct, clinical trials for our product candidates outside the United States and the FDA may not accept data from such trials.

Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for our product candidates, if not conducted under an IND, this is subject to certain conditions set out in 21 C.F.R. § 312.120. For example, in order for the FDA to accept data from such a foreign clinical trial, the study must have been conducted in accordance with Good Clinical Practice (GCP) including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. The FDA must also be able to validate the data from the study through an onsite inspection if the agency deems it necessary. In addition, foreign clinical data submitted to support FDA applications should be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.

Risks Related to Our Dependence on Third Parties

We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA.

We depend on third-party suppliers for clinical and commercial supplies for the supply of materials and components necessary for clinical and commercial production of YUTREPIA, including the active pharmaceutical ingredients which are used in our product candidates. These supplies may not always be available to us at the standards we require or on terms acceptable to us, or at all, and we may not be able to locate alternative suppliers in a timely manner, or at all. If we are unable to obtain necessary clinical or commercial supplies, our manufacturing operations and clinical trials and the clinical trials of our collaborators may be delayed or disrupted and our business and prospects may be materially and adversely affected as a result.

For example, we currently rely on a sole supplier for treprostinil, the active pharmaceutical ingredient of YUTREPIA, which sources treprostinil from a manufacturer in South Korea, with whom we have a long-term supply agreement. If our supplier is unable to supply treprostinil to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, or if it ceases its relationship with us, we may not be able to obtain alternative supplies of treprostinil from other suppliers on acceptable terms, in a timely manner, or at all. We also rely on a sole supplier for encapsulation and packaging services, with whom we have a long-term contract. Furthermore, YUTREPIA is administered using the

RS00 Model 8 DPI, which is manufactured by Plastiape, which is located in Italy. We purchase our RS00 Model 8 DPI supply pursuant to purchase orders and do not have a long-term contract with Plastiape. In the event of any prolonged disruption to our supply of treprostini, the encapsulation and packaging services, or the manufacture and supply of RS00 Model 8 DPI, our ability to develop and commercialize, and the timeline for commercialization of, YUTREPIA may be adversely affected.

We also rely upon Chengdu for the manufacture and supply of RG Cartridges for the subcutaneous administration of Treprostini Injection and upon Smiths Medical for ongoing servicing and support of the CADD-MS 3 and CADD Legacy infusion pumps. In the event of any disruption to our supply of RG Cartridges or any disruption in the availability of parts or servicing for the CADD-MS 3 and CADD Legacy infusion pumps, sales of Treprostini Injection may be adversely affected.

In addition, we are relying upon Mainbridge for the development of new pumps for the subcutaneous administration of Treprostini Injection. In the event of any failure of Mainbridge to successfully develop such a pump, sales of Treprostini Injection may be adversely affected.

Additionally, in December 2019, a novel strain of COVID-19 was reported to have surfaced in Wuhan, China and continues to be a global pandemic as of the date of this Annual Report on Form 10-K. The full impact of the COVID-19 pandemic is unknown and continues to evolve. South Korea, the country from which our supplier sources treprostini, Italy, the country in which Plastiape is headquartered, and China, the country in which Chengdu is located, have had significant outbreaks of this disease, which, in the case of Italy and China, led to lockdowns of all or portions of the entire country. The extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development and commercialization of our products and product candidates will depend on the severity, location and duration of the spread of the pandemic, and the actions undertaken to contain it or treat its ongoing effects.

If we are unable to establish or maintain licensing and collaboration arrangements with other pharmaceutical companies on acceptable terms, or at all, we may not be able to develop and commercialize additional product candidates using our PRINT technology.

We have collaborated, and may consider collaborating, with, among others, pharmaceutical companies to expand the applications for our PRINT technology through licensing as well as joint product development arrangements. In addition, if we are able to obtain marketing approval for our product candidates from regulatory authorities, we may enter into strategic relationships with collaborators for the commercialization of such products.

Collaboration and licensing arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish collaboration or other alternative arrangements should we so choose to enter into such arrangements. In addition, the terms of any collaboration or other arrangements that we may enter into may not be favorable to us or may restrict our ability to enter into further collaboration or other arrangements with third parties. For example, collaboration agreements may contain exclusivity arrangements which limit our ability to work with other pharmaceutical companies to expand the applications for our PRINT technology, as is the case in our collaboration agreement with GSK.

If we are unable to establish licensing and collaboration arrangements or the terms of such agreements we enter into are unfavorable to us or restrict our ability to work with other pharmaceutical companies, we may not be able to expand the applications for our PRINT technology or commercialize our products, if and when approved, and our business and prospects may be materially and adversely affected.

Our collaboration and licensing arrangements may not be successful.

Our collaboration and licensing arrangements, as well as any future collaboration and licensing arrangements that we may enter into, may not be successful. The success of our collaboration and licensing arrangements will depend heavily

on the efforts and activities of our collaborators, which are not within our control. We may, in the course of our collaboration and licensing arrangements, be subject to numerous risks, including, but not limited to, the following:

- our collaborators may have significant discretion in determining the efforts and resources that they will contribute;
- our collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing. For example, in July 2018, GSK notified us of its decision to discontinue development of the inhaled antiviral for viral exacerbations in COPD after completion of its related Phase 1 clinical trial and we do not believe that GSK is currently advancing any program under our collaboration;
- our collaborators may independently, or in conjunction with others, develop products that compete directly or indirectly with our product candidates;
- we may grant exclusive rights to our collaborators that would restrict us from collaborating with others. For example, we are currently subject to certain restrictions with regard to our ability to enter into collaboration arrangements for the development of inhaled therapeutics based upon our PRINT technology with third parties pursuant to our collaboration with GSK;
- our collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and our collaborators, which may cause a delay in or the termination of our research, development or commercialization activities;
- our collaboration and licensing arrangements may be terminated, and if terminated, may result in our need for additional capital to pursue further drug product development or commercialization. For example, our development and licensing agreement with G&W Laboratories, Inc., was mutually terminated in April 2018 and we are currently seeking the termination or amendment of our collaboration with GSK;
- our collaborators may own or co-own certain intellectual property arising from our collaboration and licensing arrangements with them, which may restrict our ability to develop or commercialize such intellectual property; and
- our collaborators may alter the strategic direction of their business or may undergo a change of control or management, which may affect the success of our collaboration arrangements with them.

Risks Related to our Intellectual Property

We may be subject to claims from third parties that our products infringe their intellectual property rights.

The pharmaceutical industry has experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay any introduction of new drug products or related technologies by, among others, establishing intellectual property rights over their drug products or technologies and aggressively enforcing these rights against potential new entrants into the market. We expect that we and other industry participants will be increasingly subject to infringement claims as the number of competitors and drug products grows.

Our commercial success depends in large part upon our ability to develop, manufacture, market and sell our drug products or product candidates without infringing on the patents or other proprietary rights of third parties. It is not always clear to industry participants, including us, what the scope of a patent covers. Due to the large number of patents in issue and patent applications filed in our industry, there is a risk that third parties will claim that our products or technologies infringe their intellectual property rights.

Claims for infringement of intellectual property which are brought against us, whether with or without merit, and which are generally uninsurable, could result in time-consuming and costly litigation, diverting our management's attention from our core business and reducing the resources available for our drug product development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and

our patent applications at risk of not being issued. We also may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Uncertainties resulting from the initiation and continuation of litigation or other proceedings could also have a material and adverse effect on our ability to compete in the market. Third parties making claims against us could obtain injunctive or other equitable relief against us, which could prevent us from further developing or commercializing our product candidates.

In particular, under the Hatch-Waxman Act, the owner of patents listed on the Orange Book and referenced by an NDA applicant may bring patent infringement suit against the NDA applicant after receipt of the NDA applicant's notice of paragraph IV certification. For example, in June 2020, United Therapeutics asserted a patent challenge directed to the Orange Book listed patents for Tyvaso by filing a complaint against us in the U.S. District Court for the District of Delaware, thereby triggering an automatic 30-month regulatory stay on final approval of the NDA for YUTREPIA. As a result of United Therapeutics' patent challenge, the FDA was prohibited from approving the NDA for YUTREPIA until the expiration of the 30-month stay. In August 2022, prior to the expiration of the 30-month stay, the Court found that the asserted claims of one of the patents, the '793 Patent, were both valid and infringed by the Company and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent. As a result of the Court's order, the FDA may not issue a final approval for the YUTREPIA NDA until the expiration of the '793 Patent unless either the Court's decision with respect to the '793 Patent is reversed on appeal or the PTAB's decision, invalidating the '793 Patent, is affirmed on appeal. Accordingly, we may be subject to significant delay and incur substantial costs in litigation before we are able to commercialize YUTREPIA, if at all.

In the event of a successful infringement claim against us, including an infringement claim filed in response to a paragraph IV certification, we may be required to pay damages, cease the development or commercialization of our drug products or product candidates, re-engineer or redevelop our drug products or product candidates or enter into royalty or licensing agreements, any of which could have a material and adverse impact on our business, financial condition and results of operations. Any effort to re-engineer or redevelop our products would require additional monies and time to be expended and may not ultimately be successful.

Infringement claims may be brought against us in the future, and we cannot assure you that we will prevail in any ensuing litigation given the complex technical issues and inherent uncertainties involved in intellectual property litigation. Our competitors may have substantially greater resources than we do and may be able to sustain the costs of such litigation more effectively than we can.

Our commercial success depends largely on our ability to protect our intellectual property.

Our commercial success depends, in large part, on our ability to obtain and maintain patent protection and trade secret protection in the United States and elsewhere in respect of our product candidates and PRINT technology. If we fail to adequately protect our intellectual property rights, our competitors may be able to erode, negate or preempt any competitive advantage we may have. To protect our competitive position, we have filed and will continue to file for patents in the United States and elsewhere in respect of our product candidates and PRINT technology. The process of identifying patentable subject matter and filing a patent application is expensive and time-consuming. We cannot assure you that we will be able to file the necessary or desirable patent applications at a reasonable cost, in a timely manner, or at all. Further, since certain patent applications are confidential until patents are issued, third parties may have filed patent applications for subject matters covered by our pending patent applications without us being aware of such applications, and our patent applications may not have priority over patent applications of others. In addition, we cannot assure you that our pending patent applications will result in patents being obtained. Once published, all patent applications and publications throughout the world, including our own, become prior art to our new patent applications and may prevent patents from being obtained or interfere with the scope of patent protection that might be obtained. The standards that patent offices in different jurisdictions use to grant patents are not always applied predictably or uniformly and may change from time to time.

Even if we have been or are able to obtain patent protection for our product candidates or PRINT technology, if the scope of such patent protection is not sufficiently broad, we may not be able to rely on such patent protection to prevent third parties from developing or commercializing product candidates or technology that may copy our product candidates or technology. The enforceability of patents in the pharmaceutical industry involves complex legal and

scientific questions and can be uncertain. Accordingly, we cannot assure you that third parties will not successfully challenge the validity, enforceability or scope of our patents. A successful challenge to our patents may lead to generic versions of our drug products being launched before the expiry of our patents or otherwise limit our ability to stop others from using or commercializing similar or identical products and technology. A successful challenge to our patents may also reduce the duration of the patent protection of our drug products or technology. In addition, we cannot assure you that we will be able to detect unauthorized use or take appropriate, adequate and timely actions to enforce our intellectual property rights. If we are unable to adequately protect our intellectual property, our business, competitive position and prospects may be materially and adversely affected.

Even if our patents or patent applications are unchallenged, they may not adequately protect our intellectual property or prevent third parties from designing around our patents or other intellectual property rights. If the patent applications we file or may file do not lead to patents being granted or if the scope of any of our patent applications is challenged, we may face difficulties in developing our product candidates, companies may be dissuaded from collaborating with us, and our ability to commercialize our product candidates may be materially and adversely affected. We are unable to predict which of our patent applications will lead to patents or assure you that any of our patents will not be found invalid or unenforceable or challenged by third parties. The patents of others may prevent the commercialization of product candidates incorporating our technology. In addition, given the amount of time required for the development, clinical testing and regulatory review of new product candidates, any patents protecting our product candidates may expire before or shortly after such product candidates might become approved for commercialization.

Moreover, the issuance of a patent is not conclusive as to the inventorship of the patented subject matter, or its scope, validity or enforceability. We cannot assure you that all of the potentially relevant prior art, that is, any evidence that an invention is already known, relating to our patents and patent applications, has been found. If such prior art exists, it may be used to invalidate a patent or may prevent a patent from being issued.

In addition, we, our collaborators or our licensees may 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. As a result, we may miss potential opportunities to seek patent protection or strengthen our patent position.

If we are unable to protect our trade secrets, the value of our PRINT technology and product candidates may be negatively impacted, which would have a material and adverse effect on our competitive position and prospects.

In addition to patent protection, we rely on trade secret protection to protect certain aspects of our intellectual property. While we require parties who have access to any portion of our trade secrets, such as our employees, consultants, advisers, CROs, CMOs, collaborators and other third parties, to enter into non-disclosure and confidentiality agreements with us, we cannot assure you that these parties will not disclose our proprietary information, including our trade secrets, in breach of their contractual obligations. Enforcing a claim that a party has illegally disclosed or misappropriated a trade secret is difficult, costly and time-consuming, and we may not be successful in doing so. If the steps we have taken to protect our trade secrets are deemed by the adjudicating court to be inadequate, we may not be able to obtain adequate recourse against a party for misappropriating our trade secrets.

Trade secrets can be difficult to protect as they may, over time, be independently discovered by our competitors or otherwise become known despite our trade secret protection. If any of our trade secrets were to be lawfully obtained or independently developed by our competitors, we would have no right to prevent such competitors, or those to whom they communicate such technology or information, from using that technology or information to compete with us. Such competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights.

If our trade secrets were to be disclosed to or independently developed by our competitors, our competitors may be able to exploit our PRINT technology to develop competing product candidates, and the value of our PRINT technology and our product candidates may be negatively impacted. This would have a material and adverse effect on our competitive position and prospects.

We rely on licenses to intellectual property that are owned by third parties.

We have entered and may, in the future, enter into license agreements with third parties to license the rights to use their technologies in our research, development and commercialization activities. License agreements generally impose various diligence, milestone payments, royalty, insurance and other obligations on us, and if we fail to comply with these obligations, our licensors may have the right to terminate these license agreements. Termination of these license agreements or the reduction or elimination of our licensed rights or the exclusivity of our licensed rights may have an adverse impact on, among others, our ability to develop and commercialize our product candidates. We cannot assure you that we will be able to negotiate new or reinstated licenses on commercially acceptable terms, or at all.

In addition, we license certain patent rights for our PRINT technology from UNC under the UNC License. Under the UNC License, UNC has the right to terminate our license if we materially breach the agreement and fail to cure such breach within the stipulated time. In the event that UNC terminates our license and we have a product that relies on that license, it may bring a claim against us, and if they are successful, we may be required to compensate UNC for the unauthorized use of their patent rights through the payment of royalties.

Also, the agreements under which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain or successfully enforce necessary or desirable patent protection from those patent rights. We do not have primary control over patent prosecution and maintenance for certain of the patents we license, and therefore cannot assure you that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We also cannot assure you that patent prosecution and maintenance activities by our licensors, if any, will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

Pursuant to the terms of some of our license agreements with third parties, some of our third-party licensors have the right, but not the obligation, in certain circumstances, to control the enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and we cannot assure you that we will receive such cooperation on commercially acceptable terms, or at all. We also cannot assure you that our licensors will allocate sufficient resources or prioritize their or our enforcement of these patents or defense of these claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position, business and prospects may be materially and adversely affected.

Further, licenses to intellectual property may not always be available to us on commercially acceptable terms, or at all. In the event that the licenses we rely on are not available to us on commercially acceptable terms, or at all, our ability to commercialize our PRINT technology or product candidates, and our business and prospects, may be materially and adversely affected.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on our PRINT technology and our product candidates throughout the world may be prohibitively expensive and may not be financially or commercially feasible. In countries where we have not obtained patent protection, our competitors may be able to use our proprietary technologies to develop competing product candidates.

Also, the legal systems of non-U.S. jurisdictions may not protect intellectual property rights to the same extent or in the same manner as the laws of the United States, and we may face significant difficulty in enforcing our intellectual property rights in these jurisdictions. The legal systems of certain developing countries may not favor the enforcement of patents and other intellectual property rights. We may therefore face difficulty in stopping the infringement or misappropriation of our patents or other intellectual property rights in those countries.

We need to protect our trademark, trade name and service mark rights to prevent competitors from taking advantage of our name recognition.

We believe that the protection of our trademark, trade name and service mark rights, such as Liquidia, the Liquidia logo, PRINT, and YUTREPIA, is an important factor in product recognition, protecting our brand, maintaining goodwill and maintaining or increasing market share. We may expend substantial cost and effort in an attempt to register new trademarks, trade names and service marks and maintain and enforce our trademark, trade name and service mark rights. If we do not adequately protect our rights in our trademarks, trade names and service marks from infringement, any name recognition that we have developed in those trademarks could be lost or impaired.

Third parties may claim that the sale or promotion of our products, when and if approved, may infringe on the trademark, trade name and service mark rights of others. Trademark, trade name and service mark infringement problems occur frequently in connection with the sale and marketing of pharmaceutical products. If we become involved in any dispute regarding our trademark, trade name and service mark rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time-consuming litigation that could harm our business. If the trademarks, trade names and service marks we use are found to infringe upon the trademarks, trade names or service marks of another company, we could be liable for damages and be forced to stop using those trademarks, trade names or service marks, and as a result, we could lose all the name recognition that has been developed in those trademarks, trade names or service marks.

Risks Related to the Manufacturing of our Product Candidates

Our product candidates are based on our proprietary, novel technology, PRINT, which has not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining final regulatory approval.

Our future success depends on the successful development of our novel PRINT technology and products based on it, including YUTREPIA. To our knowledge, no regulatory authority has granted final approval to market or commercialize drugs made using our PRINT technology. We may never receive final approval to market and commercialize any product candidate that uses our PRINT technology.

Even if we receive final approval to market YUTREPIA, we will need to scale up our manufacturing capabilities to effectively commercialize the product. We have never completed a scale up of our PRINT manufacturing process and, if we are unable to do so in an effective and timely manner, our ability to commercialize YUTREPIA, even if it receives final FDA approval, will be adversely affected.

Our operations are concentrated in Morrisville, North Carolina and interruptions affecting us or our suppliers due to natural disasters or other unforeseen events could materially and adversely affect our operations.

Most of our current operations are concentrated in Morrisville, North Carolina. In addition, our inventory is warehoused in a limited number of locations. A fire, flood, hurricane, earthquake or other disaster or unforeseen event resulting in significant damage to our facilities or to inventory held by us could significantly disrupt or curtail or require us to cease our operations. It would be difficult, costly and time-consuming to transfer resources from one facility to another, to repair or replace our facility or to replace inventory in the event that it is significantly damaged. In addition, our insurance may not be sufficient to cover all of our losses and may not continue to be available to us on acceptable terms, or at all. In addition, if one of our suppliers experiences a similar disaster or unforeseen event, we could face significant loss of our inventory and significant delays in obtaining our supplies or be required to source supplies from an alternative supplier and may incur substantial costs as a result. Any significant uninsured loss, prolonged or repeated disruption to operations or inability to operate, experienced by us or by our suppliers, could materially and adversely affect our business, financial condition and results of operations.

Risks Related to our Employees

We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel.

Our ability to continue our operations and manage our potential future growth depends on our ability to hire and retain suitably skilled and qualified employees, including those in senior management, in the long-term. Due to the specialized nature of our work, there is a limited supply of suitable candidates. We compete with other biotechnology and pharmaceutical companies, educational and research institutions and government entities, among others, for research, technical, clinical and sales and marketing personnel. In addition, in order to manage our potential future growth effectively, we will need to improve our financial controls and systems and, as necessary, recruit sales, marketing, managerial and finance personnel. The loss of the services of members of our sales team could seriously harm our ability to successfully implement our business strategy. If we are unable to attract and retain skilled personnel, including in particular Roger Jeffs, our Chief Executive Officer, our business and prospects may be materially and adversely affected.

Risks Related to our Common Stock

Future sales of our common stock or securities convertible into our common stock in the public market could cause our stock price to fall.

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of March 2, 2023, 64,688,314 shares of our common stock were outstanding, of which 54,806,967 shares of common stock, or 84.7% of our outstanding shares as of March 2, 2023, are freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our “affiliates,” as that term is defined in Rule 144 under the Securities Act (“Rule 144”). The resale of the remaining 9,881,347 shares held by our stockholders as of March 2, 2023 is currently prohibited or otherwise restricted as a result of securities law provisions. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

As of March 2, 2023, the holders of 1,887,937 shares, or 2.9%, of our outstanding shares as of March 2, 2023, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, including the employee stock purchase plan. Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market upon issuance or resale (as applicable), subject to lock-up agreements, if any.

We expect that the market price of our common stock may be volatile, and you may lose all or part of your investment.

The trading prices of the securities of pharmaceutical and biotechnology companies have been highly volatile. As such, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The market price for our common stock may be influenced by many factors, including:

- results of any clinical trials of any product candidate we may develop, or those of our competitors;
- the success of Sandoz’s generic version of Remodulin to which we have commercial rights to pursuant to the Promotion Agreement;

- the success of Chengdu’s launch of the RG Cartridge and the market acceptance of the RG Cartridge for the subcutaneous administration of Treprostinil Injection;
- whether Mainbridge is able to complete the development of a new pump for the subcutaneous administration of Treprostinil Injection and obtain FDA clearance on a timely basis or at all;
- our cash resources;
- the approvals or success of competitive products or technologies;
- potential approvals of any product candidate we may develop, including YUTREPIA, for marketing by the FDA or equivalent foreign regulatory authorities or any failure to obtain such approvals;
- our involvement in significant lawsuits, including stockholder or patent litigation, including *inter partes* review proceedings and Hatch-Waxman litigation with originator companies or others which may hold patents, including the ongoing appeals in connection with the patents that United Therapeutics has asserted against us;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize any product candidate we may develop, including YUTREPIA in the event we receive final approval from the FDA;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts’ reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

The stock market in general, and market prices for the securities of pharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In several recent situations when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned 36.2% of our capital stock as of March 2, 2023. Accordingly, our executive officers, directors and principal stockholders have significant influence in determining the composition of our board of directors (the “Board”), and voting on all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us that you may believe are in your best interests as one of our stockholders. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the Board or management.

As a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to do so may adversely affect investor confidence in us and, as a result, the trading price of our shares.

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. Inferior 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 common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”) or the 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 consolidated financial statements or identify other areas for further attention or improvement.

As required by the Sarbanes Oxley Act and commencing with the fiscal year ended December 31, 2019, we were required to furnish a report by management on, among other things, the effectiveness of our ICFR. See Item 4. Controls and Procedures for additional information.

We are an “emerging growth company,” as defined in the JOBS Act, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more, (ii) the last day of 2023, (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and adversely affect our stock price.

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws:

- permit the Board to issue up to 10 million shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our Board;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- create a staggered board of directors such that all members of our Board are not elected at one time;

- allow for the issuance of authorized but unissued shares of our capital stock without any further vote or action by our stockholders; and
- establish advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon at stockholders' meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL") which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any stockholder owning in excess of 15% of our outstanding stock for a period of three years following the date on which the stockholder obtained such 15% equity interest in us.

The terms of our authorized preferred stock selected by our Board at any point could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and powers, including voting rights, of holders of our common stock without any further vote or action by the stockholders. As a result, the rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued by us in the future, which could have the effect of decreasing the market price of our common stock.

Any provision of our certificate of incorporation or bylaws or Delaware corporate law that has the effect of delaying or deterring a change in control could limit opportunities for our stockholders to receive a premium for their shares of common stock, and could also affect the price that investors are willing to pay for our common stock.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; or (d) any action asserting a claim against us governed by the internal affairs doctrine; *provided*, that, this provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or Exchange Act. Furthermore, our bylaws designate the federal district courts of the United States as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors or officers. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, prospects or results of operations.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our equity securities. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our existing RIFA with HCR preclude us, and the terms of any future debt or financing agreement may preclude us, from paying dividends. As a result, capital appreciation, if any, of our equity securities will likely be your sole source of gain for the foreseeable future.

An impairment of our long-lived contract acquisition costs and intangible assets, including goodwill, could have a material non-cash adverse impact on our results of operations.

In connection with the accounting for our RareGen acquisition, we have recorded significant amounts of contract acquisition costs, intangible assets, and goodwill. Under GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill has been impaired. Contract acquisition costs and amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. The valuation of goodwill depends on a variety of factors, the success of the Company's business, including our ability to obtain regulatory approval for YUTREPIA, global market and economic conditions, earnings growth and expected cash flows. Impairments may be caused by factors outside the Company's control, such as actions by the FDA, increasing competitive pricing pressures, and various other factors. Significant and unanticipated changes or our inability to obtain or maintain regulatory approvals for our product candidates, including the NDA for YUTREPIA, could require a non-cash charge for impairment in a future period, which may significantly affect the Company's results of operations in the period of such charge.

General Risk Factors

General Risks Related to the Commercialization of our Product Candidates

Our business and operations may be adversely affected by the effects of health epidemics, including the continued spread of the COVID-19 global pandemic.

Our business and operations could be adversely affected by health epidemics in regions where we have offices, manufacturing facilities, concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of clinical trial sites, contract manufacturers or suppliers and contract research organizations upon whom we rely. For example, starting in December 2019, a novel strain of the coronavirus ("COVID-19") was reported to have surfaced in Wuhan, China and spread to multiple countries, including the U.S. and several European countries. In March 2020, the World Health Organization declared COVID-19 a global pandemic and the U.S. declared the COVID-19 pandemic a national emergency. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the United States that, among other things, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel. Throughout 2020 and 2021, similar executive orders were issued by state and local governments, and states of emergency had been declared at the state and local level in most jurisdictions throughout the U.S. As recently as April 2022, ports and airports in Shanghai, China have been closed due to another outbreak of COVID-19, resulting in a lockdown of the city and disruption to export and import activities. In the U.S., many of these executive orders have been rescinded, however, we remain vigilant and continue to monitor the ongoing COVID-19 pandemic closely to determine if additional actions are required.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and our research and development activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements may result in control deficiencies in the preparation of our financial reports, which could be material.

Such orders may also impact the availability or cost of materials, which would disrupt our supply chain and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this Annual Report on Form 10-K, such as the ultimate geographic spread of the disease, the severity and duration of future outbreaks (including from the spread of COVID-19 variants or mutant strains), the duration and effect of business disruptions and the short-term effects, the administration, availability and efficacy of vaccination programs and the ultimate effectiveness of travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. We expect the impact of COVID-19 on the FDA's operations will continue to evolve. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section and the "Risk Factors" sections of the documents incorporated by reference herein.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, an ongoing military conflict between Russia and Ukraine, and record inflation. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine, geopolitical tensions, or record inflation.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, a full-scale military invasion of Ukraine by Russian troops began. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has contributed to record inflation globally. We are continuing to monitor inflation, the situation in Ukraine and global capital markets and assessing its potential impact on our business.

Although, to date, our business has not been materially impacted by the ongoing military conflict between Russian and Ukraine, geopolitical tensions, or record inflation, we do expect that such matters will affect our business and it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such matters may impact our business. We anticipate that increases in compensation to our employees and costs paid to vendors may similarly be greater than in past periods due to ongoing inflation. The extent and duration of the conflict in Ukraine, geopolitical tensions, record inflation and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also magnify the impact of other risks described herein.

The marketing approval processes of the FDA and comparable regulatory authorities in other countries are unpredictable and our product candidates may be subject to multiple rounds of review or may not receive marketing approval.

Pursuing marketing approval for a pharmaceutical product candidate (for example, through the NDA process) is an extensive, lengthy, expensive and inherently uncertain process. We cannot assure you that any of our product candidates will receive marketing approval. Regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including, but not limited to, the following:

- the FDA or comparable regulatory authorities may, for a variety of reasons, take the view that the data collected from our preclinical and clinical trials and human factors testing, or data that we otherwise submit or reference to support an application, are not sufficient to support approval of a product candidate;
- the FDA or comparable regulatory authorities in other countries may ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers do not sufficiently demonstrate compliance with current good manufacturing practices (cGMP) to support approval of a product candidate; or

that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable regulatory authorities in other countries that our product candidate is safe and effective for its proposed indication, or that its clinical and other benefits outweigh its safety risks;
- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval.

Even if we obtain marketing approval, the FDA or comparable regulatory authorities in other countries may approve our product candidates for fewer or more limited indications than those for which we requested approval or may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates. Likewise, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or other studies or the conduct of an expensive REMS, which could significantly reduce the potential for commercial success or viability of our product candidates. We also may not be able to find acceptable collaborators to manufacture our drug products, if and when approved, in commercial quantities and at acceptable prices, or at all.

If the FDA or comparable regulatory authorities in other countries approve generic versions of our product candidates, or do not grant our product candidates a sufficient period of market exclusivity before approving their generic versions, our ability to generate revenue may be adversely affected.

Once an NDA is approved, the drug product covered will be listed as a reference listed drug in the FDA's Orange Book. In the United States, manufacturers of drug products may seek approval of generic versions of reference listed drugs through the submission of abbreviated new drug applications (ANDAs). In support of an ANDA, a generic manufacturer is generally required to show that its product has the same active pharmaceutical ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug. Generic drug products may be significantly less expensive to bring to market than the reference listed drug, and companies that produce generic drug products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug product, a significant percentage of the sales of any reference listed drug may be lost to the generic drug product.

The FDA will not approve an ANDA for a generic drug product until the applicable period of market exclusivity for the reference listed drug has expired. The applicable period of market exclusivity varies depending on the type of exclusivity granted. A grant of market exclusivity is separate from the existence of patent protection and manufacturers may seek to launch generic versions of our drug products following the expiry of their respective marketing exclusivity periods, even if our drug products are still under patent protection at the relevant time.

Any competition that our product candidates may face, if and when such product candidates are approved for marketing and commercialized, from generic versions could substantially limit our ability to realize a return on our investment in the development of our product candidates and have a material and adverse effect on our business and prospects.

General Risks Related to the Development and Regulatory Approval of our Product Candidates

Even if we obtain marketing approval for our product candidates in the United States, we or our collaborators may not obtain marketing approval for the same product candidates elsewhere.

We may enter into strategic collaboration arrangements with third parties to commercialize our product candidates outside of the United States. In order to market any product candidate outside of the United States, we or our collaborators will be required to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be recognized or accepted by regulatory authorities in other countries, and obtaining marketing approval in one country does not mean that marketing approval will be obtained in any other country. Approval processes vary among countries and additional product testing and validation, or additional administrative review periods, may be required from one country to the next.

Seeking marketing approval in countries other than the United States could be costly and time-consuming, especially if additional preclinical studies or clinical trials are required to be conducted. We currently do not have any product candidates approved for sale in any jurisdiction, including non-U.S. markets, and we do not have experience in obtaining marketing approval in non-U.S. markets. We currently also have not identified any collaborators to market our products outside of the United States and cannot assure you that such collaborators, even if identified, will be able to successfully obtain marketing approval for our product candidates outside of the United States. If we or our collaborators fail to obtain marketing approval in non-U.S. markets, or if such approval is delayed, our target market may be reduced, and our ability to realize the full market potential of our products will be adversely affected.

General Risks Related to Healthcare Regulation

The pharmaceutical industry is subject to a range of laws and regulations in areas including healthcare program requirements and fraud, waste, and abuse; healthcare and related marketing compliance and transparency; and privacy and data security. Our failure to comply with these laws and regulations as they are, or in the future become, applicable to us may have an adverse effect on our business.

Healthcare providers, physicians and third-party payors often play a primary role in the recommendation and prescription of any drug products for which we may obtain marketing approval, or for which we may provide contracted promotional services to third parties. Our current and future arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell, or distribute drug products.

In addition, we may be subject to transparency laws and patient privacy regulation by both the federal government and the states in which we conduct our business.

The laws that may affect our ability to operate include, but are not limited to, the following examples:

- The federal Anti-Kickback Statute (AKS) prohibits, among other things, persons and entities including pharmaceutical manufacturers from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, 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, or order of, or the arranging for an item or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs.
- The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act (FCA) prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Claims resulting from a violation of the federal AKS constitute a false or fraudulent claim for purposes of the federal False Claims Act. Promotion that is deemed to be “off label” can be the basis of FCA exposure.
- Federal law includes provisions (established under the Health Insurance Portability and Accountability Act of 1996) addressing healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Violations of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs.

- Privacy and data security laws may apply to our business. Under the Federal Trade Commission Act (the FTCA) Section 5(a), the FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements, for example the California Consumer Privacy Act (CCPA) created data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information.
- The federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act,” requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under government healthcare programs to annually report to the Centers for Medicare and Medicaid Services (CMS) information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Payments and transfers of value made to certain other providers such as nurse practitioners and physician assistants will also need to be reported under the Sunshine Act.
- For both investigational and commercialized products, interactions with or communications directed to healthcare professionals (HCPs), patients or patient- or disease-advocates or advocacy groups, and payors, are subject to heightened scrutiny by the FDA. Relative to nonpromotional communications, for example, there are specific and limited FDA accommodations for nonpromotional, truthful and non-misleading sharing of information regarding products in development and off-label uses including dissemination of peer-reviewed reprints, support of independent continuing medical education (CME), and healthcare economic discussions with payors. In a competitive environment, a company’s communications about products in development may also be subject to heightened scrutiny.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases may apply regardless of payor (i.e., even for self-pay scenarios). Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives. Many of these state laws differ from each other in significant ways and may not have the same effect, and may apply more broadly or be stricter than their federal counterparts, thus complicating compliance efforts; and
- Price reporting laws require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursements or discounts on our drug products. Participation in such programs and compliance with their requirements may subject us to increased infrastructure costs and potentially limit our ability to price our drug products.

Ensuring that our business and business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert management’s attention from the business, even if the government ultimately finds that no violation has occurred.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws or government regulations that apply to us, we may be subject to penalties and potentially, the curtailment or restructuring of our operations as well as additional governmental reporting obligations and oversight, any of which could adversely affect our ability to operate our business and our results of operations.

General Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials.

We currently rely on, and plan to continue to rely on, third-party contract research organizations (CROs) to monitor and manage data for our preclinical studies and clinical trials. However, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable regulatory standards and our reliance on CROs does not relieve us of our regulatory responsibilities.

The CROs on which we rely are required to comply with FDA regulations (and the regulations of comparable regulatory authorities in other countries) regarding GCP. Regulatory authorities enforce GCP standards through periodic inspections. If any of the CROs on which we rely fail to comply with the applicable GCP standards, the clinical data generated in our clinical trials may be deemed unreliable. While we have contractual agreements with these CROs, we have limited influence over their actual performance and cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical trials. A failure to comply with the applicable regulations in the conduct of the preclinical studies and clinical trials for our product candidates may require us to repeat such studies or trials, which would delay the process of obtaining marketing approval for our product candidates and have a material and adverse effect on our business and prospects.

Some of our CROs have the ability to terminate their respective agreements with us if, among others, it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination. If any of our agreements with our CROs is terminated, and if we are not able to enter into agreements with alternative CROs on acceptable terms or in a timely manner, or at all, the clinical development of our product candidates may be delayed and our development expenses could be increased.

General Risks Related to Legal Compliance Matters

Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, drug supply chain security surveillance and tracking, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and comparable requirements outside of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we may receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. We will also be required to report certain adverse reactions and production problems, if any, to the FDA or other regulatory agencies and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA or other regulatory agency approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a clinical study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or disagrees with the

promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us or our strategic partners;
- restrict the marketing or manufacturing of our products;
- seize or detain products, or require a product recall;
- refuse to permit the import or export of our product candidates; or
- refuse to allow us to enter into government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Environmental, social and governance matters may impact our business and reputation.

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to environmental, social and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While we strive to improve our ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations.

General Risks Related to our Intellectual Property

We may become involved in litigation to protect our intellectual property or enforce our intellectual property rights, which could be expensive, time-consuming and may not be successful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, we may engage in litigation to, among others, enforce or defend our intellectual property rights, determine the validity or scope of our intellectual property rights and those of third parties, and protect our trade secrets. Such actions may be time-consuming and costly and may divert our management's attention from our

core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome.

In addition, in an infringement proceeding, a court may decide that a patent owned by, or licensed to, us is invalid or unenforceable, or may refuse to stop the other party from using the technology in question on the ground that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information may be compromised by disclosure.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent, and the protection it affords, is limited. 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.

We intend to seek extensions of patent terms in the United States and, if available, in other countries where we prosecute patents. In the United States, the Hatch-Waxman Act permits patent owners to request a patent term extension, based on the regulatory review period for a product, of up to five years beyond the normal expiration of the patent, which is limited to one patent claiming the approved drug product or use in an indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO, in the United States, and comparable regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or grant more limited extensions than we had requested. In such event, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our preclinical and clinical data in their marketing approval applications with the FDA to launch their drug product earlier than might otherwise be the case.

General Risks Related to the Manufacturing of our Product Candidates

Our facilities are subject to extensive and ongoing regulatory requirements and failure to comply with these regulations may result in significant liability.

Our company and our facilities are subject to payment of fees, registration and listing requirements, ongoing review and periodic inspections by the FDA and other regulatory authorities for compliance with quality system regulations, including the FDA's cGMP requirements. These regulations cover all aspects of the manufacturing, testing, quality control and record-keeping of our drug products. Furthermore, the facilities where our product candidates are manufactured may be subject to additional inspections by the FDA before we can obtain final marketing approval and remain subject to periodic inspection even after our product candidates have received marketing approval. Suppliers of components and materials, such as active pharmaceutical ingredients, used to manufacture our drug products are also required to comply with the applicable regulatory standards.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and any contract manufacturers that we may engage in the future must comply with cGMP requirements. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination controls. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Compliance with these regulatory standards often requires significant expense and effort. If we or our suppliers are unable to comply with the applicable regulatory standards or take satisfactory corrective steps in response to adverse results of an inspection, this could result in enforcement action, including, among others, the issue of a public warning letter, a shutdown of or restrictions on our or our suppliers' manufacturing operations, delays in approving our drug products and refusal to permit the import or export of our drug products. Any adverse regulatory action taken against us could subject us to significant liability and harm our business and prospects.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters is located in Morrisville, North Carolina, and consist of approximately 45,000 square feet of space under a lease that expires on October 31, 2026 and includes an option for us to renew for an additional five years through October 31, 2031, as amended. The primary use of this location is general office, laboratory, research and development and light manufacturing. We believe that our facilities are adequate for our current needs, however, we will continue to seek additional space as needed to accommodate our growth.

Item 3. Legal Proceedings.

YUTREPIA-Related Litigation

In June 2020, United Therapeutics filed a complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA) (the "Hatch-Waxman Litigation"), asserting infringement by the Company of U.S. Patent Nos. 9,604,901, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®" (the "'901 Patent"), and 9,593,066, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®" (the "'066 Patent"), relating to United Therapeutics' Tyvaso®, a nebulized treprostinil solution for the treatment of PAH. United Therapeutics' complaint was in response to the Company's NDA for YUTREPIA, filed with the FDA, requesting approval to market YUTREPIA, a dry powder inhalation of treprostinil for the treatment of PAH. The YUTREPIA NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso® as the reference listed drug.

In July 2020, the U.S. Patent and Trademark Office (the "USPTO") issued U.S. Patent No. 10,716,793 (the "'793 Patent"), entitled "Treprostinil Administration by Inhalation", to United Therapeutics. In July 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the '793 Patent by the practice of YUTREPIA.

In June 2021, the Court held a claim construction hearing. Based on the Court's construction of the claim terms, United Therapeutics filed a stipulation of partial judgment with respect to the '901 Patent in December 2021 under which United Therapeutics agreed to the entry of judgment of the Company's non-infringement of the '901 Patent. United Therapeutics preserved its appellate rights with respect to the '901 Patent in the event the Court's construction of those terms is reversed.

Trial proceedings in the Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the '066 Patent were invalid, that the remaining asserted claims of the '066 Patent were not infringed by the Company, and that all of the asserted claims of the '793 Patent were both valid and infringed by the Company, based on the arguments presented by the Company in the Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent, which will be in 2027. Both the Company and United Therapeutics have appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In September 2022, following entry of final judgment, the Company filed a motion requesting that Judge Andrews stay enforcement of the order delaying the effective date of any final approval by the FDA of YUTREPIA until the expiration of the '793 Patent. Briefing on the motion for stay of enforcement is complete, and the motion remains pending with the Court.

In March 2020, the Company filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (the "PTAB") of the USPTO. One petition was for *inter partes* review of the '901 Patent, and sought a determination that the claims in the '901 Patent are invalid, and a second petition was for *inter partes* review of the '066 Patent, and sought a determination that the claims in the '066 Patent are invalid. In October 2020, the PTAB instituted an *inter partes* review of the '901 Patent and concurrently denied institution on the '066 Patent, stating that the '066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '901 Patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the '901 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In January 2021, the Company filed a petition for *inter partes* review with the PTAB relating to the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. In August 2021, the PTAB instituted an *inter partes* review of the '793 Patent, finding that the Company had demonstrated a reasonable likelihood that it would prevail with respect to showing that at least one challenged claim of the '793 patent is unpatentable as obvious over the combination of certain prior art cited by the Company in its petition to the PTAB. In July 2022, the PTAB ruled in the Company's favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '793 Patent. The rehearing request was denied in February 2023. United Therapeutics has publicly stated that it will appeal the PTAB's decision with respect to the '793 Patent. The PTAB's decision with respect to the '793 Patent will not override Judge Andrews' order in the Hatch-Waxman Litigation that YUTREPIA may not be approved due to infringement of the '793 Patent unless and until the decision of the PTAB is affirmed on appeal.

Trade Secret Litigation

In December 2021, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, alleging that the Company and a former United Therapeutics employee, who later joined the Company as an employee many years after terminating his employment with United Therapeutics, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2022, the Company's co-defendant in the lawsuit removed the lawsuit to the United States District Court for the Middle District of North Carolina. Subsequently, in January 2022, United Therapeutics filed an amended complaint eliminating their claim under the federal Defend Trade Secrets Act and a motion seeking to have the case remanded to North Carolina state court. In April 2022, the Court granted United Therapeutics' motion to have the case remanded to North Carolina state court. In May 2022, the Company filed a motion to dismiss all of the claims made by United Therapeutics in the lawsuit. The motion was denied by the Court in October 2022. Discovery in the case is ongoing.

RareGen Litigation

In April 2019, Sandoz and Liquidia PAH (then known as RareGen) filed a complaint against United Therapeutics and Smiths Medical in the District Court of New Jersey (Case No. No. 3:19-cv-10170), (the "RareGen Litigation"), alleging that United Therapeutics and Smiths Medical violated the Sherman Antitrust Act of 1890, state law antitrust statutes and unfair competition statutes by engaging in anticompetitive acts regarding the drug treprostinil for the treatment of PAH. In March 2020, Sandoz and Liquidia PAH filed a first amended complaint adding a claim that United Therapeutics breached a settlement agreement that was entered into in 2015, in which United Therapeutics agreed to not interfere with Sandoz's efforts to launch its generic treprostinil, by taking calculated steps to restrict and interfere with the launch of Sandoz's competing generic product. United Therapeutics developed treprostinil under the brand name Remodulin® and Smiths Medical manufactured a pump and cartridges that are used to inject treprostinil into patients continuously

throughout the day. Sandoz and Liquidia PAH allege that United Therapeutics and Smiths Medical entered into anticompetitive agreements (i) whereby Smiths Medical placed restrictions on the cartridges such that they can only be used with United Therapeutics' branded Remodulin® product and (ii) requiring Smiths Medical to enter into agreements with specialty pharmacies to sell the cartridges only for use with Remodulin®.

In November 2020, Sandoz and Liquidia PAH entered into a binding term sheet (the "Term Sheet") with Smiths Medical in order to resolve the outstanding RareGen Litigation solely with respect to disputes between Smiths Medical, Liquidia PAH and Sandoz. In April 2021, Liquidia PAH and Sandoz entered into a Long Form Settlement Agreement (the "Settlement Agreement") with Smiths Medical to further detail the terms of the settlement among such parties as reflected in the Term Sheet. Pursuant to the Term Sheet and the Settlement Agreement, the former RareGen members and Sandoz received a payment of \$4.25 million that was evenly split between the parties. In addition, pursuant to the Term Sheet and Settlement Agreement, Smiths Medical disclosed and made available to Sandoz and Liquidia PAH certain specifications and other information related to the cartridge that Smiths Medical developed and manufactures for use with the CADD-MS 3 infusion pump (the "CADD-MS 3 Cartridge"). Pursuant to the Settlement Agreement, Smiths Medical also granted Liquidia PAH and Sandoz a non-exclusive, royalty-free license in the United States to Smiths Medical's patents and copyrights associated with the CADD-MS 3 Cartridge and certain other information for use of the CADD-MS 3 pump and the CADD-MS 3 Cartridges. Smiths also agreed in the Settlement Agreement to provide information and assistance in support of Liquidia PAH's efforts to receive FDA clearance for the RG Cartridge and to continue to service certain CADD-MS 3 pumps that are available for use with the Treprostinil Injection through January 1, 2025. Liquidia PAH and Sandoz agreed, among other things, to indemnify Smiths from certain liabilities related to the RG Cartridge.

In September 2021, United Therapeutics filed a motion for summary judgment with respect to all of the claims brought by Sandoz and Liquidia PAH against United Therapeutics. At the same time, Sandoz filed a motion for summary judgment with respect to the breach of contract claim. In March 2022, the Court issued an order granting partial summary judgment to United Therapeutics with respect to the antitrust and unfair competition claims, denying summary judgment to United Therapeutics with respect to the breach of contract claim, and granting partial summary judgment to Sandoz with respect to the breach of contract claim. The RareGen Litigation will now proceed to a trial to determine the amount of damages due from United Therapeutics to Sandoz with respect to the breach of contract claim. The Court has ordered that a three-day bench trial will be scheduled for summer of 2023.

Under the Promotion Agreement, all proceeds from the litigation will be divided evenly between Sandoz and Liquidia PAH. Under the litigation finance agreements that Liquidia PAH has entered into with Henderson and PBM, any net proceeds received by Liquidia PAH with respect to the RareGen Litigation will be divided between Henderson and PBM.

We may become subject to additional legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, except as disclosed herein, there are currently no claims that would have a material adverse effect on our financial position, results of operations or cash flows.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on the Nasdaq Capital Market under the symbol “LQDA” since November 19, 2020. Between July 26, 2018 and November 18, 2020, the common stock of Liquidia Technologies, our wholly owned subsidiary and predecessor-in-interest for SEC reporting purposes, was listed on the Nasdaq Capital Market under the symbol “LQDA.” Prior to July 26, 2018, there was no established public trading market for our common stock.

Holder

As of March 2, 2023, there were 62 record holders of our common stock, based upon information received from our transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. We estimate that there are more than 1,000 beneficial owners of our common stock.

Dividend Policy

We have never paid any cash dividends on our capital stock. We anticipate that we will retain earnings, if any, to support operations and to finance the growth and development of our business. In addition, the terms of our RIFA with HCR precludes us from paying cash dividends, except in certain prescribed circumstances, without the prior written consent of HCR. Therefore, we do not expect to pay cash dividends for the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding equity compensation plans is set forth in Item 12 of this Annual Report on Form 10-K and is incorporated herein by reference.

Stock Performance Graph

Not applicable.

Sale of Unregistered Securities

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our securities during the year ended December 31, 2022.

Item 6. [Reserved].

Item 7. 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 financial statements and related notes appearing in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Objective

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the two-year period ended December 31, 2022 and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition, results of operations, and cash flows. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2022, as compared to the year ended December 31, 2021. This discussion should be read in conjunction with our consolidated financial statements for the two-year period ended the year ended December 31, 2022 and related notes included elsewhere in this Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension (PH). We operate as a single entity through our two wholly owned operating subsidiaries, Liquidia Technologies and Liquidia PAH.

We currently generate revenue pursuant to a Promotion Agreement between Liquidia PAH and Sandoz Inc. ("Sandoz") sharing profit derived from the sale of the first-to-file fully substitutable generic treprostinil injection ("Treprostinil Injection") in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. We employ a targeted sales force calling on physicians and hospital pharmacies in the treatment of pulmonary arterial hypertension (PAH), as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient base to expand from for the launch of YUTREPIA upon approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.

We conduct research, development, and manufacturing of novel products by applying our subject matter expertise in cardiopulmonary diseases and our proprietary PRINT® technology, a particle engineering platform which enables precise production of uniform drug particles designed to improve the safety, efficacy, and performance of a wide range of therapies. Through development of our own products and research with third parties, we have developed expertise in applying PRINT across multiple routes of administration and drug payloads including inhaled therapies, vaccines, biologics, nucleic acids and ophthalmic implants, among others.

Our lead product candidate is YUTREPIA for the treatment of PAH. YUTREPIA is an inhaled dry powder formulation of treprostinil designed with PRINT to improve the therapeutic profile of treprostinil by enhancing deep lung delivery while using a convenient, low resistance dry-powder inhaler ("DPI") and by achieving higher dose levels than current inhaled therapies. The United States Food and Drug Administration (FDA) tentatively approved our New Drug Application (NDA) for YUTREPIA for the treatment of PAH in November 2021. The FDA also confirmed that the clinical data in the NDA would support our pursuit of a supplemental NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity for the nebulized form of treprostinil in March 2024.

Since our inception, we have incurred significant operating losses. Our net loss was \$41.0 million and \$34.5 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of \$350.6 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and prepare for commercialization of any approved product candidates. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates.

Recent Events

Revenue Interest Financing Agreement

On January 9, 2023, we entered into a Revenue Interest Financing Agreement (the “RIFA”) with HealthCare Royalty Partners IV, L.P. (“HCR”) and HealthCare Royalty Management, LLC. Pursuant to the RIFA and subject to customary closing conditions, HCR has agreed to pay us an aggregate investment amount of up to \$100.0 million (the “Investment Amount”). Under the terms of the RIFA, \$32.5 million of the Investment Amount was funded on January 27, 2023 (the “Initial Investment Amount”), \$22.4 million of which was used to satisfy in full and retire our indebtedness under the Amended and Restated Loan and Security Agreement with Silicon Valley Bank (“SVB”) and SVB Innovation Credit Fund VIII, L.P. (“Innovation”) (the “A&R SVB LSA”), with the excess proceeds funded to the Company. See Note 16 to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for information regarding repayment.

Device Development and Supply Agreement with Mainbridge and Sandoz

On December 1, 2022, we entered into a Device Development and Supply Agreement (the “Pump Development Agreement”) with Mainbridge Health Partners, LLC (“Mainbridge”) and Sandoz Inc. (“Sandoz”). The Pump Development Agreement provides for the cooperation between us, Sandoz and Mainbridge to develop a new pump that is suitable for the subcutaneous administration of Treprostinil Injection. Mainbridge will perform all development, validation and testing activities required for the pump and related consumables in anticipation of submitting a 510(k) clearance application for the pump to the FDA in 2023. In connection with the Pump Development Agreement, we and Sandoz have agreed to pay Mainbridge certain future contingent milestone payments in accordance with the terms and conditions set forth therein.

Fourth Amendment to the Sandoz Promotion Agreement

On March 10, 2023, we entered into a Fourth Amendment to the Sandoz Promotion Agreement, which provides for, among other things, (i) an agreement between us and Sandoz to enter into an agreement with a third party for the repair and servicing of CADD-MS 3 pumps (the “New Agreement”), (ii) an agreement to split all payments due under the New Agreement evenly between us and Sandoz, and (iii) to clarify certain terms and conditions related to the profit sharing between us and Sandoz under the Promotion Agreement.

Components of Statements of Operations

Revenue

We primarily generate revenue pursuant to the Promotion Agreement, under which we receive a 50% share in the profit derived from the sale of Treprostinil Injection in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. On May 21, 2021, Liquidia PAH’s manufacturing partner, Chengdu Shifeng Medical Technologies LTD (“Chengdu”) began selling the RG Cartridge, which may be used to supply medications to PAH patients with the CADD-MS 3 pump manufactured by Smiths Medical ASD, Inc. We recently became aware of shortages of critical components of the CADD-MS 3 pump that have caused the number of CADD-MS 3 infusion pumps available for the subcutaneous administration of Treprostinil Injection to be limited. Due to this limitation in the availability of pumps, specialty pharmacies are not currently placing new patients on to subcutaneous Treprostinil Injection therapy in order to preserve the available pumps for those patients already receiving subcutaneous administration of Treprostinil Injection. As a result of these shortages, future revenue may be impacted until new components or alternative pumps are available. See Recent Events for more information.

Cost of Revenue

Cost of revenue consists of (i) the cost of employing a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of PAH, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection and (ii) a portion of the amortization of the intangible asset associated with the Promotion

Agreement. We amortize the intangible asset associated with the Promotion Agreement in a manner consistent with our recognition of the related revenue.

Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing process development and scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation for personnel in research and development functions;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for utilities and other facility-related costs.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. In the near term we expect that our research and development expenses to increase as we complete manufacturing activities and explore potential clinical trials. However, levels of research and development spending are highly dependent upon the selection and progression of product candidates. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate

could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, or our ability to manufacture and supply product, we could be required to expend significant additional financial resources and time on the completion of clinical development. Drug commercialization will take several years and millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation. Other general and administrative expenses include facility-related costs, patent filing and prosecution costs and professional fees for marketing, legal, auditing and tax services and insurance costs.

Other Income (Expense)

Other income (expense) is comprised of interest income and expense and loss on extinguishment of debt. Interest income consists of interest earned on our cash deposits. Interest expense consists of interest charges on finance leases and debt. These charges include monthly recurring interest on such obligations in addition to non-cash charges. Non-cash charges include interest accretion, expensing of debt issuance costs and amortization of discounts on long-term debt to interest expense.

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations:

	Year Ended December 31,		\$ Change	% Change
	2022	2021		
Revenue	\$ 15,935	\$ 12,853	\$ 3,082	24 %
Costs and expenses:				
Cost of revenue	2,859	3,023	(164)	(5)%
Research and development	19,435	20,517	(1,082)	(5)%
General and administrative	32,411	23,110	9,301	40 %
Total costs and expenses	54,705	46,650	8,055	17 %
Loss from operations	(38,770)	(33,797)	(4,973)	15 %
Other income (expense):				
Interest income	1,090	33	1,057	3,203 %
Interest expense	(2,338)	(762)	(1,576)	207 %
Loss on extinguishment of debt	(997)	(53)	(944)	1,781 %
Total other expense, net	(2,245)	(782)	(1,463)	187 %
Net loss and comprehensive loss	\$ (41,015)	\$ (34,579)	\$ (6,436)	19 %

Revenue

Revenue was \$15.9 million for the year ended December 31, 2022, compared with \$12.9 million for the year ended December 31, 2021. During the year ended December 31, 2022, the profit split percentage we received under the Promotion Agreement was 50%, whereas during the year ended December 31, 2021 the profit split percentage decreased from 80% to 50% as a result of achievement of predetermined cumulative sales thresholds. This decrease in profit split percentage was offset by an increase in the number of units sold.

Cost of Revenue

Cost of revenue was \$2.9 million for the year ended December 31, 2022, compared with \$3.0 million for the year ended December 31, 2021. Cost of revenue related to the Promotion Agreement as noted above.

Research and Development Expenses

Research and development expenses were \$19.4 million for the year ended December 31, 2022 compared with \$20.5 million for the year ended December 31, 2021. The decrease of \$1.1 million or 5% was primarily due to a \$0.9 million decrease in personnel, consulting, and stock-based compensation expenses. During the year ended December 31, 2022 ended, we incurred \$7.0 million related to YUTREPIA compared to \$6.7 million during the year ended December 31, 2021.

General and Administrative Expenses

General and administrative expenses were \$32.4 million for the year ended December 31, 2022, compared with \$23.1 million for the year ended December 31, 2021. The increase of \$9.3 million or 40% was primarily due to a \$4.2 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA and a \$3.1 million increase in stock-based compensation expense driven by an option modification charge recorded in March 2022.

Other Income (Expense)

Total other expense, net was \$2.2 million for the year ended December 31, 2022, compared with \$0.8 million for the year ended December 31, 2021. The increase of \$1.4 million was primarily due to a \$1.0 million loss on extinguishment of debt related to the refinance of our long-term debt during January 2022 and a \$1.6 million increase in interest expense due to a higher debt balance and higher interest rate on our debt from the A&R SVB LSA, offset by a \$1.1 million increase in interest income from higher cash and cash equivalents balances.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our growth and operations through a combination of funds generated from revenues, the issuance of convertible preferred stock and common stock, bank borrowings, the issuance of convertible notes, and revenue interest financing. Our principal uses of cash have been for working capital requirements and capital expenditures. As of December 31, 2022, we had cash and cash equivalents of \$93.3 million, stockholders' equity of \$90.4 million and an accumulated deficit of \$350.6 million.

In January 2023, we entered into a Revenue Interest Financing Agreement (the "RIFA") with HealthCare Royalty Partners IV, L.P. ("HCR") and HealthCare Royalty Management, LLC. Pursuant to the RIFA and subject to customary closing conditions, HCR has agreed to pay the Company an aggregate investment amount of up to \$100.0 million (the "Investment Amount"). Under the terms of the RIFA, \$32.5 million of the Investment Amount was funded on January 27, 2023 (the "Initial Investment Amount"), \$22.4 million of which was used to satisfy in full and retire the Company's indebtedness under the A&R SVB LSA. See "Recent Events" above for further information.

In April 2022, we sold 11,274,510 shares of our common stock in an underwritten registered public offering at an offering price of \$5.10 per share (the "Offering"). The Offering closed on April 18, 2022, and we received net proceeds of approximately \$54.5 million from the sale of the shares, after deducting the underwriting discounts and commissions and other offering expenses. We intend to use the net proceeds from this Offering for ongoing commercial development of YUTREPIA, for continued development of YUTREPIA in other clinical trials, for pre-clinical pipeline activities and for general corporate purposes.

In January 2022, we entered into the A&R SVB LSA with SVB and Innovation, which provided us with up to \$40.0 million in term loans of which \$20.0 million was funded, \$10.5 million of which was used to satisfy our existing obligations under the Loan and Security Agreement with SVB dated February 26, 2021 (“the “SVB LSA”), with the excess proceeds of approximately \$9.5 million funded to the Company. The debt facility was to mature on December 1, 2025 and consisted of interest-only payments through December 31, 2023. The outstanding principal amount of the term loans accrued interest at a floating rate per annum equal to the greater of 7.25% and the prime rate of interest plus 4.0%.

In April 2021, we entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) with certain institutional, accredited investors (the “Purchasers”) for the sale by us in a private placement (the “Private Placement”) of an aggregate of 8,626,037 shares (the “Private Placement Shares”) of our common stock, at a purchase price of \$2.52 per Private Placement Share. The gross proceeds from the sale of the Private Placement Shares were \$21.7 million.

Future Funding Requirements

Prior to the potential FDA approval of YUTREPIA and until such time as we can generate significant revenues from its sale, if ever, we anticipate we will incur net losses and negative cash flows. We plan to focus in the near-term on preparations for the potential commercial launch of YUTREPIA, continuing promotion of Treprostinil Injection, expanding our corporate infrastructure, and continuing to invest in research and development efforts to explore additional product candidates. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our product candidates when we expect, or at all.

Our primary uses of capital are, and we expect will continue to be, compensation and related personnel expenses, clinical costs, manufacturing process development costs, external research and development services, laboratory and related supplies, regulatory expenses, legal costs, administrative and overhead costs and repayments under the RIFA. We also expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution as we prepare to potentially receive regulatory approval for YUTREPIA. Our future funding requirements will be heavily determined by the timing of the potential commercialization of YUTREPIA and the resources needed to support development of our product candidates. If the Company is unable to access the contingent Investment Amounts from the RIFA or generate substantial YUTREPIA product revenue by the second quarter of 2024, the Company will require additional capital.

We believe based on our current operating plan, excluding any potential contingent Investment Amounts from the RIFA and future YUTREPIA product revenue, that cash and cash equivalents will be sufficient to fund operations and capital expenditure requirements and allow us to remain in compliance with our minimum cash covenants pursuant to the RIFA for at least twelve months from the issuance date of this Annual Report on Form 10-K. If we are unable to access additional Investment Amounts from the RIFA, there could be substantial doubt about our ability to continue as a going concern as of the date of the issuance of our second quarter 2023 financial statements. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. If we conclude that we require but are unable to obtain additional funding, we could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect business prospects.

We may raise additional capital through licensing activities, other business arrangements or the sale of equity or convertible debt securities. In such an event, the ownership of our existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights associated with holdings of our common stock.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceuticals, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the number and characteristics of the product candidates we pursue;

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of manufacturing our product candidates and any product we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

See “Risk Factors” for additional risks associated with our substantial capital requirements.

Cash Flows

The following table summarizes our sources and uses of cash:

	Year Ended December 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ (28,588)	\$ (34,035)
Investing activities	(587)	(107)
Financing activities	64,964	26,320
Net increase (decrease) in cash and cash equivalents	<u>\$ 35,789</u>	<u>\$ (7,822)</u>

Operating Activities

Net cash used in operating activities decreased \$5.4 million to \$28.6 million for the year ended December 31, 2022, from \$34.0 million for the year ended December 31, 2021. The decrease was primarily due to working capital changes of \$10.2 million offset by \$4.8 million higher net loss adjusted for non-cash items. The increase in working capital was primarily driven by the timing of receipts from Sandoz in connection with the Promotion Agreement and the timing of vendor payments.

Investing Activities

Net cash used in investing activities was \$0.6 million for the year ended December 31, 2022 compared to \$0.1 million for the year ended December 31, 2021 and consisted primarily of property, plant and equipment purchases.

Financing activities

Net cash provided by financing activities was \$65.0 million during the year ended December 31, 2022 compared with \$26.3 million provided by financing activities the year ended December 31, 2021. During the year ended December 31, 2022, we received \$54.5 million net proceeds from the Offering which closed on April 18, 2022, \$9.3 million excess proceeds from the refinancing of our long-term debt in January 2022, \$1.1 million from the issuance of common stock under stock incentive plans, and \$0.5 million in litigation financing deployments. These inflows were offset by \$0.3 million in principal payments on our finance leases. During the year ended December 31, 2021, we received \$21.7 million net proceeds from the Private Placement which closed on April 13, 2021, \$5.0 million in litigation financing deployments, and \$0.1 million excess proceeds from the refinancing of our long-term debt. These

inflows were offset by \$0.5 million in principal payments on our finance leases. Funds received from litigation deployments are paid directly to the attorneys involved in the RareGen Litigation (as described in Item 3, Legal Proceedings), ongoing costs of which are included as operating outflows.

Contractual Obligations and Commitments

Milestone and Royalty Obligations

Under the UNC License Agreement, the Company is obligated to pay UNC royalties equal to a low single digit percentage of all net sales of drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC License Agreement, including YUTREPIA.

In March 2012, the Company entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to the Company's manufacturing capabilities during the term of the agreement. The Company agreed to pay future contingent milestones and royalties on net sales totaling no more than \$1.5 million, none of which has been earned as of December 31, 2022.

Purchase Obligations

We enter into contracts in the normal course of business with contract service providers to assist in the performance of our research and development and manufacturing activities. Subject to required notice periods and our obligations under binding purchase orders, we can elect to discontinue the work under these agreements at any time. As of December 31, 2022, the Company has non-cancelable commitments for product manufacturing costs of approximately \$3.7 million for the year ending December 31, 2023.

In addition, we have entered into a multi-year supply agreement with LGM Pharma, LLC ("LGM") to produce active pharmaceutical ingredients for YUTREPIA. Under our supply agreement with LGM, we are required to provide rolling forecasts, a portion of which will be considered a binding, firm order, subject to an annual minimum purchase commitment of \$2.7 million for the term of the agreement. The agreement expires five years from the first marketing authorization approval of YUTREPIA.

Lease Obligations

We have operating lease obligations including rental amounts due on leases of certain laboratory, manufacturing and office space and equipment under the terms of non-cancelable operating leases. These leases expire at various times through October 2026. Minimum operating lease payments are \$1.3 million in 2023, \$1.3 million in 2024, \$1.4 million in 2025, and \$1.2 million in 2026.

We lease specialized laboratory equipment under finance leases expiring in 2024. Minimum finance lease payments are \$0.2 million in 2023, and \$0.1 million in 2024.

Other Obligations and Contingencies

We from time-to-time are subject to claims and litigation in the normal course of business, none of which we believe represent a risk of material loss or exposure.

We also have employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control or termination without cause, occur.

Critical Accounting Estimates

We prepare our consolidated financial statements in conformity with U.S. GAAP. The preparation of these financial statements requires the use of estimates, judgments and assumptions that affect the reported amounts of assets and

liabilities at the date of the financial statements and reported amounts of revenues and expenses during the periods presented. Actual results could differ from those estimates and assumptions.

While we describe our significant accounting policies in Note 2 to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we have identified the following critical accounting estimates:

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our incurred expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses are related to expenses incurred with respect to CROs, CMOs and other vendors in connection with research and development and manufacturing activities. We do not currently capitalize costs associated with the production of YUTREPIA.

We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotations and contracts with such vendors that conduct research and development and manufacturing activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the applicable research and development or manufacturing expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented within this Annual Report on Form 10-K.

JOBS Act

As an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Subject to certain conditions, as an emerging growth company, we rely on certain of these exemptions, including without limitation:

- reduced disclosure about our executive compensation arrangements;
- no advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of 2023; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions.

Smaller Reporting Company

As a “smaller reporting company,” as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), in addition to providing reduced disclosure about our executive compensation arrangements and business developments, among other reduced disclosure requirements available to smaller reporting companies, we present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Our financial statements required to be filed pursuant to this Item 8 appear in a separate section of this Annual Report on Form 10-K, beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been prevented or detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of its inherent limitations, misstatements due to error or fraud may occur and not be prevented or detected.

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2022, management, with the participation of the Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2022, the end of the period covered by this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, with the participation of the Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the Company’s internal control over financial reporting as of December 31, 2021 based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation under the framework in Internal Control — Integrated Framework (2013), management concluded that the Company’s internal control over financial reporting was effective as of December 31, 2022.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption from such requirement for emerging growth companies.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required to be disclosed by this Item with respect to our executive officers is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Executive Officers and Director and Officer Compensation: Executive Officers” contained in our definitive proxy statement for our 2023 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2022.

Information required to be disclosed by this Item about our Board is incorporated into this Annual Report on Form 10-K by reference from the section entitled “The Class II Director Election Proposal” contained in our definitive proxy statement for our 2023 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2022.

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Delinquent Section 16(a) Reports” contained in our definitive proxy statement for our 2023 annual meeting of stockholders, if applicable, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2022.

Information required to be disclosed by this Item about our Board, the Audit Committee of our Board, our audit committee financial expert, our code of conduct, as amended, or our Code of Conduct, and other corporate governance matters is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Liquidia Corporate Governance” contained in our definitive proxy statement for our 2023 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2022.

The text of our Code of Conduct, which applies to our directors and employees (including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions), is posted in the “Corporate Governance” section of the Investors section of our website, www.liquidia.com. A copy of the Code of Conduct can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Conduct that are required to be disclosed pursuant to the rules of the SEC and The Nasdaq Stock Market.

The information presented on our website is not a part of this Annual Report on Form 10-K and the reference to our website is intended to be an inactive textual reference only.

Item 11. Executive Compensation.

Information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Executive Officers and Director and Officer Compensation” contained in our definitive proxy statement for our 2023 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2022.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information regarding our equity compensation plans as of December 31, 2022:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights(1)	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	6,708,700 (2)	\$ 4.80	270,895 (3)
Equity compensation plans not approved by security holders	1,689,562 (4)	\$ 3.25	12,800
Total	8,398,262 (2)	\$ 4.49	283,695

- (1) Represents the weighted-average exercise price of outstanding stock options only.
- (2) Includes an aggregate of (i) 437,373 option shares and 8,446 shares underlying restricted stock units assumed by Liquidia Corporation under the Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan, (ii) 135,574 option shares assumed by Liquidia Corporation under the Liquidia Technologies, Inc. 2016 Equity Incentive Plan, as amended, and (iii) 92,487 option shares assumed by Liquidia Corporation under the Liquidia Technologies, Inc. Stock Option Plan, as amended.
- (3) On January 1, 2023, an additional 2,580,716 shares of common stock were automatically added to the shares authorized for issuance under the Liquidia Corporation 2020 Long-Term Incentive Plan (the “2020 Plan”), pursuant to an “evergreen” provision contained therein. Pursuant to such provision, on January 1 of each year through 2030, the number of shares authorized for issuance under the 2020 Plan is automatically increased by a number equal to four percent of the outstanding shares of common stock as of the end of our immediately preceding fiscal year, or any lesser number of shares of common stock determined by our Board or Compensation Committee of our Board.
- (4) Includes an aggregate of (i) 1,392,362 nonstatutory stock option shares with an exercise price equal to \$3.00 granted to Damian deGoa, our former Chief Executive Officer and a current director, on December 14, 2020 (the “deGoa Option”). The deGoa Option remains outstanding and exercisable during Mr. deGoa’s Board tenure, and (ii) 297,200 nonstatutory stock option shares issued under the Liquidia Corporation 2022 Inducement Plan. These options shares were granted outside of the 2020 Plan as an inducement material to acceptance of employment with our company and are subject to nonstatutory stock option agreements. The options were approved by the Compensation Committee of the Board in compliance with and in reliance on Nasdaq Listing Rule 5635(c)(4).

The remaining information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the sections entitled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” contained in our definitive proxy statement for our 2023 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2022.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required to be disclosed by this Item is incorporated in this Annual Report on Form 10-K by reference from the sections entitled “Certain Relationships and Related Party Transactions” and “Liquidia Corporate Governance” contained in our definitive proxy statement for our 2023 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2022.

Item 14. Principal Accounting Fees and Services.

The information required to be disclosed by this Item is incorporated into this Annual Report on Form 10-K by reference from the section entitled “Principal Accounting Fees and Services” contained in our definitive proxy statement for our 2023 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2022.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements.

Report of Independent Registered Public Accounting Firm (PCAOB ID: 238)	F-2
Consolidated Balance Sheets as of December 31, 2022 and 2021	F-3
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2022 and 2021	F-4
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2022 and 2021	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2022 and 2021	F-6
Notes to Financial Statements	F-7

(2) Financial Statement Schedules.

All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

(3) Exhibits.

See Exhibit Index below.

(b) The following exhibits are filed as part of this Annual Report on Form 10-K.

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of June 29, 2020, by and among the Company, Liquidia Technologies, Inc., RareGen, LLC, Gemini Merger Sub I, Inc., Gemini Merger Sub II, LLC and PBM RG Holdings, LLC (incorporated by reference to Exhibit 2.1 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
2.2	Limited Waiver and Modification to Agreement and Plan of Merger, dated as of August 3, 2020, by and among the Company, Liquidia Technologies, Inc., RareGen, LLC, Gemini Merger Sub I, Inc., Gemini Merger Sub II, LLC and PBM RG Holdings, LLC (incorporated by reference to Exhibit 2.2 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
3.1	Certificate of Incorporation of Liquidia Corporation (incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
3.2	Bylaws of Liquidia Corporation (incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
4.1	Form of Specimen Common Stock Certificate of Liquidia Corporation (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
4.2	Form of Warrant to Purchase Shares of Preferred Stock, issued by Liquidia Technologies, Inc. in January 2017 and February 2017 (incorporated herein by reference to Exhibit 4.4 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018).
4.3	Seventh Amended and Restated Investors' Rights Agreement, dated as of February 2, 2018, by and among the Company, the Investors party thereto and the Common Holders party thereto (incorporated herein by reference to Exhibit 4.5 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018).

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- 4.4 [Warrant to Purchase Stock, issued February 26, 2021, by Liquidia Corporation to Silicon Valley Bank \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 3, 2021\).](#)
- 4.5 [Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and Silicon Valley Bank \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022\).](#)
- 4.6 [Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and SVB Innovation Credit Fund VIII, L.P. \(incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022\).](#)
- 4.7 [Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and Innovation Credit Fund VIII-A L.P. \(incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022\).](#)
- 4.8 [Description of Securities of the Company \(incorporated herein by reference to Exhibit 4.5 to the Company's Annual Report on Form 10-K, filed with SEC on March 25, 2021\).](#)
- 10.1# [Liquidia Technologies, Inc. Stock Option Plan \(2004\), as amended, and forms of award agreements thereunder \(incorporated herein by reference to Exhibit 10.1 to Liquidia Technologies, Inc.'s Annual Report on Form 10-K, filed with the SEC on February 26, 2019\).](#)
- 10.2# [Liquidia Technologies, Inc. 2016 Equity Incentive Plan, as amended, and forms of award agreements thereunder \(incorporated herein by reference to Exhibit 10.2 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
- 10.3# [Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan, and forms of award agreements thereunder \(incorporated herein by reference to Exhibit 99.3 to Liquidia Technologies, Inc.'s Registration Statement on Form S-8, filed with the SEC on July 26, 2018\).](#)
- 10.4# [Liquidia Corporation 2020 Long-Term Incentive Plan, and forms of award agreements thereunder \(incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K, filed with the SEC on March 25, 2021\).](#)
- 10.5# [Amendment to the Liquidia Corporation 2020 Long-Term Incentive Plan \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 17, 2022\).](#)
- 10.6# [Liquidia Corporation 2022 Inducement Plan \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 31, 2022\).](#)
- 10.7# [Form of Stock Option Grant Notice and Stock Option Agreement under the 2022 Inducement Plan \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 31, 2022\).](#)
- 10.8# [Form of Indemnification Agreement with the Company's executive officers and directors \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on 8-K12B, filed with the SEC on November 18, 2020\).](#)
- 10.9 [Litigation Funding and Indemnification Agreement, dated as of November 17, 2020, by and between RareGen, LLC and PBM RG Holdings, LLC \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K12B, filed with the SEC on November 18, 2020\).](#)
- 10.10 [Form of Lock-Up Agreement by and among the Company, Liquidia Technologies, Inc. and each of the RareGen members party thereto \(incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020\).](#)
- 10.11+* [Revenue Interest Financing Agreement, dated as of January 9, 2023, by and among Liquidia Technologies, Inc., Healthcare Royalty Partners IV, L.P., and HCR Collateral Management, LLC.](#)
- 10.12+ [Inhaled Collaboration and Option Agreement, dated as of June 15, 2012, by and between Liquidia Technologies, Inc. and Glaxo Group Limited \(incorporated herein by reference to Exhibit 10.14 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
- 10.13+ [Amendment No. 1 to the Inhaled Collaboration and Option Agreement, dated as of May 13, 2015, by and between Liquidia Technologies, Inc. and Glaxo Group Limited \(incorporated herein by reference to Exhibit 10.15 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
- 10.14+ [Second Amendment to the Inhaled Collaboration and Option Agreement, dated as of November 19, 2015, by and between Liquidia Technologies, Inc. and Glaxo Group Limited \(incorporated herein by reference to](#)

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- 10.15++ [Exhibit 10.16 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
[Amendment No. 3 to the Inhaled Collaboration and Option Agreement, effective as of June 24, 2019, by and between Liquidia Technologies, Inc. and Glaxo Group Limited \(incorporated herein by reference to Exhibit 10.1 to Liquidia Technologies, Inc.'s Current Report on Form 8-K, filed with the SEC on June 28, 2019\).](#)
- 10.16+ [Amended and Restated License Agreement, dated as of December 15, 2008, by and between Liquidia Technologies, Inc. and The University of North Carolina at Chapel Hill \(incorporated herein by reference to Exhibit 10.17 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
- 10.17+ [First Amendment to Amended and Restated License Agreement, dated as of June 8, 2009, by and between Liquidia Technologies, Inc. and The University of North Carolina at Chapel Hill \(incorporated herein by reference to Exhibit 10.18 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
- 10.18 [6th Amendment to Amended and Restated License Agreement, dated as of June 10, 2016, by and between Liquidia Technologies, Inc. and The University of North Carolina at Chapel Hill \(incorporated herein by reference to Exhibit 10.19 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
- 10.19+ [Manufacturing Development and Scale-up Agreement, dated as of March 19, 2012, by and between Liquidia Technologies, Inc. and Chasm Technologies, Inc. \(incorporated herein by reference to Exhibit 10.20 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
- 10.20+ [1st Amendment to Manufacturing Development and Scale up Agreement, dated as of May 25, 2017, by and between Liquidia Technologies, Inc. and Chasm Technologies, Inc. \(incorporated herein by reference to Exhibit 10.21 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018\).](#)
- 10.21# [Nonstatutory Stock Option Inducement Award Agreement, dated as of December 15, 2020, by and between the Company and Damian deGoa \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on December 16, 2020\).](#)
- 10.22# [Separation Agreement and General Release, dated as of January 31, 2022, by and between Liquidia Technologies, Inc. and Damian deGoa \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 4, 2022\).](#)
- 10.23# [Executive Employment Agreement, dated as of January 3, 2022, by and between Liquidia Corporation and Roger A. Jeffs, Ph.D. \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 4, 2022\).](#)
- 10.24# [Executive Employment Agreement, dated as of November 30, 2020, by and between Liquidia Technologies, Inc. and Michael Kaseta \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on December 1, 2020\).](#)
- 10.25# [Amended and Restated Executive Employment Agreement, dated as of July 25, 2018, by and between Liquidia Technologies, Inc. and Robert Lippe \(incorporated herein by reference to Exhibit 10.2 to Liquidia Technologies, Inc.'s Current Report on Form 8-K, filed with the SEC on July 30, 2018\).](#)
- 10.26# [Severance Agreement and General Release, dated as of June 28, 2022, by and between Liquidia Technologies, Inc. and Tushar Shah, M.D \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 1, 2022\).](#)
- 10.27# [Executive Employment Agreement, dated as of June 13, 2022, by and between Liquidia Technologies, Inc. and Rajeev Sagar \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 22, 2022\).](#)
- 10.28 [Cooperation Agreement by and among the Company, Liquidia Technologies, Inc., PBM Capital Finance, LLC and PD Joint Holdings, LLC Series 2016-A, dated as of June 29, 2020 \(incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020\).](#)
- 10.29 [Cooperation Agreement by and among the Company, Liquidia Technologies, Inc. and Serendipity BioPharma LLC, dated as of June 29, 2020 \(incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020\).](#)

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10.30	Standstill Agreement, dated as of April 12, 2021, by and among Liquidia Corporation and the Purchasers party thereto (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on April 13, 2021).
10.31#	Liquidia Corporation 2020 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
10.32#	Amendment No. 1 to the Liquidia Corporation 2020 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K, filed with the SEC on March 17, 2022).
10.33#	Liquidia Corporation Annual Cash Bonus Plan (incorporated herein by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
10.34#	Liquidia Corporation Executive Severance and Change in Control Plan (incorporated herein by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K, filed with the SEC on March 25, 2021).
10.35	Lease Agreement, dated as of June 29, 2007, by and between Liquidia Technologies, Inc. and Durham KTP Tech 4, LLC, as amended (incorporated herein by reference to Exhibit 10.34 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
10.36++	Promotion Agreement, dated as of August 1, 2018, by and between RareGen, LLC and Sandoz Inc. (incorporated herein by reference to Exhibit 10.36 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
10.37++	First Amendment to Promotion Agreement, dated as of May 8, 2020, by and between RareGen, LLC and Sandoz Inc. (incorporated herein by reference to Exhibit 10.37 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
10.38	Second Amendment to Promotion Agreement, dated as of September 4, 2020, by and between RareGen, LLC and Sandoz Inc. (incorporated herein by reference to Exhibit 10.38 to Amendment No. 1 to the Company's Registration Statement on Form S-4, filed on September 4, 2020).
10.39++*	Third Amendment to Promotion Agreement, dated as of November 18, 2022 by and between Liquidia PAH, LLC and Sandoz Inc.
10.40	Joint Development Agreement, dated May 3, 2019, between RareGen, LLC and Carelife USA Inc. (incorporated herein by reference to Exhibit 10.39 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
10.41++	LIQ861 API Supply Agreement, dated as of January 10, 2020, by and among LGM Pharma LLC, Yonsung Fine Chemicals Co. Ltd. and Liquidia Technologies, Inc. (incorporated herein by reference to Exhibit 10.44 to the Company's Annual Report on Form 10-K, filed with the SEC on March 17, 2022).
10.42++	Commercial Manufacturing Services and Supply Agreement, dated November 12, 2020, by and between Liquidia Technologies, Inc. and Xcelience, LLC (now Lonza Tampa, LLC) (incorporated herein by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K, filed with the SEC on March 17, 2022).
10.43++*	Device Development and Supply Agreement, dated as of December 1, 2022, by and among Mainbridge Health Partners, LLC, Sandoz Inc. and Liquidia PAH, LLC.
21.1*	Subsidiaries of Liquidia Corporation.
23.1*	Consent of PricewaterhouseCoopers LLP, independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document

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101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and Contained in Exhibit 101).

+ Confidential treatment has been granted with respect as to certain portions of this exhibit. Such portions have been redacted and submitted separately to the SEC.

++ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.

* Filed herewith.

** Furnished herewith.

Indicates management contract or compensatory plan.

(c) Not applicable

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Liquidia Corporation

Date: March 20, 2023

By: /s/ Roger A. Jeffs, Ph.D.

Name: Roger A. Jeffs, Ph.D.

Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

<u>Name</u>	<u>Position</u>	<u>Date</u>
<u>/s/ Roger A. Jeffs, Ph.D.</u> Roger A. Jeffs, Ph.D.	Director and Chief Executive Officer (Principal Executive Officer)	March 20, 2023
<u>/s/ Michael Kaseta</u> Michael Kaseta	Chief Financial Officer (Principal Financial and Accounting Officer)	March 20, 2023
<u>/s/ Dr. Stephen Bloch</u> Dr. Stephen Bloch	Chairman of the Board of Directors	March 20, 2023
<u>/s/ Damian deGoa</u> Damian deGoa	Director	March 20, 2023
<u>/s/ Katherine Rielly-Gauvin</u> Katherine Rielly-Gauvin	Director	March 20, 2023
<u>/s/ Dr. Joanna Horobin</u> Dr. Joanna Horobin	Director	March 20, 2023
<u>/s/ David Johnson</u> David Johnson	Director	March 20, 2023
<u>/s/ Arthur Kirsch</u> Arthur Kirsch	Director	March 20, 2023
<u>/s/Paul B. Manning</u> Paul B. Manning	Director	March 20, 2023
<u>/s/ Raman Singh</u> Raman Singh	Director	March 20, 2023

LIQUIDIA CORPORATION

FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Liquidia Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Liquidia Corporation and its subsidiaries (the “Company”) as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of stockholders’ equity and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company may require additional financing to fund future operations. Management’s evaluation of the events and conditions and plans to mitigate this matter are also described in Note 1.

/s/ PricewaterhouseCoopers LLP
Raleigh, North Carolina
March 20, 2023

We have served as the Company’s auditor since 2014.

Liquidia Corporation
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 93,283	\$ 57,494
Accounts receivable, net	5,017	2,990
Prepaid expenses and other current assets	1,511	792
Total current assets	99,811	61,276
Property, plant and equipment, net	4,151	5,017
Operating lease right-of-use assets, net	2,101	2,412
Indemnification asset, related party	6,595	6,282
Contract acquisition costs, net	8,604	10,138
Intangible asset, net	3,726	4,390
Goodwill	3,903	3,903
Other assets	307	311
Total assets	\$ 129,198	\$ 93,729
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,197	\$ 1,070
Accrued expenses and other current liabilities	5,522	5,171
Current portion of operating lease liabilities	900	775
Current portion of finance lease liabilities	181	311
Total current liabilities	8,800	7,327
Litigation finance payable	6,594	6,143
Long-term operating lease liabilities	3,332	4,232
Long-term finance lease liabilities	171	352
Long-term debt	19,879	10,410
Total liabilities	38,776	28,464
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock — 10,000,000 shares authorized, none outstanding	—	—
Common stock — \$0.001 par value, 80,000,000 shares authorized, 64,517,912 and 52,287,737 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	64	52
Additional paid-in capital	440,954	374,794
Accumulated deficit	(350,596)	(309,581)
Total stockholders' equity	90,422	65,265
Total liabilities and stockholders' equity	\$ 129,198	\$ 93,729

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

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	<u>Year Ended December 31,</u>	
	<u>2022</u>	<u>2021</u>
Revenue	\$ 15,935	\$ 12,853
Costs and expenses:		
Cost of revenue	2,859	3,023
Research and development	19,435	20,517
General and administrative	32,411	23,110
Total costs and expenses	54,705	46,650
Loss from operations	(38,770)	(33,797)
Other income (expense):		
Interest income	1,090	33
Interest expense	(2,338)	(762)
Loss on extinguishment of debt	(997)	(53)
Total other expense, net	(2,245)	(782)
Net loss and comprehensive loss	\$ (41,015)	\$ (34,579)
Net loss per common share, basic and diluted	\$ (0.67)	\$ (0.70)
Weighted average common shares outstanding, basic and diluted	60,958,862	49,677,737

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

Liquidia Corporation
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2020	43,336,277	\$ 43	\$ 346,045	\$ (275,002)	\$ 71,086
Issuance of common stock upon exercise of stock options	14,699	—	41	—	41
Issuance of common stock under employee stock purchase plan	270,185	—	—	—	—
Issuance of common stock upon vesting of restricted stock units	40,539	—	—	—	—
Sale of common stock, net	8,626,037	9	21,701	—	21,710
Issuance of warrants	—	—	261	—	261
Stock-based compensation	—	—	6,746	—	6,746
Net loss	—	—	—	(34,579)	(34,579)
Balance as of December 31, 2021	<u>52,287,737</u>	<u>\$ 52</u>	<u>\$ 374,794</u>	<u>\$ (309,581)</u>	<u>\$ 65,265</u>
Issuance of common stock upon exercise of stock options	232,877	—	838	—	838
Issuance of common stock upon vesting of restricted stock units	54,181	—	—	—	—
Issuance of common stock under employee stock purchase plan	51,941	—	258	—	258
Issuance of warrants	—	—	1,317	—	1,317
Equity consideration for acquisition	616,666	1	(1)	—	—
Sale of common stock, net	11,274,510	11	54,450	—	54,461
Stock-based compensation	—	—	9,298	—	9,298
Net loss	—	—	—	(41,015)	(41,015)
Balance as of December 31, 2022	<u>64,517,912</u>	<u>\$ 64</u>	<u>\$ 440,954</u>	<u>\$ (350,596)</u>	<u>\$ 90,422</u>

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

Liquidia Corporation
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	2021
Operating activities		
Net loss	\$ (41,015)	\$ (34,579)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,298	6,746
Depreciation and amortization	3,647	5,612
Non-cash lease expense	311	237
Loss on disposal of property and equipment	4	44
Loss on extinguishment of debt	997	53
Non-cash interest expense	328	232
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,027)	(2,990)
Prepaid expenses and other current assets	(719)	(40)
Other non-current assets	4	80
Accounts payable	814	(7,559)
Accrued expenses and other current liabilities	545	563
Refund liability	—	(1,769)
Operating lease liabilities	(775)	(665)
Net cash used in operating activities	<u>(28,588)</u>	<u>(34,035)</u>
Investing activities		
Purchases of property, plant and equipment	(592)	(107)
Proceeds from the sale of property, plant and equipment	5	—
Net cash used in investing activities	<u>(587)</u>	<u>(107)</u>
Financing activities		
Principal payments on finance leases	(311)	(477)
Principal payments on long-term debt	(10,500)	(10,353)
Proceeds from issuance of long-term debt with warrants, net	19,767	10,410
Receipts from litigation financing	451	4,989
Proceeds from sale of common stock, net of underwriting fees and commissions	54,461	21,710
Proceeds from issuance of common stock under stock incentive plans	1,096	41
Net cash provided by financing activities	<u>64,964</u>	<u>26,320</u>
Net increase (decrease) in cash and cash equivalents	35,789	(7,822)
Cash and cash equivalents, beginning of period	57,494	65,316
Cash and cash equivalents, end of period	<u>\$ 93,283</u>	<u>\$ 57,494</u>
Supplemental disclosure of cash flow information		
Cash paid for interest	<u>\$ 1,626</u>	<u>\$ 423</u>
Cash paid for operating lease liabilities	<u>\$ 1,244</u>	<u>\$ 1,208</u>
Reduction of lease liability and right-of-use asset from lease modification	<u>\$ —</u>	<u>\$ 39</u>
Non-cash increase in property, plant and equipment through accounts payable	<u>\$ 139</u>	<u>\$ —</u>
Non-cash increase in indemnification asset through accounts payable	<u>\$ 313</u>	<u>\$ 4,895</u>

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

Liquidia Corporation
Notes to Consolidated Financial Statements
(tabular dollars in thousands)

1. Business

Description of the Business

Liquidia Corporation (“Liquidia” or the “Company”) is a biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension (“PH”). Liquidia Corporation operates through its wholly owned operating subsidiaries, Liquidia Technologies, Inc. (“Liquidia Technologies”) and Liquidia PAH, LLC (“Liquidia PAH”), formerly known as RareGen, LLC (“RareGen”).

The Company generates revenue primarily pursuant to a promotion agreement between Liquidia PAH and Sandoz Inc. (“Sandoz”), dated as of August 1, 2018, as amended (the “Promotion Agreement”), sharing profit derived from the sale of Sandoz’s substitutable generic tadalafil injection (“Tadalafil Injection”) in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Tadalafil Injection. The Company employs a targeted sales force calling on physicians and hospital pharmacies in the treatment of pulmonary arterial hypertension (“PAH”), as well as key stakeholders involved in the distribution and reimbursement of Tadalafil Injection. Strategically, the Company believes that its commercial presence in the field will enable an efficient base to expand from for the launch of YUTREPIA upon final approval, leveraging existing relationships and further validating its reputation as a company committed to supporting PAH patients.

The Company conducts research, development and manufacturing of novel products by applying its subject matter expertise in cardiopulmonary diseases and our proprietary PRINT® technology, a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy, and performance of a wide range of therapies. Through development of the Company’s own products and research with third parties, the Company has experience applying PRINT across multiple routes of administration and drug payloads including inhaled therapies, vaccines, biologics, nucleic acids and ophthalmic implants, among others.

The Company’s lead product candidate, for which it holds worldwide commercial rights, is YUTREPIA for the treatment of PAH. YUTREPIA is an inhaled dry powder formulation of tadalafil designed with PRINT to improve the therapeutic profile of tadalafil by enhancing deep lung delivery while using a convenient, low resistance dry-powder inhaler (“DPI”) and by achieving higher dose levels than the labelled dose of current inhaled therapies. The Company’s New Drug Application (“NDA”) for YUTREPIA was tentatively approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of PAH in November 2021. The FDA also confirmed that the clinical data in the NDA would support the Company’s pursuit of a supplemental NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity for the nebulized form of tadalafil in March 2024.

Recent Developments

On January 9, 2023, the Company entered into a Revenue Interest Financing Agreement (the “RIFA”) with HealthCare Royalty Partners IV, L.P. (“HCR”) and HealthCare Royalty Management, LLC. Pursuant to the RIFA and subject to customary closing conditions, HCR has agreed to pay the Company an aggregate investment amount of up to \$100.0 million (the “Investment Amount”). Under the terms of the RIFA, \$32.5 million of the Investment Amount was funded on January 27, 2023 (the “Initial Investment Amount”), \$22.4 million of which was used to satisfy in full and retire the Company’s indebtedness under the Amended and Restated Loan and Security Agreement with Silicon Valley Bank, with the excess proceeds less transaction costs of approximately \$0.7 million funded to the Company. Under the RIFA, an additional \$35.0 million of the Investment Amount will be funded fifteen business days after the earlier of regulatory approval of YUTREPIA or a favorable determination relating to the asserted patents in the ongoing patent litigation with

United Therapeutics Corporation and \$25.0 million of the Investment Amount will be funded fifteen business days after the mutual agreement of HCR and the Company to fund such amount. See Note 16 for further information.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on third parties and key personnel, protection of proprietary technology, compliance with government regulations, and the ability to secure additional capital to fund operations.

The current global macro-economic environment is volatile, which may result in supply chain constraints and elevated rates of inflation. In addition, the Company operates in a dynamic and highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: the ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company related to intellectual property, product, regulatory, or other matters; and the Company's ability to attract and retain employees necessary to support its growth.

Product candidates developed by the Company require approval from the FDA and/or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed, or the Company is unable to maintain approval, it could have a material adverse impact on the Company.

The Company relies on single source manufacturers and suppliers for the supply of its product candidates. This adds to the manufacturing risks faced by the Company, which could be left without backup facilities in the event of any failure by a supplier. Any disruption from these manufacturers or suppliers could have a negative impact on the Company's business, financial position and results of operations.

Liquidity

The Company expects to incur significant expenses and operating losses for the foreseeable future as it seeks regulatory approval and prepares for commercialization of any approved product candidates. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales. The Company may require additional capital in advance of a potential commercial launch of YUTREPIA. If the Company is unable to access the contingent Investment Amounts from the RIFA or generate substantial YUTREPIA product revenue by the second quarter of 2024, the Company will require additional capital. The Company may also require additional capital to pursue in-licenses or acquisitions of other product candidates. If the Company concludes it requires but is unable to obtain funding, the Company could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect its business prospects.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The Company has financed its growth and operations through a combination of funds generated from revenues, the issuance of convertible preferred stock and common stock, bank borrowings, bank borrowings with warrants and the issuance of convertible notes and warrants, and revenue interest financing. Since inception, the Company has incurred recurring losses, including net loss of \$41.0 million for the year ended December 31, 2022 and the Company had an accumulated deficit of \$350.6 million as of December 31, 2022. Although the Company expects to continue to generate operating losses for the foreseeable future, management believes that based on its current operating plan, excluding any potential contingent Investment

Amounts from the RIFA and future YUTREPIA product revenue, its cash and cash equivalents will be sufficient to fund operations and capital expenditure requirements and allow it to remain in compliance with its minimum cash covenants pursuant to the RIFA for at least twelve months from the issuance date of these consolidated financial statements. If the Company is unable to access additional Investment Amounts from the RIFA, there could be substantial doubt about the Company's ability to continue as a going concern as of the date of the issuance of the Company's second quarter 2023 financial statements. The Company has based these estimates on assumptions that may differ from actual results, and it could use its available resources sooner than expected.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying financial statements in conformity with generally accepted accounting principles in the United States of America ("GAAP"). Such financial statements reflect all adjustments that are, in management's opinion, necessary to present fairly, in all material respects, the Company's financial position, results of operations and cash flows and are presented in U.S. Dollars.

Consolidation

The accompanying consolidated financial statements include the Company's wholly owned subsidiaries, Liquidia Technologies and Liquidia PAH. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities, at the date of the financial statements, as well as the reported amounts of revenues and expenses during the period. These estimates are based on historical experience and various other assumptions believed reasonable under the circumstances. The Company evaluates its estimates on an ongoing basis, including those related to the valuation of stock-based awards, certain accruals, and intangible and contract acquisition cost amortization, and makes changes to the estimates and related disclosures as experience develops or new information becomes known. Actual results will most likely differ from those estimates.

Summary of Significant Accounting Policies

Cash

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents.

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents. The Company is exposed to credit risk, subject to federal deposit insurance, in the event of default by the financial institutions holding its cash and cash equivalents to the extent of amounts recorded on the consolidated balance sheet. As of December 31, 2022 all of the Company's cash and cash equivalents were held with Silicon Valley Bank ("SVB"). Following the March 10, 2023 closure of SVB, substantially all of the Company's cash and cash equivalents were moved to a different accredited financial institution. The Company has not experienced any losses on such accounts and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Such deposits have and will continue to exceed federally insured limits.

Accounts Receivable

Accounts receivable are stated at net realizable value and net of an allowance for credit losses as of each balance sheet date, if applicable. One customer accounted for 99% and 98% of accounts receivable at December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, the Company has not recorded an allowance for credit losses.

Leases

ASC 842 *Leases* sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. For operating leases, the asset and liability is expensed over the lease term on a straight-line basis, with all cash flows classified as an operating activity in the Statement of Cash Flows. For finance leases, interest on the lease liability is recognized separately from the amortization of the right-of-use asset in the Statement of Operations and Comprehensive Loss and the repayment of the principal portion of the lease liability is classified as a financing activity, while the interest component is classified as an operating activity in the Statement of Cash Flows.

Property, Plant and Equipment

Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment is computed using the straight-line method over the estimated useful lives of the assets beginning when the assets are placed in service. Estimated useful lives for the major asset categories are:

Lab and build-to-suit equipment (years)	5 - 7
Office equipment (years)	5
Furniture and fixtures (years)	10
Computer equipment (years)	3
Leasehold improvements	Lesser of life of the asset or remaining lease term

Major renewals and improvements are capitalized to the extent that they increase the useful economic life or increase the expected economic benefit of the underlying asset. Maintenance and repairs are charged to operations as incurred. When items of property, plant and equipment are sold or retired, the related cost and accumulated depreciation or amortization is removed from the accounts, and any gain or loss is included in operating expenses in the accompanying Statements of Operations and Comprehensive Loss.

Long-Lived Assets

The Company reviews long-lived assets for realizability on an ongoing basis. Changes in depreciation and amortization, generally accelerated depreciation and variable amortization, are determined and recorded when estimates of the remaining useful lives or residual values of long-term assets change. The Company also reviews for impairment when conditions exist that indicate the carrying amount of the assets may not be fully recoverable. In those circumstances, the Company performs undiscounted operating cash flow analyses to determine if an impairment exists. When testing for asset impairment, the Company groups assets and liabilities at the lowest level for which cash flows are separately identifiable. Any impairment loss is calculated as the excess of the asset's carrying value over its estimated fair value. Fair value is estimated based on the discounted cash flows for the asset group over the remaining useful life or based on the expected cash proceeds for the asset less costs of disposal. Any impairment losses would be recorded in the consolidated statements of operations. To date, no such impairments have occurred.

Goodwill

The Company assesses goodwill for impairment at least annually as of July 1 or whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. For example, significant and unanticipated changes or our inability to obtain or maintain regulatory approvals for our product candidates, including the NDA for YUTREPIA, could trigger testing of our goodwill for impairment. The Company has one reporting unit. The Company has the option to first assess qualitative factors to determine whether events or circumstances indicate it is more likely than not that the fair value of a reporting unit is greater than its carrying amount, in which case a quantitative impairment test is not required.

Per ASC 350 *Intangibles-Goodwill and Other* the quantitative goodwill impairment test is performed by comparing the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is not impaired. An impairment loss is recognized for any excess of the carrying amount of the reporting unit's goodwill over the fair value up to the amount of goodwill allocated to the reporting unit. Income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit are considered when measuring the goodwill impairment loss, if applicable.

The Company completed its annual goodwill impairment test as of July 1, 2022. There have been no significant events or circumstances affecting the valuation of goodwill subsequent to the assessment.

Revenue Recognition from Promotion Agreements

The Company recognizes revenue in accordance with ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of Topic 606 is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, the Company assesses the promised goods or services in the contract and identifies each promised good or service that is distinct.

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.

Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company evaluates any non-cash consideration, consideration payable to the customer, potential returns and refunds, and whether consideration contains a significant financing element in determining the transaction price.

Revenue is measured based on consideration specified in a contract with a customer. The Company recognizes revenue when it satisfies a performance obligation by transferring control over a service to a customer. The amount of revenue recognized reflects estimates for refunds and returns, which are presented as a reduction of Accounts receivable where the right of setoff exists.

On August 1, 2018, the Company partnered with Sandoz in the Promotion Agreement to launch the first-to-file generic of Trepstinil Injection for the treatment of patients with PAH. Under the Promotion Agreement, the Company provides certain promotional and nonpromotional activities on an exclusive basis for the product in the United States of America for the treatment of PAH, in exchange for a share of Sandoz's net profits, as defined within the Promotion Agreement. In addition, the Company paid Sandoz \$20.0 million at the inception of the Promotion Agreement, in consideration for the right to conduct the promotional activities for the product. In exchange for its services, the Company is entitled to receive a portion of net profits based on specified profit levels associated with the product.

The Company determined that certain activities within the contract are within the scope of ASC 808, *Collaborative Arrangements*. The commercialization of the product is a joint operating activity where the Company will provide promotional activities for Sandoz's intellectual property and Sandoz will be responsible for items such as supply of the product, distribution to customers, managing sales, processing returns, and regulatory matters, and protection of patents. Both parties will be active participants, each carrying out its assigned responsibilities, and participating in the joint operating activity and will share in the risks and rewards of the commercialization through the profit-sharing arrangement.

In addition, the Company determined that the services provided under the Promotion Agreement fall within the scope of Topic 606. The promotional activities the Company performs are one of the services the Company expects to provide as part of its ordinary activities, and it is receiving consideration for this service from Sandoz in the form of a share of "Net Profits" (as defined in the Promotion Agreement). The Company has one combined performance obligation under the Promotion Agreement, which is to perform promotional and non-promotional activities to encourage the appropriate use of the product in accordance with the product labeling and applicable law. As such, and in accordance with ASU 2018-18: *Clarifying the Interaction between Topic 808 and Topic 606*, the Company will account for the entire Promotion Agreement under Topic 606.

Segment Information

U.S. GAAP requires segmentation based on an entity's internal organization and reporting of revenue and operating income based upon internal accounting methods commonly referred to as the "management approach." Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker (CODM), or decision making group, in deciding how to allocate resources and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined that it has one operating and reporting segment.

Research and Development Expense

Research and development costs are expensed as incurred and include direct costs incurred to third parties related to the salaries of, and stock-based compensation for, personnel involved in research and development activities, contractor fees, administrative expenses and allocations of research-related overhead costs. Administrative expenses and research-related overhead costs included in research and development expense consist of allocations of facility and equipment lease charges, depreciation and amortization of assets and insurance directly related to research and development activities.

Patent Maintenance

The Company is responsible for all patent costs, past and future, associated with the preparation, filing, prosecution, issuance, maintenance, enforcement and defense of United States patent applications. Such costs are recorded as general and administrative expenses as incurred. To the extent that the Company's licensees share these costs, such benefit is recorded as a reduction of the related expenses.

Stock-Based Compensation

The Company estimates the grant date fair value of its stock-based awards and amortizes this fair value to compensation expense over the requisite service period or vesting term (see Note 8).

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration of common stock equivalents.

Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. Due to their anti-dilutive effect, the calculation of diluted net loss per share excludes the following common stock equivalent shares:

	Year Ended December 31,	
	2022	2021
Stock Options	7,757,017	5,234,582
Restricted Stock Units	399,349	259,705
Warrants	445,205	168,767
Total	<u>8,601,571</u>	<u>5,663,054</u>

Certain common stock warrants are included in the calculation of basic and diluted net loss per share since their exercise price is de minimis.

Fair Value of Financial Instruments

The carrying amounts reflected in the Company's consolidated balance sheets for cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other liabilities approximate their fair values due to their short-term nature.

The Company's valuation of financial instruments is based on a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities;

Level 2 — Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly; and

Level 3 — Unobservable inputs for the asset and liability used to measure fair value, to the extent that observable inputs are not available.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The following tables present the placement in the fair value hierarchy of financial liabilities measured at fair value:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
December 31, 2022				
Assets				
Money market mutual funds (cash equivalents)	\$ 92,283	\$ —	\$ —	\$ 92,283
Liabilities				
A&R Silicon Valley Bank term loan	\$ —	\$ 18,853	\$ —	\$ 19,879
December 31, 2021				
Assets				
Money market mutual funds (cash equivalents)	\$ 56,494	\$ —	\$ —	\$ 56,494
Liabilities				
Silicon Valley Bank term loan	\$ —	\$ 10,021	\$ —	\$ 10,410

Money market mutual funds are included in cash and cash equivalents on the Company's consolidated balance sheets. They are valued using quoted market prices and therefore are classified within Level 1 of the fair value hierarchy.

The fair value of debt is measured in accordance with ASC 820, *Financial Instruments*. The fair value is determined based on the remaining years to maturity, interest and principal payments, as well as an interest rate consistent with the Company's current estimated cost of debt.

Income Taxes

The asset and liability method is used in the Company's accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company records a valuation allowance against deferred tax assets when realization of the tax benefit is uncertain.

A valuation allowance is recorded, if necessary, to reduce net deferred taxes to their realizable values if management believes it is more likely than not that the net deferred tax assets will not be realized.

The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This guidance simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Effective January 1, 2022, the Company adopted ASU 2020-06, which had no impact on the Company's financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04, *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. This guidance clarifies and reduces diversity in the accounting for modifications or exchanges of freestanding equity-classified written call options (for example warrants) that remain equity classified after modification or exchange. Effective January 1, 2022, the Company adopted ASU 2021-04, which had no impact on the Company's financial statements and related disclosures.

3. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

	December 31, 2022	December 31, 2021
Lab and build-to-suit equipment	\$ 6,257	\$ 6,600
Office equipment	19	19
Furniture and fixtures	134	177
Computer equipment	291	347
Leasehold improvements	11,409	11,457
Construction-in-progress	155	—
Total property, plant and equipment	18,265	18,600
Accumulated depreciation and amortization	(14,114)	(13,583)
Property, plant and equipment, net	<u>\$ 4,151</u>	<u>\$ 5,017</u>

The Company recorded depreciation and amortization expense of \$1.4 million and \$1.8 million for the years ended December 31, 2022 and 2021, respectively. Maintenance and repairs are expensed as incurred and were \$0.3 million and \$0.1 million for the years ended December 31, 2022 and 2021, respectively.

4. Contract Acquisition Costs and Intangible Asset, and Goodwill

Contract acquisition costs and intangible asset are summarized as follows:

	December 31, 2022			December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Contract acquisition costs	\$ 12,980	\$ (4,376)	\$ 8,604	\$ 12,980	\$ (2,842)	\$ 10,138
Intangible asset	\$ 5,620	\$ (1,894)	3,726	\$ 5,620	\$ (1,230)	4,390

The Company is amortizing the value of the contract acquisition costs and customer relationship intangible asset on a pro-rata basis based on the estimated total revenue or net profits to be recognized over the period from November 18, 2020 through December 2032, the termination date of the Promotion Agreement (see Note 2-Revenue Recognition). Amortization of contract acquisition costs is recorded as a reduction of revenue and amortization of the intangible asset is recorded as cost of revenue.

The Company recorded amortization related to the contract acquisition costs of \$1.5 million and \$2.7 million for the years ended December 31, 2022 and 2021, respectively. The Company recorded amortization related to the intangible asset of \$0.7 million and \$1.1 million for the years ended December 31, 2022 and 2021, respectively. Annual amortization over the next five years is expected to be lower than prior years primarily due to an amendment to the Sandoz Agreement entered into during the fourth quarter of 2022, which extended the term of the Agreement by five years.

During the year ended December 31, 2020 the Company recorded goodwill of \$3.9 million, which primarily represents the Liquidia PAH assembled workforce and the residual value of the purchase consideration and assumed liabilities that exceeded the assets acquired (see Note 2-Goodwill). As of December 31, 2022, the Company concluded that there were no events or changes in circumstances that indicated that the carrying amount of goodwill was not recoverable.

5. Indemnification Asset with Related Party and Litigation Finance Payable

On June 3, 2020, Liquidia PAH entered into a litigation financing arrangement (the “Financing Agreement”) with Henderson SPV, LLC (“Henderson”). Liquidia PAH, along with Sandoz (collectively the “Plaintiffs”), are pursuing litigation against United Therapeutics Corporation (“United Therapeutics”) and, prior to entering into a binding settlement term sheet with Smiths Medical ASC in November 2020, were pursuing litigation against Smiths Medical. Under the Financing Agreement, Henderson will fund Liquidia PAH’s legal and litigation expenses (referred to as “Deployments”) in exchange for a share of certain litigation or settlement proceeds. Deployments received from Henderson are recorded as a Litigation finance payable.

Litigation proceeds will be split equally between Liquidia PAH and Sandoz. Unless there is an event of default by Henderson, litigation proceeds received by Liquidia PAH must be applied first to repayment of total Deployments received. Litigation proceeds in excess of Deployments received are split between Liquidia PAH and Henderson according to a formula. Unless there is an event of default by PBM, all proceeds received by Liquidia PAH are due to PBM as described further below.

On November 17, 2020, Liquidia PAH entered into a Litigation Funding and Indemnification Agreement (“Indemnification Agreement”) with PBM. PBM is considered to be a related party as it is controlled by a major stockholder (which beneficially owns approximately 9.3% of Liquidia Corporation Common Stock as of March 1, 2023) who is also a member of the Company’s Board of Directors.

Under the terms of the Indemnification Agreement, PBM now controls the litigation, with Liquidia PAH’s primarily responsibility being to cooperate to support the litigation proceedings as needed. The Indemnification Agreement provides that Liquidia PAH and its affiliates will not be entitled to any proceeds resulting from, or bear any financial or other liability for, the United Therapeutics and Smiths Medical ASC litigation unless there is an event of default by PBM. Any Liquidia PAH litigation expenses not reimbursed by Henderson under the Financing Agreement will be reimbursed by PBM. Any proceeds received which Henderson is not entitled to under the Financing Agreement will be due to PBM.

The Indemnification Asset is increased as the Company records third party legal and litigation expenses related to the United Therapeutics and Smiths Medical ASC litigation.

As of December 31, 2022, the Indemnification Asset and Litigation Finance Payable were classified as long-term assets and liabilities, respectively as it is considered unlikely that the litigation will conclude prior to December 31, 2023.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2022	December 31, 2021
Accrued compensation	\$ 2,862	\$ 3,157
Accrued research and development expenses	1,757	344
Accrued other expenses	903	1,670
Total accrued expenses and other current liabilities	<u>\$ 5,522</u>	<u>\$ 5,171</u>

7. Stockholders' Equity

Authorized Capital

As of December 31, 2022, the authorized capital of the Company consists of 90,000,000 shares of capital stock, \$0.001 par value per share, of which 80,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock.

Common Stock

Upon any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company, the holders of the common stock shall be entitled to receive that portion of the remaining funds to be distributed to the stockholders, subject to the liquidation preferences of any outstanding preferred stock, if any. Such funds shall be paid to the holders of common stock on the basis of the number of shares so held by each of them.

Issuance of Common Stock on April 18, 2022 from an Underwritten Public Offering

On April 12, 2022, the Company sold 11,274,510 shares of the Company's common stock in an underwritten registered public offering at an offering price of \$5.10 per share (the "Offering").

The Offering closed on April 18, 2022, and the Company received net proceeds of approximately \$54.5 million from the sale of the shares, after deducting the underwriting discounts and commissions and other offering expenses.

Caligan Partners LP ("Caligan"), the Company's largest stockholder, and Paul B. Manning, a member of the Company's board of directors, participated in the Offering and purchased shares of common stock in an aggregate amount of \$11.0 million at the public offering price per share and on the same terms as the other purchasers in the Offering. Caligan purchased 1,764,705 shares of common stock in the Offering for an aggregate purchase price of \$9.0 million and Paul B. Manning purchased 392,156 shares of common stock in the Offering for an aggregate purchase price of \$2.0 million.

Issuance of Common Stock on March 31, 2022 from Merger Transaction

On November 18, 2020 (the "Closing Date"), the Company completed the acquisition of RareGen as contemplated by that certain Agreement and Plan of Merger, dated as of June 29, 2020, as amended by a Limited Waiver and Modification to the Merger Agreement, dated as of August 3, 2020 (the "Merger Agreement"). On the Closing Date, an aggregate of 5,550,000 shares of the Company's common stock, were issued to RareGen members in exchange for all of the issued and outstanding RareGen equity. On March 31, 2022, an aggregate of 616,666 shares of the Company's common stock, which were held back on the Closing Date for indemnification purposes, were issued to RareGen members.

Issuance of Common Stock on April 13, 2021 from a Private Placement

On April 12, 2021, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with a fund and account managed by Caligan Partners LP and certain other accredited investors for the sale by the Company in a private placement (the "Private Placement") of an aggregate of 8,626,037 shares of the Company's Common Stock at a purchase price of \$2.52 per share. The Private Placement closed on April 13, 2021 and the Company received gross proceeds of approximately \$21.7 million.

Warrants

During the year ended December 31, 2022, no warrants to purchase shares of common stock were exercised. During the year ended December 31, 2021, 40,702 warrants to purchase shares of common stock were exercised.

As of December 31, 2022, outstanding warrants consisted of the following:

	<u>Number of warrants</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
A&R SVB Warrant - Initial Tranche (see Note 12)	250,000	\$ 5.14	January 6, 2032
SVB Warrant - Initial Tranche (see Note 12)	100,000	\$ 3.05	February 26, 2031
SVB Warrant - Term B and Term C Tranches (see Note 12)	100,000	\$ n/a	February 26, 2031
Other warrants	65,572	\$ 0.02	December 31, 2026

8. Stock-Based Compensation

2020 Long-Term Incentive Plan

The Company's 2020 Long-Term Incentive Plan (the "2020 Plan") provides for the granting of stock options, appreciation rights, stock awards, stock units, and other stock-based awards and for accelerated vesting under certain change of control transactions. The number of shares of the Company's common stock available for issuance under the 2020 Plan will automatically increase on January 1 of each year through 2030, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the Board of Directors (the "Evergreen Provision"). On January 1, 2023, the number of shares of common stock available for issuance under the 2020 Plan automatically increased by 2,580,716 shares to 2,851,611 shares pursuant to the Evergreen Provision. As of December 31, 2022, there were 270,895 shares available for future grants under the 2020 Plan.

The 2020 Plan replaced the Company's prior equity award plans and such plans have been discontinued, however, the outstanding awards will continue to remain in effect in accordance with their terms. Shares that are returned under these prior plans upon cancellation, termination or expiration of awards outstanding will not be available for grant under the 2020 Plan. As of December 31, 2022, the Company had a total of 673,880 shares of common stock reserved for issuance related to the remaining outstanding equity awards granted under the prior plans.

2022 Inducement Plan

On January 25, 2022, the Board approved the adoption of the Company's 2022 Inducement Plan (the "2022 Inducement Plan"). The 2022 Inducement Plan was recommended for approval by the Compensation Committee of the Board (the "Compensation Committee"), and subsequently approved and adopted by the Board without stockholder approval pursuant to Rule 5635(c)(4) of the rules and regulations of The Nasdaq Stock Market, LLC (the "Nasdaq Listing Rules").

The Company reserved 310,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the 2022 Inducement Plan, and the 2022 Inducement Plan will be administered by the Compensation Committee. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, equity awards under the 2022 Inducement Plan may only be made to an employee who has not previously been an employee or member of the Board (or any subsidiary of the Company), or following a bona fide period of non-employment by the Company (or a subsidiary of the Company), if he or she is granted such equity awards in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. As of December 31, 2022, the Company had a total of 12,800 shares available to issue under the 2022 Inducement Plan.

Employee Stock Purchase Plan

In November 2020, stockholders approved the Liquidia Corporation 2020 Employee Stock Purchase Plan (the “ESPP”). The ESPP allows eligible employees to purchase shares of the Company’s common stock at a discount through payroll deductions, subject to plan limitations. Unless otherwise determined by the administrator, the Company’s common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is 85% of the lesser of the fair market value of the Company’s common stock on the first and last trading day of the offering period. During the year ended December 31, 2022, 51,941 shares of common stock were issued under the ESPP. As of December 31, 2022, a total of 548,059 shares of the Company’s common stock are reserved for issuance under the ESPP. On January 1, 2023, in connection with an evergreen provision contained in the ESPP, an additional 150,000 shares of the Company’s common stock were reserved for issuance under the ESPP.

CEO Options

During December 2020, the Company issued a stock option grant to its then new Chief Executive Officer, Damian deGoo, to purchase up to 2,000,000 shares of the Company’s common stock (the “CEO Option”) at the exercise price on the grant date of \$3.00 per share. The CEO Option was issued outside of the 2020 Plan and 1,375,000 options vested in the fourth quarter of 2021 upon achievement of certain milestones and the passage of time, and ceased vesting upon the termination of Mr. deGoo’s employment on January 31, 2022. However, the CEO Option will remain exercisable so long as Mr. deGoo remains a director of the Company in accordance with his Separation Agreement. This change to vesting terms was treated as a modification of the original award resulting in a stock-based compensation charge of \$2.9 million during the year ended December 31, 2022.

On June 16, 2022, pursuant to Roger Jeffs’s executive employment agreement dated January 3, 2022 (the “Jeffs Employment Agreement”), the Company granted Dr. Jeffs 931,745 nonstatutory stock options (the “Second Tranche Option”), with an exercise price per share equal to the closing price of a share of common stock on the date of grant. The Second Tranche Option is subject to the following vesting schedule: 25% of the grant vested and became exercisable on January 3, 2023, and the remaining portion of the grant will become vested and exercisable, as applicable, in equal monthly installments over the following thirty-six months, subject to Dr. Jeffs’ continuous employment with the Company on each such vesting date. Notwithstanding the foregoing, in the event of a Change in Control (as defined in the 2020 Plan), 100% of the unvested portion of the Options shall become vested and exercisable as of the closing date of such Change in Control, provided that Dr. Jeffs is actively employed with the Company on such date.

Stock-Based Compensation Valuation and Expense

Total stock-based compensation expense recognized for employees and non-employees was as follows:

By Expense Category:	Year Ended December 31,	
	2022	2021
Research and development	\$ 1,409	\$ 1,923
General and administrative	7,889	4,823
Total stock-based compensation expense	<u>\$ 9,298</u>	<u>\$ 6,746</u>

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The following table summarizes the unamortized compensation expense and the remaining years over which such expense would be expected to be recognized, on a weighted-average basis, by type of award:

	As of December 31, 2022	
	Unamortized Expense	Weighted Average Remaining Recognition Period (Years)
Stock options	\$ 15,532	2.9
Restricted stock units	\$ 1,723	2.9

The Company accounts for its employee stock-based compensation plans using the fair value method. The fair value method requires the Company to estimate the grant-date fair value of its stock-based awards and amortize this fair value to compensation expense over the requisite service period or vesting term. The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options granted and purchase rights issued under the ESPP.

For restricted stock units (“RSUs”), the grant-date fair value is based upon the market price of the Company’s common stock on the date of the grant. This fair value is then amortized to compensation expense over the requisite service period or vesting term.

The following table summarizes the assumptions used for estimating the fair value of stock options granted under the Black-Scholes option-pricing model during the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Expected dividend yield	—	—
Risk-free interest rate	1.46% - 3.96%	0.62% - 1.67%
Expected volatility	90% - 95%	91% - 96%
Expected life (years)	5.8 - 6.1	5.2 - 6.1

The following table summarizes the assumptions used for estimating the fair value purchase rights granted to employees under the ESPP under the Black-Scholes option-pricing model during the year ended December 31, 2022:

	Year Ended December 31, 2022
Expected dividend yield	—
Risk-free interest rate	0.69% - 3.92%
Expected volatility	80% - 129%
Expected life (years)	0.50

The following describes the Company’s methodology for determining each assumption:

Expected Dividend Yield: The dividend yield percentage is zero because the Company has not historically paid dividends and does not expect to for the foreseeable future.

Risk-Free Interest Rate: The risk-free interest rate is based on the U.S. Treasury yield curve approximating the term of the expected life of the award in effect on the date of grant.

Expected Volatility: Expected stock price volatility is based on a weighted average of several peer public companies and the historical volatility of the Company’s common stock during the period for which it has traded since the initial public offering. For purposes of identifying peer companies, the Company considered characteristics such as industry, length of trading history and similar vesting terms.

Expected Life: The expected life represents the period the awards are expected to be outstanding. The Company’s historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore, the Company estimates the expected term by using the simplified method.

Stock Options

The following table summarizes the Company’s stock option activity during the year ended December 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	5,598,009	\$ 4.19		
Granted	4,489,277	5.22		
Exercised	(233,356)	3.60		
Cancelled	(1,455,668)	5.73		
Outstanding as of December 31, 2022	<u>8,398,262</u>	<u>\$ 4.49</u>	<u>8.5</u>	<u>\$ 17,628</u>
Exercisable as of December 31, 2022	<u>3,327,055</u>	<u>\$ 4.03</u>	<u>7.8</u>	<u>\$ 9,442</u>
Vested and expected to vest as of December 31, 2022	<u>7,914,670</u>	<u>\$ 4.47</u>	<u>8.5</u>	<u>\$ 16,849</u>

The weighted average fair value for options granted during the years ended December 31, 2022 and 2021 was \$3.94 and \$2.23 per share, respectively. The aggregate intrinsic value of stock options in the table above represents the difference between the \$6.37 closing price of the Company’s common stock as of December 31, 2022 and the exercise price of outstanding, exercisable, and vested and expected to vest in-the-money stock options.

Additional information related to our stock options is summarized below:

	December 31,	
	2022	2021
Cash proceeds from options exercised	\$ 837	\$ 41
Aggregate intrinsic value of options exercised	\$ 553	\$ 21
Fair value of options vested	\$ 4,427	\$ 6,169

Restricted Stock Units

Restricted Stock Units (“RSUs”) represent the right to receive shares of common stock of the Company at the end of a specified time period or upon the achievement of a specific milestone. RSUs can only be settled in shares of the Company’s common stock. During the year ended December 31, 2022, the Board of Directors approved grants of an aggregate of 503,403 time-based RSUs to employees. 93,834 of these RSUs were issued to Dr. Rajeev Saggur, the Company’s Chief Medical Officer since July 2022, pursuant to his employment agreement of which 50% will vest on the first anniversary of his start date with the balance to vest quarterly through July 2025. 63,230 of these RSUs were issued to Dr. Jeffs pursuant to his employment agreement and vest quarterly through January 2023. The remaining 346,339 RSUs vest over a four-year period similar to stock options granted to employees.

The following table summarizes the Company’s RSU activity during the year ended December 31, 2022:

	Number of RSUs	Weighted Average Grant-Date Fair Value (per RSU)
Unvested as of December 31, 2021	15,204	\$ 3.31
Granted	503,403	5.64
Vested	(54,181)	4.91
Forfeited	(56,700)	6.25
Unvested as of December 31, 2022	<u>407,726</u>	<u>\$ 5.57</u>

9. Revenue From Contracts With Customers

On August 1, 2018, the Company partnered with Sandoz in the Promotion Agreement to launch the first-to-file generic of Trepstinil Injection for the treatment of patients with PAH. Under the Promotion Agreement, the Company provides certain promotional and nonpromotional activities on an exclusive basis for the product in the United States of America for the treatment of PAH. The Company paid Sandoz \$20.0 million at the inception of the Promotion Agreement, in consideration for the right to conduct the promotional and nonpromotional activities for the product. In exchange for its services, the Company is entitled to receive a portion of net profits, as defined within the Promotion Agreement, based on specified profit levels associated with the product. See Note 2 for Revenue Recognition accounting policy.

In accordance with the Promotion Agreement, Liquidia PAH receives consideration from Sandoz in the form of a share of Net Profits for the promotional activities it performs. The share of Net Profits received is subject to adjustments from Sandoz for items such as distributor chargebacks, rebates, inventory returns, inventory write-offs and other adjustments (the “Net Profits Adjustment”). The Company expects to refund certain amounts to Sandoz through a reduction of the cash received from future Net Profits generated under the Promotion Agreement. As of December 31, 2022 and 2021, a \$0.5 million refund liability is offset against accounts receivable from Sandoz.

The Company derived approximately 98% and 99% of its revenue from the Promotion Agreement for the years ended December 31, 2022 and 2021, respectively.

10. Income Taxes

No provision for federal and state income tax expense has been recorded for the years ended December 31, 2022 and 2021 due to the valuation allowance recorded against the net deferred tax asset and recurring losses.

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows as of December 31, 2022 and 2021:

	2022	2021
Deferred income tax assets:		
Tax loss carryforwards	\$ 59,241	\$ 57,302
Research and development credits	3,942	4,204
R&D section 174 costs	4,584	—
Share-based compensation	4,637	3,213
Lease liability	1,157	1,627
Compensation	621	800
Fixed assets	369	250
Patent amortization	476	325
Accrued litigation costs	1,546	1,641
Settlement reserve	123	141
Other	2	1
Valuation allowance	(74,549)	(66,987)
Total deferred income tax assets	2,149	2,517
Deferred income tax liabilities:		
Section 481(a) adjustment	21	48
Intangible assets	1,546	1,679
Right of use asset	582	790
Total deferred income tax liabilities	2,149	2,517
Total net deferred tax	\$ —	\$ —

As of December 31, 2022 and 2021, the Company has established a full valuation allowance against its net deferred tax assets since, at the time, the Company could not assert that it was more likely than not that its deferred tax assets would be realized. As a result, there was an increase in the valuation allowance in 2022 of approximately \$7.6 million.

As of December 31, 2022, the Company had federal and state income tax loss carryforwards of \$278.7 million and \$304.1 million, respectively, which begin to expire in 2024 for federal purposes and in 2023 for state purposes. In addition, the Company has tax credit carryforwards for federal tax purposes of approximately \$4.3 million as of December 31, 2022, which begin to expire in 2026. The utilization of net operating loss and tax credit carryforwards to reduce future income taxes will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the loss carryforwards.

The Internal Revenue Code of 1986, as amended, contains provisions which limit the ability to utilize the net operating loss carryforwards in the case of certain events, including significant changes in ownership interests. If the Company's net operating loss carryforwards are limited, and the Company has taxable income which exceeds the permissible yearly net operating loss carryforwards, the Company would incur a federal income tax liability even though net operating loss carryforwards would be available in future years.

The reasons for the difference between actual income tax expense for the years ended December 31, 2022 and 2021 and the amount computed by applying the statutory federal income tax rate to income before income tax are as follows:

	2022		2021	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate	\$ (8,613)	21.0 %	\$ (7,261)	21.0 %
State income taxes, net of federal tax benefit	(1,787)	4.4	(2,626)	7.6
Non-deductible expenses	1	—	—	—
Stock-based compensation	310	(0.8)	286	(0.8)
Credits	—	—	(262)	0.8
Deferred tax true-up	1,159	(2.9)	—	—
Change in state rate	1,368	(3.3)	4,454	(12.9)
Other	—	—	18	(0.1)
Change in valuation allowance	7,562	(18.4)	5,391	(15.6)
Provision for income taxes	<u>\$ —</u>	<u>— %</u>	<u>\$ —</u>	<u>— %</u>

The Company has determined that there may be a future limitation on the Company's ability to utilize its entire federal R&D credit carryover. Therefore, the Company recognized an uncertain tax benefit associated with the federal R&D credit carryover during the years ended December 31, 2022 and 2021, as follows:

Balance at December 31, 2020	\$ 403
Increases related to 2021	52
Balance at December 31, 2021	455
Decreases related to 2022	(65)
Balance at December 31, 2022	<u>\$ 390</u>

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The Company has determined that it had no other material uncertain tax benefits for the year ended December 31, 2022. The Company's policy for recording interest and penalties related to uncertain tax provisions is to record them as a component of the provision for income taxes. The Company did not have any accrued interest or penalties associated with any unrecognized tax positions as of December 31, 2022 and 2021, and there were no such interest or penalties recognized during the years ended December 31, 2022 and 2021.

On November 18, 2021, North Carolina enacted the 2021 Appropriations Act, which included a gradual corporate income tax rate decrease from the current 2.5% to 0% by 2030. The Company is in a cumulative loss position and does not have significant deferred tax liabilities that can be utilized as a source of taxable income in the future. Therefore, in 2021, the Company reduced its deferred tax asset related to North Carolina NOLs to zero, as no benefit is expected to be realized from these deferred tax assets prior to 2030 when there would be no income tax in North Carolina. The reduction in the value of the deferred tax assets resulted in \$5.7 million of cumulative tax expense, which is fully offset by the reduction in the corresponding valuation allowance. If the Company becomes profitable prior to 2030, the Company will recognize an income tax benefit related to the portion of its deferred tax asset related to North Carolina NOLs utilized.

The Company has all tax years open to examination by federal tax and state tax jurisdictions. No income tax returns are currently under examination by taxing authorities.

11. Leases

The Company leases certain laboratory space, office space, and equipment. Leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of Topic 842, the Company combines lease and non-lease components, if any. Most leases include one or more options to renew. The exercise of lease renewal options is at the Company's sole discretion. Certain leases also include options to purchase the leased property. Consistent with past practice and current intent, the Company has recognized all such purchase options as part of its right-of-use assets and lease liabilities. The depreciable life of assets and leasehold improvements are limited by the expected lease term unless there is a transfer of title or purchase option reasonably certain of exercise. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company conducts its operations from leased facilities of approximately 45,000 square feet in Morrisville, North Carolina with a lease expiration date of October 31, 2026. In addition, the Company leases specialized laboratory equipment under finance leases. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset.

The Company does not have access to certain inputs used by its lessors to calculate the rate implicit in its finance leases. As such, the Company utilized its estimated incremental borrowing rate for the discount rate applied to its finance leases. The original incremental borrowing rate used on finance leases was 7.5%. During February 2021, the Company exercised the lease purchase option for certain finance leases that had expired and entered into a lease modification agreement with its existing lessor for certain other finance leases. The modification resulted in an increase in the remaining lease term of between 24 and 48 months as well as a decrease in the monthly payments associated with the respective modified leases. The incremental borrowing rate used on the modified leases was 6.5%. The lease modification had an immaterial impact on the Company's 2021 consolidated financial statements.

The Company's lease cost is reflected in the accompanying Statements of Operations and Comprehensive Loss as follows:

	Classification	Year Ended December 31,	
		2022	2021
Operating lease cost:			
Fixed lease cost	Research and development	\$ 702	\$ 702
Fixed lease cost	General and administrative	78	78
Finance lease cost:			
Amortization of lease assets	Research and development	135	267
Interest on lease liabilities	Interest expense	32	43
Total Lease Cost		<u>\$ 947</u>	<u>\$ 1,090</u>

The weighted average remaining lease term and discount rates as of December 31, 2022 were as follows:

Weighted average remaining lease term (years):	
Operating leases	3.8
Finance leases	1.9
Weighted average discount rate:	
Operating leases	10.3 %
Finance leases	6.5 %

The discount rate for operating leases was estimated based upon market rates of collateralized loan obligations of comparable companies on comparable terms.

The future minimum lease payments as of December 31, 2022 were as follows:

Year ending December 31:	Operating Leases	Finance Leases	Total
2023	\$ 1,283	\$ 195	\$ 1,478
2024	1,317	115	1,432
2025	1,356	64	1,420
2026	1,158	—	1,158
Total minimum lease payments	5,114	374	5,488
Less: Interest	(882)	(22)	(904)
Present value of lease liabilities	\$ 4,232	\$ 352	\$ 4,584

12. Long-Term Debt

Long-term debt consisted of the following:

	Maturity Date	December 31, 2022	December 31, 2021
A&R Silicon Valley Bank term loan	December 1, 2025	\$ 19,879	\$ —
Silicon Valley Bank term loan	September 1, 2024	—	10,410
Long-term debt		\$ 19,879	\$ 10,410

On January 9, 2023, the Company entered into a Revenue Interest Financing Agreement (the “RIFA”) with HealthCare Royalty Partners IV, L.P. (“HCR”) and HealthCare Royalty Management, LLC, pursuant to which and subject to the terms and conditions contained therein, the HCR agreed to pay the Company an aggregate investment amount of up to \$100.0 million (the “Investment Amount”). \$32.5 million of the Investment Amount was funded on January 27, 2023, \$22.4 million of which was used to satisfy the Company’s existing obligations under the A&R SVB LSA (defined below), with the excess proceeds funded to the Company. Note 16. Subsequent Events for more information.

Amended and Restated Loan and Security Agreement dated January 7, 2022

On January 7, 2022 (the “A&R SVB LSA Effective Date”), the Company entered into an Amended and Restated Loan and Security Agreement with SVB and SVB Innovation Credit Fund VIII, L.P. (“Innovation”) (the “A&R SVB LSA”). The A&R SVB LSA established a term loan facility in the aggregate principal amount of up to \$40.0 million available in three tranches. \$20.0 million was funded on the A&R SVB LSA Effective Date, \$10.5 million of which was used to satisfy its existing obligations under the SVB LSA (see below). The Company accounted for the repayment of the SVB LSA in accordance with ASC 405-20, *Extinguishments of Liabilities*, which resulted in a loss on extinguishment during the year ended December 31, 2022 of \$1.0 million.

The A&R SVB LSA was to mature on December 1, 2025 and consisted of interest-only payments through December 31, 2023. The outstanding principal amount of the term loans accrued interest at a floating rate per year equal to the greater of 7.25% and the prime rate of interest plus 4.0%.

The A&R SVB LSA contains customary affirmative and negative covenants, including but not limited to certain financial covenants, protection of intellectual property rights, the disposition of certain assets, and material adverse changes. The Company was in compliance with all such covenants at December 31, 2022.

As an inducement to enter into the A&R SVB LSA, the Company issued SVB, Innovation, and Innovation Credit Fund VIII-A L.P. (“Innovation Credit”) certain warrants to purchase shares of the Company’s common stock pursuant to the Warrant to Purchase Stock agreements by and between the Company and each recipient (collectively, the “A&R SVB Warrants”). The respective A&R SVB Warrants provided recipients the right to obtain a total of 250,000 shares of the Company’s stock at an exercise price of \$5.14 per share. The A&R SVB Warrants provide an option for a cashless exercise.

In accordance with ASC 470, *Debt*, the value of the A&R SVB Warrants and A&R SVB LSA was allocated using a relative fair value allocation. The fair value of the A&R SVB Warrants was determined to be \$1.3 million and included in additional paid-in-capital, of which \$0.7 million was recognized as a component of the loss on extinguishment and \$0.6 million as a debt discount. The remaining \$19.4 million was allocated to the A&R SVB LSA. In addition, the Company incurred fees of less than \$0.1 million, which were recorded as debt issuance costs. The debt discount and debt issuance costs are being amortized to interest expense and the Final Payment Fee is being accreted using the effective interest method over the term of the A&R SVB LSA.

The Company evaluated the features of the A&R SVB LSA and A&R SVB Warrants in accordance with ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*. The Company determined that the A&R SVB LSA and A&R SVB Warrants did not contain any features that would qualify as a derivative or embedded derivative. In addition, the Company determined that the A&R SVB Warrants should be classified as equity. The estimated fair value of the A&R SVB Warrant was calculated using the Black-Scholes Option Pricing Model based on the following inputs:

Expected dividend yield	—
Risk-free interest rate	1.76%
Expected volatility	97.2%
Expected life (years)	10.0

Loan and Security Agreement dated February 26, 2021

The Company entered into a Loan and Security Agreement with SVB on February 26, 2021 (the “Effective Date”) and a First Loan Modification Agreement with SVB on August 26, 2021 (the “SVB LSA”). The SVB LSA established a term loan facility in the aggregate principal amount of up to \$20.5 million, of which \$10.5 million was funded on March 1, 2021 and was used to satisfy the Company’s existing obligations of \$9.4 million, with the excess proceeds funded to the Company. The Company accounted for the repayment of the loan obligation in accordance with ASC 405-20, *Extinguishments of Liabilities*, which resulted in a loss on extinguishment during the nine months ended September 30, 2021 of less than \$0.1 million.

In connection with the Loan Agreement, the Company issued to SVB a warrant, dated as of the Effective Date to purchase 200,000 shares of common stock (the “SVB Warrant”), of which 100,000 shares vested on the Effective Date, with an exercise price per share equal to \$3.05 (the “Initial Tranche”). The remaining 100,000 shares did not vest as additional amounts were not funded under the SVB LSA (the “Term B and C Tranches”).

The Company evaluated the features of the SVB LSA and SVB Warrant in accordance with ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*. The Company determined that the Loan Agreement and Warrant did not contain any features that would qualify as a derivative or embedded derivative. In addition, the Company determined that the SVB Warrant should be classified as equity. The estimated fair value of the SVB Warrant of was calculated using the Black-Scholes Option Pricing Model based on the following inputs:

Expected dividend yield	—
Risk-free interest rate	1.43%
Expected volatility	90.8%
Expected life (years)	10.0

13. Defined Contribution Retirement Plan

The Company maintains a defined contribution 401(k) retirement plan for its employees, pursuant to which employees may elect to contribute a portion of their compensation on a tax-deferred basis. The Company matches 100% of eligible employee contributions up to 4% of an employee's salary, subject to the maximum amount permitted by the Internal Revenue Code. The Company's matching contributions were \$0.4 million and \$0.3 million for the years ended December 31, 2022 and 2021, respectively.

14. Legal Proceedings

YUTREPIA-Related Litigation

In June 2020, United Therapeutics filed a complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA) (the "Hatch-Waxman Litigation"), asserting infringement by the Company of U.S. Patent Nos. 9,604,901, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®" (the "'901 Patent"), and 9,593,066, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®" (the "'066 Patent"), relating to United Therapeutics' Tyvaso®, a nebulized treprostinil solution for the treatment of PAH. United Therapeutics' complaint was in response to the Company's NDA for YUTREPIA, filed with the FDA, requesting approval to market YUTREPIA, a dry powder inhalation of treprostinil for the treatment of PAH. The YUTREPIA NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso® as the reference listed drug.

In July 2020, the U.S. Patent and Trademark Office (the "USPTO") issued U.S. Patent No. 10,716,793 (the "'793 Patent"), entitled "Treprostinil Administration by Inhalation", to United Therapeutics. In July 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the '793 Patent by the practice of YUTREPIA.

In June 2021, the Court held a claim construction hearing. Based on the Court's construction of the claim terms, United Therapeutics filed a stipulation of partial judgment with respect to the '901 Patent in December 2021 under which United Therapeutics agreed to the entry of judgment of the Company's non-infringement of the '901 Patent. United Therapeutics preserved its appellate rights with respect to the '901 Patent in the event the Court's construction of those terms is reversed.

Trial proceedings in the Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the '066 Patent were invalid, that the remaining asserted claims of the '066 Patent were not infringed by the Company, and that all of the asserted claims of the '793 Patent were both valid and infringed by the Company, based on the arguments presented by the Company in the Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent, which will be in 2027. Both the Company and United Therapeutics have appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In September of 2022, following entry of final judgment, the Company filed a motion requesting that Judge Andrews stay enforcement of the order delaying the effective date of any final approval by the FDA of YUTREPIA until the expiration of the '793 Patent. Briefing on the motion for stay of enforcement is complete, and the motion remains pending with the Court.

In March 2020, the Company filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (the "PTAB") of the USPTO. One petition was for *inter partes* review of the '901 Patent and sought a determination that the claims in the '901 Patent are invalid, and a second petition was for *inter partes* review of the '066 Patent and sought a determination that the claims in the '066 Patent are invalid. In October 2020, the PTAB instituted an *inter partes* review of the '901 Patent and concurrently denied institution on the '066 Patent, stating that the '066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. In

October 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '901 Patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the '901 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In January 2021, the Company filed a petition for *inter partes* review with the PTAB relating to the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. In August 2021, the PTAB instituted an *inter partes* review of the '793 Patent, finding that the Company had demonstrated a reasonable likelihood that it would prevail with respect to showing that at least one challenged claim of the '793 patent is unpatentable as obvious over the combination of certain prior art cited by the Company in its petition to the PTAB. In July 2022, the PTAB ruled in the Company's favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '793 Patent. The rehearing request was denied in February 2023. United Therapeutics has publicly stated that it will appeal the PTAB's decision with respect to the '793 Patent. The PTAB's decision with respect to the '793 Patent will not override Judge Andrews' order in the Hatch-Waxman Litigation that YUTREPIA may not be approved due to infringement of the '793 Patent unless and until the decision of the PTAB is affirmed on appeal.

Trade Secret Litigation

In December 2021, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, alleging that the Company and a former United Therapeutics employee, who later joined the Company as an employee many years after terminating his employment with United Therapeutics, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2022, the Company's co-defendant in the lawsuit removed the lawsuit to the United States District Court for the Middle District of North Carolina. Subsequently, in January 2022, United Therapeutics filed an amended complaint eliminating their claim under the federal Defend Trade Secrets Act and a motion seeking to have the case remanded to North Carolina state court. In April 2022, the Court granted United Therapeutics' motion to have the case remanded to North Carolina state court. In May 2022, the Company filed a motion to dismiss all of the claims made by United Therapeutics in the lawsuit. The motion was denied by the Court in October 2022. Discovery in the case is ongoing.

RareGen Litigation

In April 2019, Sandoz and Liquidia PAH (then known as RareGen) filed a complaint against United Therapeutics and Smiths Medical in the District Court of New Jersey (Case No. No. 3:19-cv-10170), (the "RareGen Litigation"), alleging that United Therapeutics and Smiths Medical violated the Sherman Antitrust Act of 1890, state law antitrust statutes and unfair competition statutes by engaging in anticompetitive acts regarding the drug treprostinil for the treatment of PAH. In March 2020, Sandoz and Liquidia PAH filed a first amended complaint adding a claim that United Therapeutics breached a settlement agreement that was entered into in 2015, in which United Therapeutics agreed to not interfere with Sandoz's efforts to launch its generic treprostinil, by taking calculated steps to restrict and interfere with the launch of Sandoz's competing generic product. United Therapeutics developed treprostinil under the brand name Remodulin® and Smiths Medical manufactured a pump and cartridges that are used to inject treprostinil into patients continuously throughout the day. Sandoz and Liquidia PAH allege that United Therapeutics and Smiths Medical entered into anticompetitive agreements (i) whereby Smiths Medical placed restrictions on the cartridges such that they can only be used with United Therapeutics' branded Remodulin® product and (ii) requiring Smiths Medical to enter into agreements with specialty pharmacies to sell the cartridges only for use with Remodulin®.

In November 2020, Sandoz and Liquidia PAH entered into a binding term sheet (the "Term Sheet") with Smiths Medical in order to resolve the outstanding RareGen Litigation solely with respect to disputes between Smiths Medical, Liquidia PAH and Sandoz. In April 2021, Liquidia PAH and Sandoz entered into a Long Form Settlement Agreement (the "Settlement Agreement") with Smiths Medical to further detail the terms of the settlement among such parties as reflected in the Term Sheet. Pursuant to the Term Sheet and the Settlement Agreement, the former RareGen members and Sandoz received a payment of \$4.25 million that was evenly split between the parties. In addition, pursuant to the

Term Sheet and Settlement Agreement, Smiths Medical disclosed and made available to Sandoz and Liquidia PAH certain specifications and other information related to the cartridge that Smiths Medical developed and manufactures for use with the CADD-MS 3 infusion pump (the “CADD-MS 3 Cartridge”). Pursuant to the Settlement Agreement, Smiths Medical also granted Liquidia PAH and Sandoz a non-exclusive, royalty-free license in the United States to Smiths Medical’s patents and copyrights associated with the CADD-MS 3 Cartridge and certain other information for use of the CADD-MS 3 pump and the CADD-MS 3 Cartridges. Smiths also agreed in the Settlement Agreement to provide information and assistance in support of Liquidia PAH’s efforts to receive FDA clearance for the RG 3ml Medication Cartridge (the “RG Cartridge”) and to continue to service certain CADD-MS 3 pumps that are available for use with the Treprostinil Injection through January 1, 2025. Liquidia PAH and Sandoz agreed, among other things, to indemnify Smiths from certain liabilities related to the RG Cartridge.

In September 2021, United Therapeutics filed a motion for summary judgment with respect to all of the claims brought by Sandoz and Liquidia PAH against United Therapeutics. At the same time, Sandoz filed a motion for summary judgment with respect to the breach of contract claim. In March 2022, the Court issued an order granting partial summary judgment to United Therapeutics with respect to the antitrust and unfair competition claims, denying summary judgment to United Therapeutics with respect to the breach of contract claim, and granting partial summary judgment to Sandoz with respect to the breach of contract claim. The RareGen Litigation will now proceed to a trial to determine the amount of damages due from United Therapeutics to Sandoz with respect to the breach of contract claim. The Court has ordered that a three-day bench trial will be scheduled for summer of 2023.

Under the Promotion Agreement, all proceeds from the litigation will be divided evenly between Sandoz and Liquidia PAH. Under the litigation finance agreements that Liquidia PAH has entered into with Henderson and PBM, any net proceeds received by Liquidia PAH with respect to the RareGen Litigation will be divided between Henderson and PBM.

15. Commitments and Contingencies

Mainbridge Health Care Device Development and Supply Agreement

On December 1, 2022, the Company entered into a Device Development and Supply Agreement (the “Pump Development Agreement”) with Mainbridge Health Partners, LLC (“Mainbridge”) and Sandoz Inc. (“Sandoz”). The Pump Development Agreement provides for the cooperation between the Company, Sandoz and Mainbridge to develop a new pump that is suitable for the subcutaneous administration of Treprostinil Injection. Mainbridge will perform all development, validation and testing activities required for the pump and related consumables in anticipation of submitting a 510(k) clearance application for the pump to the FDA in 2023. In connection with the Pump Development Agreement, the Company and Sandoz have agreed to pay Mainbridge certain future contingent milestone payments in accordance with the terms and conditions set forth therein.

UNC License Agreement

The Company performs research under a license agreement with The University of North Carolina at Chapel Hill (“UNC”) as amended to date (the “UNC License Agreement”). As part of the UNC License Agreement, the Company holds an exclusive license to certain research and development technologies and processes in various stages of patent pursuit, for use in its research and development and commercial activities, with a term until the expiration date of the last to expire patent subject to the UNC License Agreement, subject to industry standard contractual compliance. Under the UNC License Agreement, the Company is obligated to pay UNC royalties equal to a low single digit percentage of all net sales of drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC License Agreement, including YUTREPIA. The Company may grant sublicenses of UNC licensed intellectual property in return for specified payments based on a percentage of any fee, royalty or other consideration received.

Chasm Technologies

In March 2012, the Company entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to the Company's manufacturing capabilities during the term of the agreement. The Company agreed to pay future contingent milestones and royalties on net sales totaling no more than \$1.5 million, none of which has been earned as of December 31, 2022.

Employment Agreements

The Company has agreements with certain employees which require the funding of a specific level or payments if certain events, such as a change in control or termination without cause, occur.

Purchase Obligations

The Company enters into contracts in the normal course of business with contract service providers to assist in the performance of research and development and manufacturing activities. Subject to required notice periods and obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. As of December 31, 2022, the Company has non-cancelable commitments for product manufacturing costs of approximately \$3.7 million for the year ending 2023.

In addition, the Company has entered into a multi-year supply agreement with LGM Pharma, LLC (LGM) to produce active pharmaceutical ingredients for YUTREPIA. Under the supply agreement with LGM, the Company is required to provide rolling forecasts, a portion of which will be considered a binding, firm order, subject to an annual minimum purchase commitment of \$2.7 million for the term of the agreement. The agreement expires five years from the first marketing authorization approval of YUTREPIA.

Other Contingencies and Commitments

The Company from time-to-time is subject to claims and litigation in the normal course of business, none of which the Company believes represent a risk of material loss or exposure. See Note 14 for further discussion of pending legal proceedings.

In addition to the commitments described above, the Company is party to other commitments, including non-cancelable leases and long-term debt, which are described elsewhere in these financial statements.

16. Subsequent Events

Revenue Interest Financing Agreement

On January 9, 2023, the Company entered into a Revenue Interest Financing Agreement (the "RIFA") with HealthCare Royalty Partners IV, L.P. ("HCR") and HealthCare Royalty Management, LLC. Pursuant to the RIFA and subject to customary closing conditions, HCR has agreed to pay the Company an aggregate investment amount of up to \$100.0 million (the "Investment Amount"). Under the terms of the RIFA, \$32.5 million of the Investment Amount was funded on January 27, 2023 (the "Initial Investment Amount"), \$22.4 million of which was used to satisfy in full and retire the Company's indebtedness under the A&R SVB LSA, with the excess proceeds less transaction costs of approximately \$0.7 million funded to the Company.

An additional \$7.5 million of the Investment Amount will be funded fifteen business days after a request made by the Company to HCR to fund acquisition of rights, whether in the form of an acquisition, license, joint venture or similar transaction, to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension, an additional \$35.0 million of the Investment Amount will be funded fifteen business days after the earlier of regulatory approval of YUTREPIA or a favorable determination relating to the asserted patents in the ongoing patent litigation with United Therapeutics, and the remaining \$25.0 million of the Investment Amount will be funded fifteen

business days after the mutual agreement of HCR and the Company to fund such amount (the “Fourth Investment Amount”).

As consideration for the Investment Amount and pursuant to the RIFA, the Company has agreed to pay HCR a tiered royalty on annual net revenue of the Company after the first commercial sale of YUTREPIA (the “Revenue Interests”). Except as may otherwise be mutually agreed to in connection with the funding of the Fourth Investment Amount, the applicable tiered percentage will range from 3.60% to 10.00% on the first \$250 million on annual net revenue, 1.44% to 4.00% on the next \$250 million in annual net revenue, and 0.36% to 1.00% on all annual net revenue in excess of \$500 million. The specific royalty rate within such ranges will depend upon the total amount advanced by the HCR and the Company’s achievement of a certain annual net revenue threshold for the calendar year 2025. The Company will also make certain fixed quarterly payments to HCR, plus an additional amount on a ratable basis to reflect the funding of additional amounts by HCR under the RIFA. The Company will be required to make additional payments to HCR in the event that the first commercial sale of YUTREPIA does not occur by June 30, 2025 and certain minimum quarterly royalty payments beginning in 2026.

If HCR has not received cumulative minimum payments from the Company equal to 60% of the amount funded to date by December 31, 2026 or 100% of the amount funded to date by December 31, 2028, the Company must make a cash payment immediately following each applicable date to HCR sufficient to gross HCR up to such minimum amounts after giving full consideration of the cumulative amounts paid to HCR by the Company through each date. The net sale thresholds described above are not to be interpreted as financial guidance or projections for future net sales of the Company.

HCR’s rights to receive the Revenue Interests will terminate on the date on which HCR has received payments equal to 175% of funded portion of the Investment Amount less the aggregate amount of all payments made to HCR as of such date (the “Hard Cap”), plus an amount, if any, that HCR would need to receive to yield an internal rate of return on the funded Investment Amount equal to 18% (the “IRR True-Up Payment”), unless the RIFA is earlier terminated. If a change of control of the Company occurs, HCR may accelerate payments due under the RIFA up to the Hard Cap, plus the IRR True-Up Payment, plus any other obligations payable under the RIFA. Upon the occurrence of an event of default, HCR may accelerate payments due under the RIFA up to the Hard Cap, plus the IRR True-Up Payment, plus any other obligations payable under the RIFA.

The RIFA contains customary affirmative and negative covenants and customary events of default and other events that would cause acceleration, including, among other things, the occurrence of certain material adverse events or the material breach of certain representations and warranties and specified covenants, in which event HCR may elect to terminate the RIFA and require the Company to make payments to HCR equal to the lesser of the Hard Cap, plus any other obligations payable under the RIFA, or the funded portion of the Investment Amount, minus payments received by HCR in respect of the Revenue Interests, plus the IRR True-Up Payment. If the FDA grants final approval to an inhaled treprostinil product therapeutically equivalent to YUTREPIA and HCR has not received 100% of the amount funded by HCR to date, then the Company will be required to make payments to HCR equal to 100% of the amount funded by HCR to date, minus payments received by HCR in respect of the Revenue Interests.

In addition, the RIFA contains a financial covenant that requires us to maintain cash and cash equivalents in an amount at least equal to \$7.5 million during the calendar year beginning on January 1, 2024 and at least equal to \$15.0 million for the remainder of the payment term after the calendar year ended December 31, 2024.

As of the filing date of this Annual Report on Form 10-K, the Company was not aware of any breach of covenants, occurrence of material adverse event, nor had it received any notice of event of default from HCR.

REVENUE INTEREST FINANCING AGREEMENT

by and among

LIQUIDIA TECHNOLOGIES, INC.,
as the Company,

HEALTHCARE ROYALTY PARTNERS IV, L.P.,
as the Investor

and

HCR COLLATERAL MANAGEMENT, LLC,
as the Investor Representative

Dated January 9, 2023

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REVENUE INTEREST FINANCING AGREEMENT

This REVENUE INTEREST FINANCING AGREEMENT (this “Agreement”) dated as of January 9, 2023 (the “Effective Date”), is by and among LIQUIDIA TECHNOLOGIES, INC., a Delaware corporation (the “Company”), HEALTHCARE ROYALTY PARTNERS IV, L.P., a Delaware limited partnership (the “Investor”), and HCR COLLATERAL MANAGEMENT, LLC, a Delaware limited liability company (the “Investor Representative”), solely in its capacity as agent for, and representative of, the Investor. Each of the Company and the Investor are referred to in this Agreement as a “Party” and, collectively, as the “Parties”.

WITNESSETH:

WHEREAS, the Company is developing the Existing Yutrepia Product (defined in Section 1.1) for the purposes of sale in the United States; and

WHEREAS, the Company desires to secure financing from the Investor, and the Investor has indicated its willingness to provide financing, upon and subject to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual agreements, representations and warranties set forth herein and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, intending to be legally bound, the Parties hereto covenant and agree as follows:

ARTICLE I DEFINED TERMS AND RULES OF CONSTRUCTION

Section 1.1 Defined Terms. The following terms, as used herein, shall have the following respective meanings:

“Acquisition” means any acquisition by any member of the Company Group, whether by purchase, merger, consolidation, contribution or otherwise, of (a) at least a majority of the assets or property and/or liabilities, or a business line, product line, unit or division of, any other Person, (b) Equity Interests of any other Person such that such other Person becomes a Subsidiary and (c) additional Equity Interests of any Subsidiary not then held by any member of the Company Group.

“Additional Amounts” has the meaning set forth in Section 3.1(i).

“Affiliate” means, with respect to any Person, any other Person that, directly or indirectly, controls, is controlled by or is under common control with such Person. For purposes of this definition, “control” of a Person means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of securities entitled to elect the Board of Directors or management board, by Contract or otherwise, and the terms “controlled” and “controlling” have meanings correlative to the foregoing.

“Agreement” has the meaning set forth in the preamble.

“Annual Net Revenues” means, with respect to any Calendar Year, the aggregate amount of worldwide Net Revenues for that Calendar Year.

“Anti-Corruption Laws” means all Laws of any jurisdiction applicable to the Company or any of its Affiliates from time to time concerning or relating to bribery or corruption, including without limitation the United States Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 and other similar legislation in any other jurisdictions.

“Anti-Terrorism Laws” means any Laws relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the Laws comprising or implementing the Bank Secrecy Act, the Trading with the Enemy Act, as amended, and each of the foreign assets control regulations of the United States Treasury Department (31 CFR, Subtitle B, Chapter V, as amended) and any other enabling legislation or executive order relating thereto.

“Applicable Law” means, with respect to any Person, all Laws, rules, regulations and orders of Governmental Authorities applicable to such Person or any of its properties or assets.

“Applicable Tiered Percentage” means, for any given Calendar Quarter, the percentage royalty rate for calculating the Included Product Payment Amount, as set forth in Table 1 on Schedule 1.1-1 and corresponding to (a) the row indicating the then-current Investment Amount as of the last day of such Calendar Quarter and (b) the column indicating the applicable portion of Annual Net Revenues; provided that, if Net Sales attributable to the Existing Yutrepia Product in the United States for the Calendar Year ending December 31, 2025, do not exceed [***], then the percentage royalty rate for calculating the Included Product Payment Amount shall be determined by reference to Table 2 on Schedule 1.1-1 (and not Table 1) for the Calendar Quarter beginning January 1, 2026 and thereafter.

“Asserted Patents” means U.S. Patent Nos. 9,593,066; 9,604,901; and 10,716,793.

“Audited Financial Statements” means the audited consolidated balance sheets of the Parent Company and its Subsidiaries for the fiscal year ended December 31, 2021, and the related consolidated statements of operations and comprehensive loss, stockholders’ equity and cash flows for such fiscal year of the Parent Company and its Subsidiaries, including the notes thereto, audited by independent public accountants of recognized national standing and prepared in conformity with GAAP.

“Bankruptcy Event” means the occurrence of any of the following in respect of a Person:

(a) such Person shall generally not, shall be unable to, or an admission in writing by such Person of its inability to, pay its debts as they come due or a general assignment by such Person for the benefit of creditors;

(b) the filing of any petition or answer by such Person seeking to adjudicate itself as bankrupt or insolvent, or seeking for itself any liquidation, winding-up, reorganization,

arrangement, adjustment, protection, relief or composition of such Person or its debts under any Applicable Law relating to bankruptcy, insolvency, receivership, winding-up, liquidation, reorganization, examination, relief of debtors or other similar Applicable Law now or hereafter in effect, or seeking, consenting to or acquiescing in the entry of an order for relief in any case under any such Applicable Law, or the appointment of or taking possession by a receiver, trustee, custodian, liquidator, examiner, assignee, sequestrator or other similar official for such Person or for any substantial part of its property;

(c) corporate or other entity action taken by such Person to authorize any of the actions set forth in clause (a) or clause (b) above; or

(d) without the consent or acquiescence of such Person, the commencement of an action seeking entry of an order for relief or approval of a petition for relief or reorganization or any other petition seeking any reorganization, arrangement, composition, readjustment, liquidation, dissolution or other similar relief under any present or future bankruptcy, insolvency, receivership, winding-up, liquidation, reorganization, examination, relief of debtors or similar Applicable Law, or the filing of any such petition against such Person, or, without the consent or acquiescence of such Person, the commencement of an action seeking entry of an order appointing a trustee, custodian, receiver or liquidator of such Person or of all or any substantial part of the property of such Person, in each case where such petition or order shall remain unstayed or shall not have been stayed or dismissed within ninety (90) days from entry thereof.

“Board of Directors” means (a) with respect to a company or corporation, the board of directors of the company or corporation or any committee thereof duly authorized to act on behalf of such board, (b) with respect to a partnership, the board of directors or similar governing body of the general partner of the partnership, (c) with respect to a limited liability company, the managing member or members or any controlling committee of managing members thereof, and (d) with respect to any other Person, the board or committee of such Person serving a similar function.

“Business Day” means any day that is not a Saturday, Sunday or other day on which commercial banks in New York City are authorized or required by Applicable Law to remain closed.

“Calendar Quarter” means (a) for the first such Calendar Quarter, the period beginning on the Initial Closing Date and ending on the last day of the calendar quarter in which the Initial Closing Date falls, and (b) for each Calendar Quarter thereafter, each successive period of three consecutive calendar months ending on March 31, June 30, September 30 or December 31.

“Calendar Year” means (a) for the first such Calendar Year, the period beginning on the Initial Closing Date and ending on December 31 of the calendar year in which the Initial Closing Date occurs, (b) for each calendar year of the Payment Term thereafter, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31, and (c) for the last year of the Payment Term, the period beginning on January 1 of the year in which this Agreement expires or terminates and ending on the effective date of expiration or termination of this Agreement.

“Cash Equivalents” means (a) United States dollars, (b) readily-marketable securities issued or directly, unconditionally and fully guaranteed or insured by the United States government or any agency or instrumentality thereof having maturities of less than one year from the date of acquisition, (c) certificates of deposit and Eurodollar time deposits with maturities of less than one year from the date of acquisition, bankers’ acceptances with maturities of less than one year and overnight bank deposits, in each case with any domestic commercial bank having capital and surplus in excess of \$100,000,000, (d) repurchase obligations with a term of not more than seven days for underlying securities of the types described in clauses (b) and (c) entered into with any financial institution meeting the qualifications specified in clause (c) immediately above, (e) commercial paper having the highest rating obtainable from Moody’s Investors Service, Inc., or S&P’s Ratings Services and in each case maturing within nine months after the date of acquisition and (f) interests in money market mutual funds which invest solely in assets and securities of the type described in clauses (a) through (e) immediately above.

“CDA” means that certain Confidentiality Agreement, dated as of [***], by and between HealthCare Royalty Management, LLC and the Company.

“Change of Control” means the occurrence of any of the following events:

(a) any reorganization, recapitalization, consolidation or merger (or similar transaction or series of related transactions) of the Parent Company or issuance, sale or exchange of Equity Interests (or similar transaction or series of related transactions) of the Parent Company in which the holders of the Parent Company’s outstanding Equity Interests immediately before consummation of such transaction or series of related transactions do not, immediately after consummation of such transaction or series of related transactions, retain Equity Interests representing more than fifty percent (50.0%) of the voting power of the surviving entity of such transaction or series of related transactions (or the parent of such surviving entity if such surviving entity is wholly owned by such parent), in each case without regard to whether the Parent Company is the surviving entity,

(b) the Disposition of all or substantially all of the assets of the Parent Company;

(c) during any period of twelve (12) consecutive months, a majority of the members of the Board of Directors of the Parent Company cease to be composed of individuals (i) who were members of that Board of Directors on the first day of such period, (ii) whose election, appointment or nomination to that Board of Directors was approved by individuals referred to in clause (i) above constituting at the time of such election, appointment or nomination at least a majority of that Board of Directors (either by a specific vote or by approval of the proxy statement of the Parent Company in which such member was named as a nominee for election as a director, without objection to such nomination) or (iii) whose election or nomination to that Board of Directors was approved by individuals referred to in clauses (i) and (ii) above constituting at the time of such election, appointment or nomination at least a majority of that Board of Directors;

(d) any “change of control”, “fundamental change” or any comparable event, occurs under any Permitted Debt Facility Document which permits the holder or other investor of any Permitted Debt to require the issuer to purchase such Permitted Debt;

(e) any member of the Company Group grants or transfers the right to Commercialize the Existing Yutrepia Product to any Person, other than a Permitted Licensee; or

(f) the Company shall cease to be a wholly-owned Subsidiary of the Parent Company.

“Change of Control Payment” means, as of any date of determination, the amount equal to the sum of (a) the Hard Cap less the aggregate of (i) all of the payments of the Company in respect of the Total Fixed Payments and the Total Included Product Payments (including any Under Performance Payment or Generic Product Payment) made to the Investor prior to such date and (ii) any amounts received by the Investor pursuant to the Insurance Policy, if any, plus (b) after taking into account the payments made under the foregoing clause (a), the IRR True-Up Payment Amount plus (c) any other Obligations (other than inchoate Obligations) payable by the Company Parties under this Agreement and the other Transaction Documents (if any).

“Closing” has the meaning set forth in Section 8.1.

“Closing Date” means the Initial Closing Date, the Second Closing Date, the Third Closing Date or the Fourth Closing Date, as applicable.

“Collateral” has the meaning set forth in the Security Agreement.

“Collateral Documents” means, collectively, the Security Agreement, Perfection Certificate, any collateral access agreement, each Deposit Account Control Agreement, each Securities Account Control Agreement, each Commodities Account Control Agreement and each other agreement or instrument pursuant to or in connection with which any Company Party or any other Person grants a security interest in any Collateral to Investor Representative.

“Commercialization” means, on a country by country basis, any and all activities with respect to the manufacture, distribution, marketing, detailing, promotion, selling and securing of reimbursement of Included Products in accordance with the Product Plans in a country after Marketing Authorization for an Included Product in that country has been obtained, which shall include, as applicable, post-marketing approval studies, post-launch marketing, promoting, detailing, marketing research, distributing, customer service, selling the Included Product, importing, exporting or transporting the Included Product for sale, and regulatory compliance with respect to the foregoing, in each case in accordance with the Product Plans. When used as a verb, “Commercialize” means to engage in Commercialization.

“Commercially Reasonable and Diligent Efforts” means, with respect to the efforts to be expended with respect to any Included Product in any country or regulatory jurisdiction, such efforts and resources normally used by a reasonably prudent company in the biotechnology industry of a size and product portfolio comparable, and with similar resources available, to the Company and its Affiliates with the marketing, sale and product development and research plans similar to the Product Plans in the biopharmaceutical industry, taken as a whole, in such applicable

country or jurisdiction, with respect to a pharmaceutical product for which substantially the same Regulatory Approval is held as for such Included Product, which pharmaceutical product is owned or licensed in the same manner as such Included Product, which pharmaceutical product is at a similar stage in its product life and of similar market and profit potential as such Included Product, taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in such country or jurisdiction, pricing/reimbursement for the pharmaceutical product in such country or jurisdiction relative to other countries and jurisdictions, the intellectual property and regulatory protection of the pharmaceutical product in such country or jurisdiction, the regulatory structure in such country or jurisdiction and the profitability of the pharmaceutical product in such country or jurisdiction, all as measured by the facts and circumstances in existence at the time such efforts are due.

“Commodities Account” means a “commodity account” (as defined in Article 9 of the UCC).

“Commodities Account Control Agreement” means the commodities account control agreement entered into by the commodities intermediary, the Investor Representative and any Company Party (and any Permitted Debt Creditors, if applicable), which shall be in form and substance reasonably acceptable to the Investor Representative and the Company.

“Company” has the meaning set forth in the preamble.

“Company Group” means the Parent Company and its Subsidiaries.

“Company Indemnification Cap” has the meaning set forth in Section 10.6(a).

“Company Indemnification Obligations” has the meaning set forth in Section 10.1.

“Company Indemnified Party” has the meaning set forth in Section 10.2.

“Company Party” means any of the Company and the Guarantors.

“Comparable Yield” has the meaning set forth in Section 6.22(a).

“Competitive Party” has the meaning set forth on Schedule 1.1-2.

“Compliance Certificate” means a certificate substantially in the form of Exhibit B.

“Confidential Information” means any and all technical and non-technical non-public information provided by either Party to the other (including, without limitation, the reports provided pursuant to Section 3.4 and any notices or other information provided pursuant to ARTICLE VI), either directly or indirectly, and including any materials prepared on the basis of such information, whether in graphic, written, electronic or oral form, including without limitation information relating to a Party’s technology, products and services, and any business, financial or customer information relating to a Party. The existence and terms of this Agreement shall be deemed the Confidential Information of both Parties. For clarity, this Agreement shall supersede the CDA and the CDA shall cease to be of any force and effect following the execution of this Agreement; provided, however, that all information falling within the definition of “Confidential

Information” set forth in the CDA shall also be deemed Confidential Information disclosed pursuant to this Agreement, and the use and disclosure of such Confidential Information following the date of this Agreement shall be subject to the provisions of ARTICLE IX.

“Contract” means any contract, agreement, commitment, government bid, instrument, license, sublicense, subcontract, real or personal property lease or sublease, legally binding letters of intent, memorandum of understanding, offer letter, note, indenture, mortgage, bond, letter of credit, guarantee, purchase order, or other legally binding business arrangement, whether written or oral, together with any amendments, restatements, supplements or other modifications thereto.

“Contractual Obligation” means, as to any Person, any provision of any security issued by such Person or of any other Contract by which such Person is a party or by which it or any of its property is bound.

“Copyright License” means any Contract providing for the grant of any right to use any Work under any Copyright.

“Copyrights” means (a) all proprietary rights afforded Works pursuant to Title 17 of the United States Code, including, without limitation, all rights in mask works, copyrights and original designs, and all proprietary rights afforded such Works by other countries for the full term thereof (and including all rights accruing by virtue of bilateral or international treaties and conventions thereto), whether registered or unregistered, including, but not limited to, all applications for registration, renewals, extensions, reversions or restorations thereof now or hereafter provided for by Law and all rights to make applications for registrations and recordations, regardless of the medium of fixation or means of expression, which are owned by or licensed to any member of the Company Group or with respect to which any member of Company Group is authorized or granted rights under or to; and (b) all copyright rights under the copyright Laws of the United States and all other countries for the full term thereof (and including all rights accruing by virtue of bilateral or international copyright treaties and conventions), whether registered or unregistered, including, but not limited to, all applications for registration, renewals, extensions, reversions or restorations of copyrights now or hereafter provided for by Law and all rights to make applications for copyright registrations and recordations, regardless of the medium of fixation or means of expression, which are owned by or licensed to any member of the Company Group or with respect to which any member of the Company Group is authorized or granted rights under or to.

“Debtor Relief Laws” means the Bankruptcy Code of the United States, and all other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief Laws of the United States or other applicable jurisdictions from time to time in effect.

“Default” means any event or condition that constitutes an Event of Default or that, with the giving of any notice, the passage of time, or both, would be an Event of Default.

“Deposit Account” means a “deposit account” (as defined in Article 9 of the UCC), investment account or other account in which funds are held or invested to or for the credit or account of any Company Party.

“Deposit Account Control Agreement” means the deposit account control agreement entered into by the Depository Bank, the Investor Representative and any Company Party (and any Permitted Debt Creditors, if applicable), which shall be in form and substance reasonably acceptable to the Investor Representative and the Company.

“Depository Bank” means such bank or financial institution specified to Investor Representative in writing by the Company on or prior to the Initial Closing Date or such other bank or financial institution specified to Investor Representative in writing by the Company.

“Designated Jurisdiction” means any country, territory or region to the extent that such country, territory or region is the subject of any Sanction.

“Disposition”, “Dispose” and “Disposed” means the sale, transfer, out-license, lease or other disposition (including any sale and leaseback transaction, or any issuance by any Subsidiary of the Parent Company of its Equity Interests other than to a Company Party or any Division) of any property or any economic interest by any member of the Company Group, including any sale, assignment, transfer or other disposal, with or without recourse, of any notes or accounts receivable or any rights and claims associated therewith, but excluding the following (collectively, the “Permitted Transfers”):

(a) the sale, lease, license, transfer or other disposition of inventory in the ordinary course of business;

(b) the sale, lease, license, transfer or other disposition in the ordinary course of business of surplus, obsolete or worn out property no longer used or useful in the conduct of the business of the Parent Company and its Affiliates;

(c) any sale, lease, license, transfer or other disposition of property by one Company Party to another Company Party;

(d) the abandonment or other disposition of Product Rights that are not material or are no longer used or useful in any material respect to the business of any member of the Company Group;

(e) licenses, sublicenses, leases or subleases (other than relating to IP Rights, in each case) granted to third parties in the ordinary course of business and not interfering with the business of the Parent Company and its Affiliates;

(f) any dispositions consisting of the sale, transfer, assignment or other disposition of unpaid and overdue accounts receivable, other than the portion of Net Revenues payable to the Investor hereunder, in connection with the collection, compromise or settlement thereof in the ordinary course of business;

(g) any Involuntary Disposition or any sale, lease, license or other disposition of property (other than, for the avoidance of doubt, IP Rights) in settlement of, or to make payment in satisfaction of, any property or casualty insurance;

(h) Permitted Licenses;

(i) the sale or other disposition of cash or Cash Equivalents in a manner not prohibited by this Agreement or the other Transaction Documents;

(j) sales, leases, licenses, transfers or other dispositions of property (other than, for the avoidance of doubt, IP Rights) to the extent that (i) such property is exchanged for credit against the purchase price of similar replacement or property or (ii) the proceeds of such sale, lease, license, transfer or other disposition are promptly applied to the purchase price of similar replacement property; and

(k) the sale, transfer, issuance or other disposition of a *de minimis* number of shares of the Equity Interests of a Foreign Subsidiary of a Company Party in order to qualify members of the governing body of such Subsidiary if required by Applicable Law.

It is understood and agreed that, notwithstanding anything to the contrary set forth in this definition, in no event shall a “Permitted Transfer” include (a) any license of any Included Product or IP Rights associated therewith other than Permitted Licenses, (b) prior to the achievement of the Net Sales Threshold, (i) any Disposition of the Sandoz Agreement, or (ii) any Disposition of the Sandoz Device Agreement that would have a material adverse effect on the Commercialization of the Sandoz Product in the United States, or (c) any Disposition of any Yutrepia Device Agreement that would have a material adverse effect on the Commercialization of the Existing Yutrepia Product in the United States.

“Disputes” has the meaning set forth in Section 4.10(k).

“Disqualified Capital Stock” means any Equity Interests that (i) by its terms, (ii) by the terms of any security into which it is convertible or for which it is exchangeable, or (iii) by Contract or otherwise, is, or upon the happening of any event or passage of time would be, required to be redeemed, or is redeemable at the option of the holder thereof, in any such case on or prior to the date that is ninety-one (91) days after the Legal Maturity Date; provided that only the portion of Equity Interests (or portion of security into which it is convertible or for which it is exchangeable) which is, or upon the happening of any event or passage of time would be, required to be redeemed, or is redeemable at the option of the holder thereof, on or prior to such date will be deemed to be Disqualified Capital Stock; and provided further that if such Equity Interests are issued to any plan for the benefit of directors, managers, employees, officers or consultants of any member of the Company Group or by any such plan to such directors, managers, employees, officers or consultants, such Equity Interests shall not constitute Disqualified Capital Stock solely because it may be required to be repurchased by any member of the Company Group in order to satisfy applicable statutory or regulatory obligations. Notwithstanding the preceding sentence, any Equity Interests that would constitute Disqualified Capital Stock solely because the holders thereof have the right to require the redemption or repurchase of such Equity Interests upon the occurrence of a Change of Control, fundamental change or an asset sale will not constitute Disqualified Capital

Stock if the “asset sale”, “fundamental change” or “Change of Control” provisions applicable to such Equity Interests provide that the issuer thereof will not redeem or repurchase any such Equity Interests pursuant to such provisions prior to all other Obligations (other than contingent indemnification obligations for which no claim has been asserted) having been irrevocably paid in full in cash.

“Division” means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, Section 17-220 of the Delaware Revised Uniform Limited Partnership Act for limited partnerships formed under Delaware law, or any analogous action taken pursuant to any other Applicable Law with respect to any corporation, limited liability company, partnership or other entity.

“Dollar” or the sign “\$” means United States dollars.

“Domain Names” means all domain names and URLs that are registered and/or owned by or licensed to any member of the Company Group or with respect to which any member of the Company Group is authorized or granted rights under or to.

“Domestic Subsidiary” means any Subsidiary that is organized under the Laws of the United States, any state of the United States or the District of Columbia.

“Drug Application” means an application for Regulatory Approval to market, sell and distribute a drug or product in a country or region, including (a) a New Drug Application, a Supplemental or an Abbreviated New Drug Application, as those terms are defined in the FDCA and the FDA regulations promulgated thereunder, for any Included Product, as appropriate, in each case of any member of the Company Group, (b) any corresponding foreign application in any country or jurisdiction in the world, and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

“EEA” means the European Economic Area, namely the EEA Member Countries.

“EEA Financial Institution” means (a) any credit institution or investment firm established in any EEA Member Country which is subject to the supervision of an EEA Resolution Authority, (b) any entity established in an EEA Member Country which is a parent of an institution described in clause (a) of this definition, or (c) any financial institution established in an EEA Member Country which is a subsidiary of an institution described in clauses (a) or (b) of this definition and is subject to consolidated supervision with its parent.

“EEA Member Country” means any of the member states of the European Union, the United Kingdom, Iceland, Liechtenstein, and Norway.

“EEA Resolution Authority” means any public administrative authority or any Person entrusted with public administrative authority of any EEA Member Country (including any delegee) having responsibility for the resolution of any EEA Financial Institution.

“Effective Date” has the meaning set forth in the preamble.

“Equity Interests” means, with respect to any Person, all of the shares of capital stock of (or other ownership or profit interests in) such Person, all of the warrants, options or other rights for the purchase or acquisition from such Person of shares of capital stock of (or other ownership or profit interests in) such Person, all of the securities convertible into or exchangeable for shares of capital stock of (or other ownership or profit interests in) such Person or warrants, rights or options for the purchase or acquisition from such Person of such shares (or such other interests), and all of the other ownership or profit interests in such Person (including partnership, member, membership or trust interests therein), whether voting or nonvoting, and whether or not such shares, warrants, options, rights or other interests are outstanding on any date of determination.

“ERISA” means the Employee Retirement Income Security Act of 1974 as amended.

“ERISA Affiliate” means any trade or business (whether or not incorporated) under common control with the Company within the meaning of Section 414(b) or (c) of the Internal Revenue Code (and Sections 414(m) and (o) of the Internal Revenue Code for purposes of provisions relating to Section 412 of the Internal Revenue Code).

“ERISA Event” means (a) a Reportable Event with respect to a Pension Plan, (b) the withdrawal of the Parent Company or any ERISA Affiliate from a Pension Plan subject to Section 4063 of ERISA during a plan year in which such entity was a “substantial employer” as defined in Section 4001(a)(2) of ERISA or a cessation of operations that is treated as such a withdrawal under Section 4062(e) of ERISA, (c) a complete or partial withdrawal (within the meaning of Sections 4203 and 4205 of ERISA) by the Parent Company or any ERISA Affiliate from a Multiemployer Plan, (d) the filing by the plan administrator of a notice of intent to terminate a Pension Plan or the treatment of a Pension Plan amendment as a termination under Sections 4041 of ERISA, (e) the institution by the PBGC of proceedings under Section 4042 of ERISA to terminate a Pension Plan, (f) the determination that any Multiemployer Plan is considered an at-risk plan or a plan in endangered or critical status within the meaning of Section 432 of the Internal Revenue Code or Section 305 of ERISA or is insolvent, within the meaning of Section 4245 of ERISA, or has been terminated, within the meaning of Section 4041A of ERISA, (g) the determination that any Pension Plan is in at-risk status within the meaning of Section 303 of ERISA, or (h) the imposition of any liability pursuant to Sections 4062(e) or 4069 of ERISA or by reason of the application of Section 4212(c) of ERISA upon the Parent Company or any ERISA Affiliate.

“Event of Default” means any of the events set forth in Section 11.1.

“Event of Default Payment” means, as of any date of determination, the amount equal to the sum of (a) the Hard Cap less the aggregate of (i) all of the payments of the Company in respect of the Total Fixed Payments and the Total Included Product Payments (including any Under Performance Payment or Generic Product Payment) made to the Investor prior to such date, and (ii) any amounts received by the Investor pursuant to the Insurance Policy, if any, plus (b) after taking into account the payments made under clause (a), the IRR True-Up Payment Amount, plus

(c) any other Obligations (other than inchoate Obligations) payable by the Company Parties under this Agreement and the other Transaction Documents (if any).

“Excluded Account” means, any Deposit Account, Commodities Account or Securities Account (a) that is used solely for payroll, payroll taxes and other employee wage and benefit payments, (b) that solely functions as a trust, fiduciary, escrow, withholding or tax payment account, (c) that is subject to a zero balance, (d) that is maintained solely for the benefit of third parties as cash collateral for obligations owing to such third parties or for cash of third parties, or (e) that do not at any time have cash, investment property, or other amounts, including Cash Equivalents, on deposit therein in excess of \$[***], individually, or \$[***] in the aggregate for all such accounts.

“Excluded Assets” means, with respect to a Company Party:

(a) “intent-to-use” trademark applications prior to the filing and acceptance by the United States Patent and Trademark Office, of a “Statement of Use” or “Amendment to Allege Use” with respect thereto, to the extent, if any, that, and solely during the period, if any, in which, the grant or attachment of a security interest therein would impair the validity or enforceability or result in the cancellation or voiding of such intent-to-use trademark application or any registration issuing therefrom under applicable federal law;

(b) any permit, lease, license, contract or agreement (including, without limitation, any joint venture agreement) to which any Company Party is a party or any of its rights or interests thereunder or any asset (or any agreement evidencing such asset) the grant or perfection of a security interest in which, in each case, would (x) be prohibited under any Applicable Law (including, without limitation, any rule and/or regulation of any Governmental Authority or agency), (y) require any consent, approval, license or authorization, in each case to the extent such consent, approval, license or authorization has not been obtained or (z) result in the termination of such permit, lease, license, contract, agreement or asset, in each case of clauses (x) through and (z), after giving effect to the applicable anti-assignment provisions of the UCC or any other Applicable Law;

(c) motor vehicles and any other assets subject to certificates of title;

(d) any asset subject to a purchase money Lien or capital lease permitted hereunder, if the terms of the agreement pursuant to which such Lien is granted (or in the document providing for such capital lease) restricts, prohibits, or expressly requires a consent (that has not been obtained) of a Person (other than any member of the Company Group) as a condition to the creation of any other Lien on such asset, to the extent such restriction, prohibition and/or requirement of consent is not rendered ineffective by Applicable Law;

(e) any Governmental Licenses or state or local franchises, charters and authorizations, to the extent security interests in favor of the Investor Representative in such licenses, franchises, charters or authorizations are prohibited or restricted thereby and is not rendered ineffective by Applicable Law (including, without limitation, pursuant to Sections 9-406, 9-407, 9-408 or 9-409 of the UCC);

(f) any interest in real property;

(g) Excluded Accounts;

(h) any asset with respect to which Investor Representative has determined in good faith in consultation with the Company, that the costs, burden, difficulty or consequence of obtaining, perfecting or maintaining a security interest in such asset (including any mortgage, stamp, intangibles or other tax or expense relating to such security interest) outweighs, or is excessive in light of the practical benefit to the Investor Representative afforded thereby (it being understood that the maximum guaranteed or secured amount may be limited to minimize stamp duty, notarization, registration or other similar fees, taxes and duties);

(i) margin stock; and

(j) Litigation Finance Collateral;

provided, however, that (x) Excluded Assets shall not include any Proceeds of any item of General Intangibles, and (y) any item of General Intangibles or Equipment that at any time ceases to satisfy the criteria for Excluded Assets (whether as a result of the applicable Company Party obtaining any necessary consent, any change in any rule of law, statute or regulation, payment in full of the purchase money indebtedness or capitalized lease obligation to which such asset is subject, or otherwise, as applicable) shall no longer be an Excluded Asset, in each case, with the exclusion of the Litigation Finance Collateral, which shall always be deemed an Excluded Asset.

“Excluded Foreign Subsidiary” means any Foreign Subsidiary that: (i) does not hold any right, title or interest in any IP Rights, Drug Applications, Regulatory Approvals, other Governmental Licenses and all applications and requests for Governmental Licenses; and (ii) is not a party to any Material Contract.

“Excluded Liabilities and Obligations” has the meaning set forth in Section 2.2.

“Excluded Taxes” means (i) Taxes imposed on or measured by the Investor’s net income, however denominated, franchise (and similar) Taxes, and branch profits Taxes (or any similar Taxes), in each case, imposed by any jurisdiction as a result of the Investor being organized in or having its principal office in such jurisdiction, or as a result of any other present or former connection between the Investor and such jurisdiction other than any connections arising from executing, delivering, being a party to, engaging in any transactions contemplated by, performing its obligations under, receiving payments under, or enforcing any Transaction Document, (ii) Taxes attributable to the failure of the Investor to deliver any documentation reasonably requested by the Company that the Investor is legally eligible to deliver, (iii) any U.S. federal withholding Taxes imposed on any payment by or on account of any Obligation of any Company Party under any Transaction Document to an Investor pursuant to a Law in force at the time such Investor becomes a party hereto (or designates a new funding office), except to the extent that such Investor (or its assignor, if any) was entitled, immediately prior to the designation of a new funding office (or assignment), to receive additional amounts with respect to such withholding Tax pursuant to Section 6.22(c), and (iv) any withholding Taxes imposed under FATCA.

“Existing Yutrepia Product” means Yutrepia (treprostinil inhalation powder) Oral Inhalation, which is the subject of New Drug Application No. 213005 filed with the FDA.

“FATCA” means Sections 1471 through 1474 of the Internal Revenue 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 current Section 1471(b)(1) of the Internal Revenue Code (or any amended or successor version described above) and any fiscal or regulatory legislation, rules or official administrative guidance adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and that implement such Sections of the Internal Revenue Code.

“Favorable Determination” means the earlier to occur of (a) with respect to each claim in U.S. Patent No. 10,716,793 asserted against the Company, a final Non-Appealable Decision of either (i) a U.S. District Court decision that such claim is invalid and/or not infringed by the Existing Yutrepia Product, or (ii) *inter partes* review of such claim before the Patent Trial and Appeal Board of the United States Patent and Trademark Office that such claim is invalid (with respect to clause (a), so long as there has not been a court decision that the Existing Yutrepia Product infringes at least one valid claim of an Asserted Patent other than U.S. Patent No. 10,716,793), and (b) Regulatory Approval of the Existing Yutrepia Product in the United States. For clarity, Regulatory Approval of the Existing Yutrepia Product in the United States shall not be deemed to have been granted until final approval of New Drug Application No. 213005 has been granted by FDA.

“FCPA” has the meaning set forth in Section 4.23(b).

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

“Financial Statements” means the Audited Financial Statements and the Interim Financial Statements.

“First Commercial Sale” means the first bona fide, arm’s length sale or transfer of the Existing Yutrepia Product to a Third Party in the United States following receipt of Regulatory Approval for the Existing Yutrepia Product. For clarity, Regulatory Approval for the Existing Yutrepia Product in the United States shall not be deemed to have been granted until final approval of New Drug Application No. 213005 has been granted by FDA.

“Foreign Subsidiary” means any Subsidiary that is not a Domestic Subsidiary.

“Fourth Closing” has the meaning set forth in Section 8.1(d).

“Fourth Closing Date” has the meaning set forth in Section 8.1(d).

“Fourth Investment Amount” has the meaning set forth in Section 2.1(d).

“Fundamental Representations” means those representations and warranties of the Company and of any other Company Party set forth in the first sentence of Section 4.1 (Organization), Section 4.2 (No Conflicts), Section 4.3 (Authorization), Section 4.4 (Ownership), Section 4.10 (Intellectual Property Matters) Section 4.12 (Material Contracts) to the extent relating to (a) prior to the achievement of the Net Sales Threshold, the Sandoz Agreement and the Sandoz

Device Agreement, or (b) any Yutrepia Device Agreement that is material to the development, manufacturing, commercialization or supply of a device that is necessary to administer Yutrepia in the United States, [Section 4.13](#) (Bankruptcy), [Section 4.17](#) (No Default; No Special Termination Event), [Section 4.21](#) (Perfection of Security Interests), [Section 4.23](#) (Sanctions Concerns; Anti-Corruption Laws; PATRIOT Act) and [Section 4.28](#) (Tax) and, in each case, in any other Transaction Document to the extent any of the foregoing are incorporated therein.

“[GAAP](#)” means generally accepted accounting principles in effect as the standard financial accounting guidelines in the United States from time to time (consistently applied and on a basis consistent with the accounting policies, practices, procedures, valuation methods and principles used in preparing the Financial Statements), and any successor thereto; provided that if any change in such generally accepted accounting principles or the application thereof would substantively change the recognition of revenue with respect to Net Revenues (defined as of the Effective Date) and its calculation as set forth in this Agreement, then the Parties shall mutually agree to amendments to this Agreement in order to cause the Included Product Payment Amount as determined after giving effect to such change in generally accepted accounting principles to be substantially the same as the amount as determined under generally accepted accounting principles in effect as the standard financial accounting guidelines in the United States as of the Effective Date and, pending any such amendment, Net Revenues shall be calculated in a manner consistent with generally accepted accounting principles prior to giving effect to such change.

“[Generic Product Payment](#)” has the meaning set forth in [Section 3.1\(b\)\(ii\)](#).

“[Generic Product Payment Event](#)” has the meaning set forth on [Schedule 1.1-11](#).

“[Governmental Authority](#)” means the government of the United States, any other nation or any political subdivision thereof, whether state, local or otherwise, and any agency, authority (including supranational authority), commission, instrumentality, regulatory body, court, central bank or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government, including each Patent Office, the FDA and any other government authority in any jurisdiction.

“[Governmental Licenses](#)” means all authorizations issuing from a Governmental Authority, including the FDA, based upon or as a result of applications to and requests for approval from a Governmental Authority for the right to manufacture, import, store, market, promote, advertise, offer for sale, sell, use and/or otherwise distribute a Included Product, which are owned by or licensed to any member of the Company Group, acquired by any member of the Company Group via assignment, purchase or otherwise or that any member of the Company Group is authorized or granted rights under or to.

“[Grantors](#)” means the Company and the Guarantors.

“[Guarantors](#)” means (i) the Parent Company, (ii) Liquidia PAH, (iii) any Subsidiary providing a Guaranty in favor of the Investor Representative, and (iv) any other Subsidiary of the Company that executes and delivers a Joinder Agreement pursuant to [Section 6.1](#); provided, that, no Excluded Foreign Subsidiary shall be or be required to be a Guarantor for so long as such Subsidiary remains an Excluded Foreign Subsidiary.

“Guaranty” means the guaranty to be executed in favor of the Investor Representative, for the benefit of the Investor, by the Company and each of the Guarantors.

“Hard Cap” means, as of any time of determination, the amount equal to one hundred seventy-five percent (175%) of the Investment Amount.

“Included Product” means Yutrepia, the Sandoz Product and any other product or service developed, imported, manufactured, marketed, offered for sale, promoted, sold, tested or otherwise distributed by any member of the Company Group. For clarity, references in this Agreement to “an” Included Product or to “the” Included Product(s) refer to any Included Product(s).

“Included Product Payment Amount” means, for each Calendar Quarter, (i) if the Third Investment Amount has not been funded, an amount equal to the Applicable Tiered Percentage multiplied by the Quarterly Net Revenues for such Calendar Quarter and (ii) if the Third Investment Amount has been funded, then (x) for any Calendar Quarter ending prior to January 1, 2026, an amount equal to the Applicable Tiered Percentage multiplied by the Quarterly Net Revenues for such Calendar Quarter, or (y) for any Calendar Quarter commencing on or after January 1, 2026, an amount equal to the greater of (A) the Applicable Tiered Percentage multiplied by the Quarterly Net Revenues for such Calendar Quarter and (B) Five Million Dollars (\$5,000,000), until such time as the Investor Representative has received Included Product Payment Amounts for the relevant Calendar Year for which determination is being made equal to Twenty Million Dollars (\$20,000,000), in which case the amount set forth in clause (ii)(y)(A) shall apply for the balance of such Calendar Year. For clarity, the Applicable Tiered Percentage used to calculate the Included Product Payment Amount for a given Calendar Quarter will be based on the aggregate Net Revenues billed or invoiced in such Calendar Quarter and all prior Calendar Quarters in the applicable Calendar Year. The Included Product Payment Amount for each Quarterly Payment Date shall be determined in a manner consistent with the example of such calculation set forth in Exhibit C.

“Indebtedness” of any Person means (a) any obligation of such Person for borrowed money, (b) any obligation of such Person evidenced by a bond, debenture, note or other similar instrument, (c) any obligation of such Person to pay the deferred purchase price of property or services (except (i) trade accounts payable that arise in the ordinary course of business, (ii) payroll liabilities and deferred compensation, and (iii) any purchase price adjustment, royalty, earnout, milestone payments, contingent payment or deferred payment of a similar nature incurred in connection with any license, lease, contract research and clinic trial arrangements or acquisition to the extent an amount due thereunder has not been determined and is not due and payable), (d) any obligation of such Person as lessee under a capital lease (under GAAP as in effect on the date hereof), (e) any obligation of such Person to purchase securities or other property that arises out of or in connection with the sale of the same or substantially similar securities or property (other than any such obligation permitted by clause (d) of the definition of Cash Equivalents), (f) any non-contingent obligation of such Person to reimburse any other Person in respect of amounts paid under a letter of credit or other guaranty issued by such other Person, (g) any Indebtedness of others secured by a Lien on any asset of such Person, and (h) any Indebtedness of others guaranteed by such Person; provided that intercompany loans among the Company and its Affiliates shall not constitute Indebtedness.

“Indemnified Taxes” means all Taxes imposed on or with respect to any payment made by or on account of any Obligation of any Company Party under any Transaction Document, other than Excluded Taxes.

“Initial Closing” has the meaning set forth in Section 8.1(a).

“Initial Closing Date” has the meaning set forth in Section 8.1(a).

“Initial Investment Amount” has the meaning set forth in Section 2.1(a).

“Interim Financial Statements” means the unaudited, condensed and consolidated balance sheets of the Parent Company and its Subsidiaries for the nine (9)-month period ended September 30, 2022, and the related condensed and consolidated statements of operation and comprehensive loss, stockholders’ equity and cash flows for such period of the Parent Company and its Subsidiaries, including the notes thereto.

“Internal Revenue Code” means the United States Internal Revenue Code of 1986, as amended.

“Investment” means any beneficial ownership interest in any Person (including stock, partnership, membership or other ownership interest or other equity securities), and any loan, advance or capital contribution to any Person.

“Investment Amount” means, as of any time of determination, the aggregate of the Initial Investment Amount and, if funded pursuant to Section 2.1(b), the Second Investment Amount and, if funded pursuant to Section 2.1(c), the Third Investment Amount and, if funded pursuant to Section 2.1(d), the Fourth Investment Amount. For clarity, the Investment Amount reflects the total amount funded by Investor under this Agreement as of any time of determination without regard to whether any such amount has been prepaid or repaid (including any amounts received by the Investor pursuant to the Insurance Policy).

“Investor” has the meaning set forth in the preamble.

“Investor Account” means such account as designated by the Investor Representative to the Company in writing from time to time.

“Investor Indemnification Obligations” has the meaning set forth in Section 10.2.

“Investor Indemnified Party” has the meaning set forth in Section 10.1.

“Investor Representative” has the meaning set forth in the preamble.

“Involuntary Disposition” means any loss of, damage to or destruction of, or any condemnation or other taking for public use of, any property of any Company Party or any of its Subsidiaries.

“IP Rights” means, collectively, all Copyrights, all Copyright Licenses, all Domain Names, all Patent Licenses, all Patent Rights (including, for the avoidance of doubt, the Yutrepia

Patent Rights), all Proprietary Databases, all Proprietary Software, all Trademarks, all Trademark Licenses, all Trade Secrets and all Confidential Information of any member of the Company Group, including (but not limited to) the items listed on Schedule 4.10(a) and Schedule 4.10(r).

“IRR True-Up Payment Amount” means, as of any time of determination, the amount that the Investor would need to receive to yield an internal rate of return on the Investment Amount equal to eighteen percent (18%), calculated using the “XIRR function” in Microsoft® Excel® and determined after taking into account the Total Fixed Payments, the Total Included Product Payments, the Under Performance Payments, the Generic Product Payment and any payments under the Insurance Policy received by the Investor Representative and/or the Investor, if any. For reference, information on the XIRR function in Microsoft® Excel® is available at <https://support.microsoft.com/en-us/office/xirr-function-de1242ec-6477-445b-b11b-a303ad9adc9d>. An illustrative example of the calculation of the IRR True-Up Payment Amount is attached as Exhibit E hereto.

“IRS” means the United States Internal Revenue Service.

“Joinder Agreement” means a joinder agreement substantially in the form of Exhibit D executed and delivered by each Subsidiary of the Parent Company in accordance with the provisions of Section 6.1.

“Know-How” means all non-public information, results and data of any type whatsoever, in any tangible or intangible form (and whether or not patentable), including databases, practices, methods, techniques, specifications, formulations, formulae, knowledge, skill, experience, data and results (including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical study data and results), analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

“Knowledge” means, with respect to any Company Party, (a) for purposes of ARTICLE IV, the knowledge, after due inquiry, as of the Effective Date and as of each Closing Date, of the officers of all Company Parties identified on Schedule 1.1-3, and (b) for all other purposes of this Agreement, the knowledge, after due inquiry, as of a specified time, of any of the officers of all Company Parties identified on Schedule 1.1-3 or, in each case, any successor to any such officer holding the same or substantially similar officer position at such time.

“Laws” means, collectively, all international, foreign, federal, state and local statutes, treaties, rules, guidelines, regulations, ordinances, codes and administrative or judicial precedents or authorities, including the interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders directed duties, and Permits with any Governmental Authority, in each case, having the force of law.

“Legal Maturity Date” means the date that is the twelve (12) year anniversary of the Initial Closing Date.

“License Agreement” means (i) each Contract identified on Schedule 1.1-4 as of the Effective Date and (ii) any New License Agreements entered into after the Effective Date, which will be added to Schedule 1.1-4 pursuant to Section 6.10(a)(iii).

“Licensee” means, with respect to any Included Product, a Third Party to whom the Parent Company or any Affiliate of the Parent Company has granted a license or sublicense (or any Third Party to whom such Third Party has granted a license or sublicense) to develop, have developed, make, have made, seek Regulatory Approvals for, distribute, use, have used, import, sell, offer to sell, have sold or otherwise Commercialize such Included Product under the applicable License Agreement.

“Lien” means any security interest, mortgage, pledge, hypothecation, assignment, deposit arrangement, encumbrance, lien (statutory or otherwise), charge against or interest in property or other priority or preferential arrangement of any kind or nature whatsoever, in each case to secure payment of a debt or performance of an obligation, including any conditional sale or any sale with recourse.

“Litigation Financing Agreements” means (i) that certain Financing Agreement dated as of June 4, 2020, by and between Liquidia PAH and Henderson SPV, LLC and (ii) that certain Litigation Funding and Indemnification Agreement by and between PBM RG Holdings, LLC and Liquidia PAH, in each case (x) related solely to the case captioned *Sandoz Inc. and RareGen, LLC v. United Therapeutics Corporation and Smiths Medical ASD, Inc., Case No. 3:19 cv 10170* and (y) as in effect as of the Effective Date or as amended, supplemented, modified or restated from time to time after the Effective Date in a manner that will not result in increased costs under the Litigation Financing Agreements to any member of the Company Group or any change to the Litigation Financing Collateral.

“Litigation Financing Collateral” means the term “Collateral” as defined under each of the Litigation Financing Agreements, as in effect as of the Effective Date.

“Liquidia PAH” means Liquidia PAH, LLC, a Delaware limited liability company.

“Loss” means any loss, assessment, award, cause of action, claim, charge, Tax (other than any Tax for which additional amounts are paid by the Company to the Investor under Section 6.22(c)), cost, expense (including reasonable expenses of investigation and reasonable and documented out-of-pocket attorneys’ fees), fine, judgment, liability, obligation or penalty; provided, however that Loss shall not include any lost profits or revenue or consequential, punitive, special or incidental damages except (a) any Included Product Payment Amounts that are not received by Investor Representative (on behalf of the Investor) due to failure by any Third Party to make payment thereof (other than resulting from any matter described in Section 10.1, Section 10.2, Section 10.3 or Section 10.4) and (b) any lost profits or revenue or consequential, punitive, special or incidental damages awarded or payable by an Investor to a Third Party in connection with a claim or action for which the Company is required to indemnify the Investor pursuant to Section 10.1.

“Marketing Authorization” means, with respect to an Included Product, the Regulatory Approval required by Applicable Law to sell such Included Product in a country or

region, including, to the extent required by Applicable Law for the sale of such Included Product, all pricing approvals and government reimbursement approvals.

“Material Adverse Effect” means (a) a material adverse change in, or a material adverse effect upon, the business, assets, properties, liabilities or condition (financial or otherwise) of the Company Group taken as a whole, (b) a material impairment of the rights and remedies of the Investor under any Transaction Document to which it is a party or a material impairment in the perfection or priority of the Investor’s security interests in the Collateral, (c) an impairment of the ability of the Company Parties (taken as a whole) to perform their respective obligations under the Transaction Documents that could reasonably be expected to have a material adverse effect on the business, assets, properties, liabilities or condition (financial or otherwise) of the Company Group taken as a whole, (d) a material adverse effect upon the legality, validity, binding effect or enforceability against any Company Party of any Transaction Document, when taken as a whole, to which it is a party, or (e) an adverse effect (other than a de minimis effect) on the timing, amount or duration of payments due in respect of Net Revenues in accordance with the Transaction Documents to which it is a party or the right of the Investor to receive payments due in respect of Net Revenues; provided, however, that “Material Adverse Effect” shall not include (x) any event, occurrence, fact, condition or change, directly or indirectly, arising out of or attributable to the failure to achieve a Favorable Determination or the occurrence of an Other Determination or (y) the failure, in and of itself, of any Company Party to achieve any previously forecasted or any previously achieved level of sales or Net Revenue.

“Material Contract Counterparty” means a counterparty to any Material Contract.

“Material Contracts” means each Contract to which any member of the Company Group is a party, and that is material to the marketing, sale, distribution, supply or production (including manufacturing, packaging or labeling) of any Included Product (including, without limitation, all waivers, amendments, supplements and other modifications thereto). The Material Contracts as of the Effective Date are set forth on Schedule 4.12(a). For clarity, each of the following is a Material Contract: (a) prior to the achievement of the Net Sales Threshold, the Sandoz Agreement and the Sandoz Device Agreement; and (b) any Yutrepia Device Agreement that is material to the development, manufacturing, commercialization or supply of a device that is necessary to administer Yutrepia in the United States.

“Minimum Cash Account” has the meaning set forth in Section 7.8.

“Minimum Multiple” means the multiples of the then-current Investment Amount as set forth in Column A of the chart in Section 3.1(b).

“Multiemployer Plan” means any “employee benefit plan” (as defined in Section 3(3) of ERISA) that is a “multiemployer plan” as defined in Section 4001(a)(3) of ERISA, to which the Company or any ERISA Affiliate makes or is obligated to make contributions, or during the preceding 5 plan years, has made or been obligated to make contributions.

“Net Revenues” means, without duplication, the Net Sales, Other Royalty Payments, payments received under the Sandoz Agreement that any member of the Company Group recognizes as revenue in accordance with GAAP, and any other payments made in lieu of

the sale of any Included Product (to the extent such payments are not included in the Net Sales or Other Royalty Payments) recognized as revenue by any member of the Company Group in accordance with GAAP.

“Net Sales” means, with respect to each Included Product and without duplication, for any period of determination, the sum of: (i) “net revenue” with respect to the sale by any member of the Company Group of Included Products, as reported in the Parent Company’s (or any successor’s) periodic reports filed with the SEC on Form 10-Q and Form 10-K (as applicable); and (ii) for any sales of any Included Product by any member of the Company Group that are not reported in the Parent Company’s (or any successor’s) periodic reports filed with the SEC on Form 10-Q and Form 10-K (as applicable) under the preceding clause (i) as “net revenue”, then “net sales” of each Included Product shall be calculated in such case as the difference between (notwithstanding anything to the contrary and for the avoidance of doubt, no “net sales” calculated in the preceding clause (i) shall be included in the “net sales” calculation pursuant to clause (ii)):

(a) the gross amount recognized as revenue in accordance with GAAP with respect to sales or other dispositions to a Third Party of the Included Product by any member of the Company Group or any of their Subsidiaries, minus

(b) the following deductions:

(i) rebates, credits or allowances actually granted for damaged or defective products, returns or rejections of Included Products or recalls, or for retroactive price reductions and billing errors;

(ii) normal and customary trade, cash, quantity and other customary discounts, allowances and credits (including chargebacks) given to Third Parties in the ordinary course;

(iii) excise taxes, sales taxes, duties, VAT taxes and other taxes to the extent imposed upon and paid with respect to the sales price, and a pro rata portion of pharmaceutical excise taxes imposed on sales of pharmaceutical products as a whole and not specific to Included Products (such as those imposed by the U.S. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, as amended) (and excluding in each case national or local taxes based on income);

(iv) freight, postage, shipping and shipping insurance expense and other transportation charges directly related to the distribution of the Included Product;

(v) non-affiliated brokers or agent commissions, distribution services agreement fees and other similar amounts allowed or paid to Third Party distributors, including specialty distributors of the Included Product;

(vi) rebates made with respect to sales paid for by any Governmental Authority (including, without limitation, Medicaid and Medicare), their agencies and purchasers and reimbursers, managed health care organizations, or to trade customers;

(vii) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to the Included Product;

(viii) any invoiced amounts that are not collected and are written off by the Company, its Affiliates or Licensees, including bad debts; and

(ix) any customary or similar payments related to the foregoing clauses (i) through (viii) that apply to the sale or disposition of pharmaceutical products.

In the case of any sale or other disposal for value of an Included Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of such Included Product in the country of sale or disposal, as determined in accordance with GAAP.

In the event that an Included Product is sold as part of a combination product (i.e., a pharmaceutical product comprised of two or more active pharmaceutical ingredients (a "Combination Product")), then Net Sales for such Combination Product in a Calendar Quarter (solely for the purposes of determining the applicable Revenue Interest payment amount to be paid) shall be calculated by multiplying the Net Sales of the Combination Product in such Calendar Quarter by the fraction: A divided by (A+B), in which A is the average selling price of the Included Product, as applicable, sold in substantial quantities comprising the related Included Product as the sole therapeutically active ingredient in the applicable country, and B is the average selling price of any product that is sold separately in substantial quantities comprising the other therapeutically active ingredients in such country, in each case during the accounting period in which the sales of the Combination Product were made, or if no sales of the Included Product, as applicable, or product comprising the other active ingredients occurred during such period, then such average selling prices as sold during the most recent accounting period in which such sales did occur in such country.

If an Included Product, as contained in such Combination Product, is not sold separately in finished form in such country, the applicable member of the Company Group and the Investor shall submit the matter to an independent valuation to be conducted by a valuation firm mutually accepted by the Parties. In the event that the Parties cannot mutually agree on an independent valuation firm, then the matter shall be resolved by binding arbitration before a panel of three arbitrators, consisting of a single arbitrator selected by each Party and the third arbitrator selected by the first two arbitrators. The arbitrators shall have experience in commercial valuation disputes and shall be drawn from the JAMS panel located in New York City. Any such determination shall be made in accordance with the above formula, 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. The decision of the arbitration panel shall be final.

"Net Sales Threshold" means has the meaning set forth on Schedule 1.1-8.

"New Drug Application" means a New Drug Application, as defined in the FDCA and the FDA regulations promulgated thereunder.

“New License Agreement” means any partnership agreement, license agreement or similar agreement entered into by the Company or its Affiliate, pursuant to which the Company or an Affiliate of the Company has granted a license or sublicense to any Third Party to develop, have developed, make, have made, seek Regulatory Approvals for, distribute, use, have used, import, sell, offer to sell, have sold or otherwise Commercialize an Included Product.

“Non-Appealable Decision” means a decision which cannot be appealed (other than to the United States Supreme Court) because either (a) all appeals have been taken (except for a petition for certiorari to the United States Supreme Court) or (b) the deadline for filing an appeal has lapsed (except for a petition for certiorari to the United States Supreme Court).

“Obligations” means all liabilities, indebtedness, obligations, covenants and duties of any nature (monetary (including post-petition interest, costs, fees, expenses and other amounts, whether allowed or not) or otherwise) of each of the Company Parties arising under this Agreement or any other Transaction Document, any Collateral Document, in each case howsoever created, arising or evidenced, whether direct or indirect, absolute or contingent, now or hereafter existing, or due or to become due.

“OFAC” means the Office of Foreign Assets Control of the United States Department of the Treasury.

“One-Time Fixed Payment” has the meaning set forth in Section 3.1(a)(i).

“Orange Book” means the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations”, as may be amended from time to time.

“Organization Documents” means, (a) with respect to any corporation, the certificate or articles of incorporation and the bylaws (or equivalent or comparable constitutive documents with respect to any jurisdiction outside the United States), (b) with respect to any limited liability company, the certificate or articles of formation or organization and operating agreement, and (c) with respect to any partnership, joint venture, trust or other form of business entity, the partnership, joint venture or other applicable agreement of formation or organization and any agreement, instrument, filing or notice with respect thereto filed in connection with its formation or organization with the applicable Governmental Authority in the jurisdiction of its formation or organization and, if applicable, any certificate or articles of formation or organization of such entity.

“Other Determination” means Regulatory Approval of the Existing Yutrepia Product in the United States remains delayed until the expiration of the Asserted Patents due to a Non-Appealable Decision that the Existing Yutrepia Product infringes at least one valid claim of the Asserted Patents. For clarity, Regulatory Approval of the Existing Yutrepia Product in the United States shall not be deemed to have been granted until final approval of New Drug Application No. 213005 has been granted by FDA. The foregoing notwithstanding, for purposes of this definition only, it will be deemed that there has not been a Non-Appealable Decision with respect to U.S. Patent No. 10,716,793 until there has been a Non-Appealable Decision with respect to both (i) the lawsuit involving such Asserted Patent before the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA), and (ii) the *inter partes* review of such Patent before

the Patent Trial and Appeal Board of the United States Patent and Trademark Office (IPR2021-00406).

“Other Royalty Payments” means, without duplication, any net revenue recognized by any member of the Company Group in their financial statements prepared in accordance with GAAP from partnership distributions, royalty payments, upfront payments, milestone payments or similar payments or any other amounts payable by the Licensees to any member of the Company Group or its Affiliates under or in respect of the applicable License Agreement or any other amounts or proceeds arising from the applicable License Agreement other than: (a) payments by Licensees for payment or reimbursement of expenses, including patent prosecution, defense, enforcement or maintenance expenses in respect of any IP Rights; (b) the fair market value of payments received by Company Group from a Licensee for any debt and/or equity securities or instruments issued by Company Group, or payments for an acquisition of all or substantially all of its assets that include the assignment of this Agreement; (c) funds received from a Licensee as a reimbursement of expenses for bona fide research and development of Included Products (including payments for full-time employees, clinical development and manufacturing expenses); and (d) currently unrecognized revenue from any cash payments received on or before the Initial Closing Date under license agreements in effect as of the Initial Closing Date. For the avoidance of doubt, Other Royalty Payments does not include any payments received by any member of the Company Group under the Sandoz Agreement for so long as such payments constitute Net Revenues.

“Other Taxes” means all stamp, court, documentary, intangible, excise, recording, filing or similar Taxes that arise from any payment made pursuant to any Transaction Document or from the execution, delivery, registration or enforcement of, or otherwise with respect to, any Transaction Document.

“Owned Patent Rights” means Patent Rights which are owned by any Company Party, including any Yutrepia Patent Rights which are owned by any Company Party.

“Parent Company” means Liquidia Corporation, a Delaware corporation.

“Party” and “Parties” have the meanings set forth in the preamble.

“Patent License” means any Contract providing for the grant of any right under any Patent Rights by any member of the Company Group or with respect to which any member of the Company Group is authorized or granted rights under or to.

“Patent Office” means the applicable patent office, including the United States Patent and Trademark Office and any comparable foreign patent office, for any Patent Rights.

“Patent Rights” means all letters patent and patent applications in the United States and all other countries (and all letters patent that issue therefrom or from an application claiming priority therefrom) and all patent term extensions, supplementary protection certificates, reissues, reexaminations, extensions, renewals, divisions and continuations (including continuations-in-part and continuing prosecution applications) thereof, for the full term thereof, together with the right to claim the priority thereto and the right to sue for past infringement of any of the foregoing (“Patents”), in each case which are owned by or licensed to any member of the Company Group

or with respect to which any member of the Company Group is authorized or granted rights under or to.

“Payment Term” means the time period commencing on the Initial Closing Date and expiring on the date upon which the Investor Representative has received in full (a) cash payments in respect of the Total Fixed Payments and Total Included Product Payments totaling, in the aggregate, the Hard Cap less any amounts received by the Investor pursuant to the Insurance Policy, if any, plus (b) after taking into account the payments made under clause (a) above, the IRR True-Up Payment Amount plus (c) any other Obligations (other than inchoate Obligations) payable by the Company Parties under this Agreement and the other Transaction Documents.

“Payoff” means the repayment in full of all outstanding loans and other amounts due under that certain Amended and Restated Loan and Security Agreement, dated as of January 7, 2022, by and among Silicon Valley Bank, SVB Innovation Credit Fund VIII, L.P., the Parent Company, the Company and Liquidia PAH, as such agreement may be further amended, supplemented, modified or restated from time to time.

“Pension Plan” means any “employee pension benefit plan” (as defined in Section 3(2) of ERISA), other than a Multiemployer Plan, that is maintained or is contributed to by the Company and any ERISA Affiliate and is either covered by Title IV of ERISA or is subject to minimum funding standards under Section 412 of the Internal Revenue Code.

“Perfection Certificate” means the Perfection Certificate, dated as of the Effective Date, delivered by each Company Party in connection with this Agreement.

“Permits” means licenses, Governmental Licenses, certificates, accreditations, Regulatory Approvals, other authorizations, registrations, permits, consents, clearances and approvals required in connection with the conduct of any member of the Company Group’s business or to comply with any Applicable Laws, and those issued by state governments for the conduct of any member of the Company Group’s business.

“Permitted Acquisition” means any Acquisition by any member of the Company Group if:

(a) no Default or Event of Default has occurred and is continuing or would result therefrom;

(b) all actions required to be taken with respect to such acquired or newly formed Subsidiary or such acquired assets under Section 6.1 and Section 6.5 will be taken in accordance therewith;

(c) such Acquisition is not “hostile”;

(d) immediately after giving effect to the consummation of the Acquisition, each member of the Company Group shall be in compliance with Section 7.8;

(e) after giving effect to such Acquisition, each member of the Company Group shall be in compliance with Section 7.4;

(f) all material consents necessary for such Acquisition have been acquired and such Acquisition is consummated in accordance with the applicable acquisition documents and Applicable Law;

(g) the applicable Company Party is a surviving legal entity after completion of the contemplated transaction; and

(h) as soon as practicable after the closing of such Acquisition, and in any event within fifteen (15) Business Days after such closing, the Company shall deliver copies of all documents executed in connection with such Acquisition to the Investor Representative.

“Permitted Convertible Notes” means unsecured Indebtedness of the Parent Company to be issued in the form of convertible notes that provide for the issuance of common stock upon conversion thereof or cash in lieu of such common stock at the option of the Parent Company and which include customary change of control or fundamental change out provisions and that have the benefit of covenants and events of default customary for comparable convertible securities; provided that: (i) such convertible notes shall not be guaranteed by any Subsidiary of the Parent Company, (ii) the aggregate of the principal amounts of such convertible notes shall not exceed [***]% of the market capitalization of the Parent Company (determined at the time of signing of the definitive agreement for the issuance of such convertible notes, after taking into account the issuance purchase or sale of such convertible notes) and (iii) such convertible notes shall not have a fixed maturity date earlier than the seven (7) year anniversary of the Initial Closing Date.

“Permitted Convertible Notes Creditors” means the lenders or holders of Permitted Convertible Notes.

“Permitted Debt” means any of the following Indebtedness of any member of the Company Group (which, for purposes of determining whether such Indebtedness exceeds any maximum amount provided in the applicable clause below, shall be calculated on a consolidated basis with respect to the Company Group as a whole):

(a) the Indebtedness of any member of the Company Group in respect of any Permitted Convertible Notes;

(b) Indebtedness under the Transaction Documents;

(c) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(d) Guarantees of any member of the Company Group in respect of Indebtedness and other obligations of any member of the Company Group otherwise expressly permitted hereunder;

(e) Indebtedness incurred by any member of the Company Group consisting of (i) the financing of the payment of insurance premiums, (ii) take or pay obligations contained in supply agreements, in each case, in the ordinary course of business or consistent with past practice, (iii) deferred compensation or equity based compensation to current or former officers, directors,

consultants, advisors or employees thereof, in each case in the ordinary course of business and (iv) customer deposits and advance payments received in the ordinary course of business or consistent with past practice from customers for goods or services purchased in the ordinary course of business or consistent with past practice;

(f) Indebtedness owed to any Person providing worker's compensation, health, disability or other employee benefits or property, casualty or liability insurance to any member of the Company Group incurred in connection with such Person providing such benefits or insurance pursuant to customary reimbursement or indemnification obligations to such Person;

(g) Indebtedness in respect of performance, indemnity, bid, stay, customs, appeal, replevin and surety bonds, performance and completion guarantees and other similar bonds or guarantees, trade Contracts, government Contracts and leases, in each case, incurred in the ordinary course of business but excluding Guaranties with respect to any obligations for borrowed money;

(h) Indebtedness arising from Treasury Management Arrangements;

(i) Indebtedness of (A) the Parent Company supported by a letter of credit issued pursuant to any Permitted Debt Facility Documents in an amount not in excess of the stated amount of such letter of credit, and (B) the Company Group in respect of letters of credit, bankers' acceptances, guarantees or other similar instruments or obligations issued or relating to liabilities or obligations incurred in the ordinary course of business; provided, that, the aggregate outstanding amount of such letters of credit issued under clause (B) above shall not exceed [***] at any time outstanding;

(j) Indebtedness in the form of (i) guarantees of loans and advances to officers, directors, consultants, managers and employees, in an aggregate amount not to exceed [***] at any one time outstanding, and (ii) reimbursements owed to officers, directors, managers, consultants and employees of any member of the Company Group for business expenses of any member of the Company Group;

(k) Indebtedness consisting of obligations to make payments to current or former officers, directors and employees of any member of the Company Group, their respective estates, spouses or former spouses with respect to the cancellation, purchase or redemption of Equity Interests of any member of the Company Group to the extent such cancellation, purchase or redemption is permitted under Section 7.7;

(l) the incurrence by any member of the Company Group of Indebtedness arising from agreements providing for indemnification, holdback, earnout, adjustment of purchase price, working capital adjustments or similar obligations, or guarantees or letters of credit, surety bonds or performance bonds securing any obligations of any member of the Company Group pursuant to such agreements, in any case incurred in connection with a Permitted Acquisition;

(m) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred to finance the acquisition, repair, improvement or construction of fixed or capital assets of such Person, provided that the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired

or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made); provided, that, (i) the total of all such Indebtedness for all such Persons taken together shall not exceed an aggregate principal amount of [***] at any one time outstanding, (ii) such Indebtedness when incurred shall not exceed the purchase price of (or the repair, improvement or constructions costs for) the asset(s) financed and (iii) no such Indebtedness shall be refinanced, renewed or extended for a principal amount in excess of the principal balance outstanding thereon at the time of such refinancing, renewal or extension;

(n) Indebtedness in respect of hedging agreements; provided, that, such obligations are (or were) entered into by such Person in the ordinary course of business for the purpose of directly mitigating risks associated with liabilities, commitments, investments, assets, or property held or reasonably anticipated by such Person, or changes in the value of securities issued by such Person, and not for purposes of speculation or taking a “market view”;

(o) Subordinated Debt;

(p) Indebtedness incurred to refinance the Permitted Debt set forth in any of clauses (a) through (q); provided that the type and amount of such refinancing Indebtedness is permitted under such clause;

(q) Indebtedness secured by Liens of any of the types described under clauses (d), (e) and (g) of the definition of Permitted Liens, but only to the extent of the Indebtedness related thereto;

(r) Indebtedness incurred pursuant to the Litigation Financing Agreements; and

(s) the Indebtedness set forth on Schedule 4.15.

“Permitted Debt Creditors” means the lenders or noteholders, and any administrative agent, collateral agent, security agent or similar agent under any Permitted Debt.

“Permitted Debt Facility Documents” means the documents relating to the Permitted Debt.

“Permitted Foreign Transaction” means any transaction, or series of transactions, pursuant to which the Company or an Affiliate of the Company (a) grants a license or sublicense to any rights relating to the Commercialization of an Included Product outside of the United States, or (b) Disposes of any asset relating solely to the Included Products in a jurisdiction other than the United States and that is not necessary or useful to the Included Product in the United States, in each case (a) and (b) to any Person, including any Foreign Subsidiaries, for the purpose of enabling such Person to Commercialize an Included Product outside of the United States.

“Permitted Investments” means any of the following Investments of any member of the Company Group:

(a) Investments (including, without limitation, in Subsidiaries) existing on the Effective Date and disclosed in writing to the Investor Representative as set forth on Schedule 1.1-5;

(b) Investments consisting of Cash Equivalents;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of any member of the Company Group;

(d) Investments consisting of Deposit Accounts, Commodities Accounts, and Securities Accounts (but only to the extent that the Company Parties are permitted to maintain such accounts pursuant to this Agreement and in which the Investor Representative has a first priority perfected security interest (other than in respect of Excluded Accounts));

(e) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of the Parent Company pursuant to employee stock purchase plans or agreements approved by the board of directors of the Parent Company;

(f) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(g) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (g) shall not apply to Investments of any Company Party; and

(h) Permitted Acquisitions and any Strategic Transaction.

“Permitted Licensee” means a Third Party counterparty to a Permitted License.

“Permitted Licenses” means, collectively:

(a) licenses of over-the-counter software that is commercially available to the public,

(b) non-exclusive and exclusive licenses for the use of the IP Rights of any member of the Company Group outside of the United States;

(c) non-exclusive licenses for the use of the IP Rights of any member of the Company Group in the United States entered into in the ordinary course of business;

(d) Permitted Foreign Transactions; provided that, with respect to each such license described in clause (a) or (b), (i) no Special Termination Event, Change of Control, Default

or Event of Default has occurred or is continuing at the time of entry into such license, (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment from the Company or its Affiliates to a Third Party of any IP Rights that, at the time of execution of such license, comprises a portion of the Collateral or the assets of the Company Parties relating to an Included Product, and do not restrict the ability of any member of the Company Group, as applicable, to pledge, grant a Lien on or assign or otherwise transfer such IP Rights (in each case other than customary non-assignment provisions that restrict the assignability of the license but do not otherwise restrict the ability of any member of the Company Group (as applicable) to pledge, grant a Lien on or assign any such IP Rights) and (iii) the Company delivers to the Investor Representative a copy of the final executed transaction documents promptly upon consummation thereof, subject to reasonable redaction to comply with obligations of confidentiality;

(e) any license granted to any Third Party for the manufacture of any Included Product or otherwise granted to a vendor or service provider in order to provide services for the benefit of the Company or its Affiliates;

(f) any sponsored research or similar agreement providing for the development of an Included Product that does not grant Commercialization rights to such Included Product;

(g) a non-exclusive or exclusive license to a Third Party for any indication outside of the field of the treatment of pulmonary hypertension; and

(h) those licenses set forth in Schedule 1.1-6 in the form existing as of the Effective Date or amended or restated in a manner that otherwise constitutes a Permitted License.

It is understood and agreed that, notwithstanding anything to the contrary set forth in this definition, except as permitted under clause (g) of “Permitted Licenses” above, in no event shall a “Permitted License” include any exclusive license to Commercialize an Included Product (or any IP Rights associated therewith) in the United States (or any state or other political subdivision thereof), and a “Permitted License” may include (i) a non-exclusive license to a Third Party in the ordinary course of the Company’s business in the import, export, manufacture, making, use, sale, offer for sale, promotion or distribution of such Included Products so long as such non-exclusive license does not grant to any Third Party the right to sell, offer for sale, market or promote such Included Product on a royalty payment basis, profit sharing basis or any other similar payment structure, or (b) an exclusive license to a Third Party in the ordinary course of the Company’s business in the import, export, manufacture, making or development of an Included Product (or any IP Rights associated therewith) so long as such exclusive license does not grant to any Third Party the exclusive right to Commercialize an Included Product (or any IP Rights associated therewith) in the United States (or any state or other political subdivision thereof).

“Permitted Liens” means:

(a) Liens created in favor of the Investor Representative, for the benefit of the Investor, pursuant to the Transaction Documents;

(b) Liens incurred by the Investor;

(c) [Reserved].

(d) Liens in respect of property of any member of the Company Group imposed by Applicable Law which were incurred in the ordinary course of business and do not secure Indebtedness, such as carriers', warehousemen's, distributors', wholesalers', materialmen's, mechanics' and landlord's Liens and other similar Liens arising in the ordinary course of business and secure payment obligations (i) not then due, (ii) if due, not yet overdue by more than thirty (30) days, (iii) that if overdue by more than thirty (30) days, are being contested in good faith by appropriate proceedings for which adequate reserves have been established in accordance with GAAP or (iv) with respect to which the failure to make payment would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect;

(e) Liens incurred in the ordinary course of business in connection with worker's compensation, unemployment insurance or other forms of governmental insurance or benefits, insurance, surety bonds, or other obligations of a like nature or to secure the performance of letters of credit, banker's acceptances, bids, tenders, statutory obligations, leases and Contracts (other than for borrowed money) entered into in the ordinary course of business, other than any Lien imposed by ERISA which has resulted or would result in liability, together with any other Lien imposed by ERISA, in an aggregate amount in excess of [***];

(f) Liens for Taxes that are not delinquent or remain payable without interest or penalty or that are being contested in good faith and with due diligence by appropriate proceedings and for which adequate reserves have been established in accordance with GAAP;

(g) banker's Liens for collection or rights of set off or similar rights and remedies as to Deposit Accounts or other funds maintained with depository institutions; provided that such Deposit Accounts or funds are not established or deposited for the purpose of providing collateral for any Indebtedness and are not subject to restrictions on access by any Company Party in excess of those required by applicable banking regulations;

(h) Liens in favor of the Company Parties;

(i) Liens existing on the date of this Agreement which are shown on the Perfection Certificate or arising under this Agreement or other Collateral Document;

(j) Liens securing Indebtedness permitted to be incurred under clause (m) of the definition of "Permitted Debt" covering only the assets acquired with or financed by such Indebtedness; provided that individual financings provided by one lender may be cross collateralized to other financings provided by such lender or its Affiliates;

(k) customary Liens incurred in the ordinary course of business to secure obligations in respect of payment processing services, business credit card programs, and netting services, overdrafts and related liabilities arising from treasury, depository and cash management services;

(l) Liens on insurance policies, premiums and proceeds thereof, or other deposits, to secure insurance premium financings with respect to unearned premiums and other liabilities to insurance carriers;

(m) Liens on specific items of inventory or other goods (and the proceeds thereof) of the Company securing such Person's obligations in respect of bankers' acceptances issued or created for the account of such Person to facilitate the purchase, shipment or storage of such inventory or other goods;

(n) Liens arising out of conditional sale, title retention, consignment or similar arrangements for the sale of goods entered into in the ordinary course of business;

(o) 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 in the ordinary course of business;

(p) any interest or title of a lessor or licensor under any lease, sublease, license or sublicense entered into by any member of the Company Group entered into in the ordinary course of its business;

(q) Liens on cash collateral securing hedging agreements entered into for bona fide hedging purposes in the ordinary course of business and not for speculative purposes;

(r) Liens arising from (i) judgments, decrees, attachments or awards and associated rights related to litigation that do not constitute an Event of Default, and (ii) Liens on the Litigation Financing Collateral arising pursuant to the Litigation Financing Agreements;

(s) Liens on cash deposits or other cash amounts held in escrow to secure payments (contingent or otherwise) payable by any member of the Company Group with respect to (i) the settlement, satisfaction, compromise or resolution or judgments, litigation, arbitration or other Disputes and (ii) any commercial Contracts for manufacturing, production and other service arrangements entered into in the ordinary course of business;

(t) survey exceptions, encumbrances, ground leases, easements (including reciprocal easement agreements), survey exceptions or reservations of, or rights of others for, licenses, rights of way, sewers, electric lines, telegraph and telephone lines and other similar purposes, or zoning, building codes or other restrictions (including minor defects or irregularities in title and similar encumbrances) as to the use of real property or Liens incidental to the conduct of the business of such Person or to the ownership of its properties that do not in the aggregate materially adversely affect the value of said properties or materially impair their use in the operation of the business of such Person;

(u) Liens securing Indebtedness permitted to be incurred under clause (o) of the definition of "Permitted Debt" and meeting the requirements of the definition of Subordinated Debt; and

(v) Liens set forth on Schedule 1.1-10.

"Permitted Transfer" has the meaning set forth in the definition of "Disposition" herein.

“Person” means any natural person, firm, corporation, limited liability company, partnership, joint venture, association, joint-stock company, trust, unincorporated organization, Governmental Authority or any other legal entity, including public bodies, whether acting in an individual, fiduciary or other capacity.

“Personal Information” has the meaning set forth in Section 4.24(b).

“Plan” means any “employee benefit plan” within the meaning of Section 3(3) of ERISA (including a Pension Plan) that is maintained for employees of the Company or, in the case of any Pension Plan, any ERISA Affiliate or to which the Company or, in the case of any Pension Plan, any ERISA Affiliate is required to contribute on behalf of any of its employees.

“Product Plan” means the key manufacturing, marketing, sale and product development and research plans with respect to the Sandoz Product and the Existing Yutrepia Product in the United States set forth on Schedule 1.1-7.

“Product Rights” means, collectively, all IP Rights, all Drug Applications, all Regulatory Approvals, all other Governmental Licenses, all applications and requests for Governmental Licenses, all Websites, and all Website Agreements, in each case, which are owned by, issued or licensed to, licensed by, or hereafter acquired or licensed by, any member of the Company Group.

“Proprietary Databases” means any material non-public proprietary database or information repository which is owned by or exclusively licensed to any member of the Company Group or with respect to which any member of the Company Group is authorized or granted rights under or to.

“Proprietary Software” means any proprietary software (other than any software that is generally commercially available, off-the-shelf and/or open source) including, without limitation, the object code and source code forms of such software and all associated documentation, which is owned by or exclusively licensed to any member of the Company Group or with respect to which any member of the Company Group is authorized or granted rights under or to.

“Purpose” has the meaning set forth in Section 9.1.

“Quarterly Fixed Payments” means, with respect to any Calendar Quarter for which a payment is due under Section 3.1(a)(i), the amount equal to (a) Five Hundred Thousand Dollars (\$500,000), plus (b) with respect to each Quarterly Payment Date following any Closing Date (other than the Initial Closing Date), an additional amount to reflect the increased Investment Amount on a ratable basis determined in a manner consistent with the example of such calculation set forth in Exhibit C, and plus (c) if the First Commercial Sale has not occurred by June 30, 2025, Three Million Dollars (\$3,000,000) as set forth in Section 3.1(a)(i). For clarity, the Quarterly Fixed Payments do not include the One-Time Fixed Payment.

“Quarterly Net Revenues” means, with respect to any Calendar Quarter, the aggregate amount of Net Revenues for that Calendar Quarter.

“Quarterly Payment Date” means, with respect to a Calendar Quarter, the date that is forty-five (45) days after the end of each Calendar Quarter after the Initial Closing Date (provided if any such date is not a Business Day, the Quarterly Payment Date shall be the next succeeding Business Day, and provided, further, that for such Calendar Quarter ending December 31, the Quarterly Payment Date shall mean the date that is seventy-five (75) days following the end of each such Calendar Quarter).

“Recipient” has the meaning set forth in Section 9.1.

“Reference Date” means the reference dates set forth in the Column B of the chart in Section 3.1(b).

“Refinancing Convertible Notes” has the meaning set forth in Section 7.7.

“Regulatory Agency” means a Governmental Authority with responsibility for the approval of the marketing and sale of pharmaceuticals or other regulation of pharmaceuticals in any jurisdiction.

“Regulatory Approvals” means, collectively, all regulatory approvals, registrations, certificates, authorizations, permits and supplements thereto, as well as associated materials (including the product dossier) pursuant to which the Included Product may be marketed, sold and distributed in a jurisdiction, issued by the appropriate Regulatory Agency.

“Reportable Event” means any of the events set forth in Section 4043(c) of ERISA, other than events for which the thirty-day notice period has been waived.

“Responsible Officer” means the officers of the Company identified on Schedule 1.1-3 or any successor to any such officer holding the same or substantially similar officer position at the applicable time and, solely for purposes of the delivery of certificates pursuant to this Agreement, the secretary or any assistant secretary of a Company Party. Any document delivered hereunder that is signed by a Responsible Officer of a Company Party shall be conclusively presumed to have been authorized by all necessary corporate, partnership and/or other action on the part of such Company Party and such Responsible Officer shall be conclusively presumed to have acted on behalf of such Company Party.

“Restricted Payment” means

(a) any dividend or other distribution, direct or indirect, on account of any shares (or equivalent) of any class of Equity Interests of any member of the Company Group, now or hereafter outstanding;

(b) any redemption, retirement, sinking fund or similar payment, purchase or other acquisition for value, direct or indirect, of (i) any shares (or equivalent) of any class of Equity Interests of any member of the Company Group, now or hereafter outstanding or (ii) any call option on any shares (or equivalent) of any class of Equity Interests of any member of the Company Group (irrespective of whether such call option can be cash, net share or physically settled);

(c) any payment made to retire, or to obtain the surrender of, any outstanding warrants, options or other rights to acquire shares of any class of Equity Interests of any member of the Company Group, now or hereafter outstanding; and

(d) any payment made in cash to the holders of Permitted Debt under the Permitted Debt Facility Documents in excess of the original principal (or notional) amount thereof, interest thereon and any fees due thereunder.

“Revenue Interests” means all right, title and interest in and to, free and clear of any and all Liens, that portion of Annual Net Revenues of each member of the Company Group in an amount equal to the Included Product Payment Amount for each Calendar Quarter until such time as the Investor Representative has received payments equal to the Hard Cap.

“Royalty Company” means any Person (inclusive of such Person’s Affiliates) engaged primarily in the business of royalty financing or royalty monetization transactions in the life sciences industry, including the purchase or sale of, or financing in exchange for the receipt of, royalties (whether existing or synthetic), net sales, net revenues or other contingent payments (including milestone payments) with respect to pharmaceutical, biological and/or medical device products, or other similar financing transactions for life sciences companies.

“Safety Notices” means any recalls, field notifications, market withdrawals, warnings, “dear doctor” letters, investigator notices, safety alerts or other notices of action issued or instigated by any member of the Company Group or any Governmental Authority relating to an alleged lack of safety or regulatory compliance of the Included Products.

“Sanction(s)” means any sanction administered or enforced by the United States government (including, without limitation, OFAC), the United Nations Security Council, the European Union, His Majesty’s Treasury (“HMT”) or other relevant sanctions authority.

“Sandoz Agreement” means that certain Promotion Agreement, dated as of August 1, 2018, by and between Sandoz Inc. and Liquidia PAH (formerly known as RareGen, LLC), as amended by the First Amendment, dated as of May 8, 2020, and the Second Amendment, dated as of September 4, 2020, and Third Amendment, dated as of November 18, 2022, and any other Contract granting the Company or any of its Affiliates any rights in or to the Sandoz Product.

“Sandoz Device Agreement” means at any given time, either (a) that certain Device Development and Supply Agreement, dated December 1, 2022, by and among Mainbridge Health Partners, LLC, Liquidia PAH and Sandoz Inc. (the “Mainbridge Agreement”), or (b) any other comparable agreement between any Company Party and/or Sandoz and/or any Third Party entered into in accordance with Section 6.8(c) relating to the development, manufacturing, commercialization or supply of a device that is necessary to administer the Sandoz Product in the United States (a “New Sandoz Device Agreement”).

“Sandoz Inc.” means Sandoz Inc., a corporation organized and existing under the laws of Colorado and counterparty to the Sandoz Agreement, and all of its successors and permitted assigns.

“Sandoz Product” means any and all of the Company’s rights in and to (a) treprostinil injection (therapeutic equivalent to Remodulin®) as approved by the FDA for sale in the United States under Abbreviated New Drug Application No. 203649 owned by Sandoz Inc., and (b) any other “Product”, as such term is defined under the Sandoz Agreement.

“SEC” means the Securities and Exchange Commission or any successor agency or authority thereto.

“Second Closing” has the meaning set forth in Section 8.1(b).

“Second Closing Date” has the meaning set forth in Section 8.1(b).

“Second Closing Notice” has the meaning set forth in Section 8.3.

“Second Investment Amount” has the meaning set forth in Section 2.1(b).

“Securities Account” means a “securities account” (as defined in Article 8 of the UCC) or other account to or for the credit or account of any Company Party to which a financial asset is or may be credited in accordance with an agreement under which the Person maintaining the account undertakes to treat the Person for whom the account is maintained as entitled to exercise the rights that comprise the financial asset.

“Securities Account Control Agreement” means any securities account control agreement entered into by any “securities intermediary”, the Investor Representative and any Company Party with respect to any Securities accounts, which shall be in form and substance reasonably acceptable to the Investor Representative.

“Security Agreement” means the security agreement dated as of the Initial Closing Date executed in favor of the Investor Representative, for the benefit of the Investor, by the Company and each of the Guarantors.

“Set-off” means any set-off, off-set, reduction or similar deduction.

“Special Maturity Payment Amount” means, as of the Legal Maturity Date, the sum of (a) the Hard Cap less the aggregate of (i) all of the payments of the Company in respect of the Total Fixed Payments and the Total Included Product Payments (including any Under Performance Payment or Generic Product Payment) made to the Investor prior to such date and (ii) any amounts received by the Investor pursuant to the Insurance Policy, if any, plus (b) after taking into account the payments made under clause (a), the IRR True-Up Payment Amount, plus (c) any other Obligations (other than inchoate Obligations) payable by the Company Parties under this Agreement and the other Transaction Documents (if any).

“Special Termination Amount” has the meaning set forth in Schedule 1.1-9.

“Special Termination Event” has the meaning set forth in Schedule 1.1-9.

“Strategic Transaction” means any acquisition of rights by any member of the Company Group, whether in the form of an Acquisition, license, joint venture or similar

transaction, to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension, if (a) no Default or Event of Default has occurred and is continuing or would result therefrom, (b) immediately after giving effect to the consummation of the Strategic Transaction each member of the Company shall be in compliance with Section 7.8, (c) after giving effect to such Strategic Transaction, each member of the Company Group shall be in compliance with Section 7.4, (d) all material consents necessary for such Strategic Transaction have been acquired and such Strategic Transaction is consummated in accordance with the applicable definitive agreement and Applicable Law, (e) the applicable Company Party is a surviving legal entity after completion of the Strategic Transaction, and (f) solely in connection with a Strategic Transaction that is an Acquisition, such Acquisition meets the criteria set forth in clauses (b) and (c) of the definition of "Permitted Acquisition". As soon as practicable after the closing of such Acquisition, license, joint venture or similar transaction, and in any event within fifteen (15) Business Days after such closing, the Company shall deliver copies of all documents executed in connection with such Acquisition, license, joint venture or similar transaction to the Investor Representative.

"Subordinated Debt" means Indebtedness of any member of the Company Group (which, for purposes of determining whether such Indebtedness exceeds any maximum amount provided in the applicable clause below, shall be calculated on a consolidated basis with respect to the Company Group as a whole) that satisfies each of the criteria set forth below:

(a) any Indebtedness that is secured on a junior basis to the Obligations or any unsecured Indebtedness not otherwise permitted hereunder including any revolving line(s) of credit, provided that under no circumstances shall the aggregate outstanding principal amount of such permitted Indebtedness exceed [***];

(b) such Indebtedness is subordinated in right of payment and, to the extent secured, in right of Lien to any of the Obligations of the Company Group hereunder pursuant to an intercreditor agreement or subordination agreement on terms satisfactory to the Investor Representative in its sole discretion;

(c) any obligor of such Indebtedness must be a Company Party; and

(d) in the case of any secured Indebtedness, such Indebtedness may not be secured by assets other than the Collateral under the Collateral Documents.

"Subsidiary" means with respect to any Person (a) any entity as to which such Person directly or indirectly owns outstanding voting securities with power to vote more than fifty percent (50%) of the outstanding Voting Stock of such entity or (b) any entity as to which more than fifty percent (50%) of its outstanding Voting Stock are directly or indirectly owned, controlled or held by such Person with power to vote such securities. As of the Effective Date, the Subsidiaries of the Company are set forth on Schedule 4.20.

"Tax" or "Taxes" means all present or future U.S. federal, state, local or non-U.S. tax, levy, impost, duty, assessment or withholding or other similar fee, deduction or charge, including all income, excise, withholding, estimated, 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).

“Third Closing” has the meaning set forth in Section 8.1(c).

“Third Closing Date” has the meaning set forth in Section 8.1(c).

“Third Closing Notice” has the meaning set forth in Section 8.4.

“Third Investment Amount” has the meaning set forth in Section 2.1(c).

“Third Party” means any Person other than (a) the Company, (b) the Investor or (c) an Affiliate of either the Company or any of the Investor (as applicable).

“Third Party Claim” means any claim, action, suit or proceeding by a Third Party, excluding any lender, officer, directors, employee or agent or other representative of a Party, including any investigation by any Governmental Authority.

“Third Party Information” has the meaning set forth on Schedule 3.4.

“Third Party Reports” has the meaning set forth on Schedule 3.4.

“Total Fixed Payments” means, as of any time of determination, the aggregate amount of payments made by Company pursuant to Section 3.1(a)(i).

“Total Included Product Payments” means, as of any time of determination, the aggregate amount of payments made by Company pursuant to Section 3.1(a)(ii).

“Trade Secrets” means all rights in data or information that is not commonly known by or available to the public, and which (a) derives economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other Persons who can obtain economic value from its disclosure or use, and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy, in each case which are owned by or licensed to any member of the Company Group or with respect to which any member of the Company Group is authorized or granted rights under or to.

“Trademark License” means any Contract providing for the grant of any right to use any Trademark by any member of the Company Group or with respect to which any member of the Company Group is authorized or granted rights under or to.

“Trademarks” means all statutory and common-law trademarks, trade names, corporate names, company names, business names, fictitious business names, trade styles, service marks, logos and other source or business identifiers, and the goodwill associated therewith, now existing or hereafter adopted or acquired, all registrations and recordings thereof, and all applications to register in connection therewith, under the Laws of the United States, any state thereof or any other country or any political subdivision thereof, or otherwise, for the full term and all renewals thereof, which are owned by or licensed to any member of the Company Group or

with respect to which any member of the Company Group is authorized or granted rights under or to.

“Transaction Documents” means this Agreement, the Collateral Documents, the Guaranty and any Joinder Agreement and all other documents, instruments and Contracts executed and delivered by any Company Party or any other Person to or for the benefit of Investor Representative and/or the Investor in connection with this Agreement or any other Transaction Document.

“Treasury Management Arrangement” means any agreement or other arrangement governing the provision of treasury or cash management services, including Deposit Accounts, netting services, overdraft, credit or debit card, funds transfer, automated clearinghouse, zero balance accounts, returned check concentration, controlled disbursement, lockbox, account reconciliation and reporting, direct debit, cash concentration, trade finance services and other cash management services.

“U.S.” or “United States” means the United States of America, its 50 states, each territory and possession thereof and the District of Columbia.

“UCC” means the Uniform Commercial Code as in effect from time to time in the State of New York; provided, that, if, with respect to any financing statement or by reason of any provisions of Applicable Law, the perfection or the effect of perfection or non-perfection of any security interest or any portion thereof granted pursuant to any Collateral Document is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than the State of New York, then “UCC” means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of this Agreement and any financing statement relating to such perfection or effect of perfection or non-perfection.

“Under Performance Payments” has the meaning set forth in Section 3.1(b).

“Unused Amounts” has the meaning set forth in Section 7.7(k).

“Voting Stock” means, with respect to any Person, Equity Interests issued by such Person, the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the Board of Directors of such Person, even though the right so to vote has been suspended by the happening of such a contingency.

“Website Agreements” means all agreements between a Company Party and any other Person pursuant to which such Person provides any services relating to the hosting, design, operation, management or maintenance of any Website, including without limitation, all agreements with any Person providing website hosting, database management or maintenance or disaster recovery services to any member of the Company Group and all agreements with any domain name registrar.

“Websites” means all websites that any member of the Company Group shall operate, manage or control through a Domain Name, whether on an exclusive basis or a nonexclusive basis, including, without limitation, all content, elements, data, information, materials, hypertext markup language (HTML), software and code, works of authorship, textual

works, visual works, aural works, audiovisual works and functionality embodied in, published or available through each such website and all IP Rights in each of the foregoing. “Work” means any work or subject matter that is subject to protection pursuant to Title 17 of the United States Code.

“Yutrepia” means the Existing Yutrepia Product, and, except for the Sandoz Product, any other pharmaceutical or biological composition containing tadalafil, including any modifications or improvements thereto.

“Yutrepia Device Agreement” means any agreement entered into after the Effective Date between any Company Party and a Third Party relating to the development, manufacturing, commercialization or supply of a device that is necessary to administer Yutrepia in the United States.

“Yutrepia Patent Rights” means any Patent Rights relating to Yutrepia.

Section 1.2 Rules of Construction. Unless the context otherwise requires, in this Agreement:

(a) An accounting term not otherwise defined has the meaning assigned to it in accordance with GAAP.

(b) Words of the masculine, feminine or neuter gender shall mean and include the correlative words of other genders.

(c) The definitions of terms shall apply equally to the singular and plural forms of the terms defined.

(d) The terms “include”, “including” and similar terms shall be construed as if followed by the phrase “without limitation”.

(e) Unless otherwise specified, references to an agreement or other document (including any Transaction Document) include references to such agreement or document as from time to time amended, restated, amended and restated, reformed, supplemented or otherwise modified or replaced in accordance with the terms thereof (subject to any restrictions on such amendments, restatements, amendments and restatements, reformations, supplements or modifications or replacements set forth herein or in any of the other Transaction Documents) and include any annexes, exhibits and schedules attached thereto.

(f) References to any Applicable Law shall include such Applicable Law as from time to time in effect, including any amendment, modification, codification, replacement or reenactment thereof or any substitution therefor.

(g) References to any Person shall be construed to include such Person’s successors and permitted assigns (subject to any restrictions on assignment, transfer or delegation set forth herein or in any of the other Transaction Documents), and any reference to a Person in a particular capacity excludes such Person in other capacities.

(h) The word “will” shall be construed to have the same meaning and effect as the word “shall”.

(i) The words “hereof”, “herein”, “hereunder” and similar terms when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision hereof, and Article, Section and Exhibit references herein are references to Articles and Sections of, and Exhibits to, this Agreement unless otherwise specified.

(j) In the computation of a period of time from a specified date to a later specified date, the word “from” means “from and including” and each of the words “to” and “until” means “to but excluding”.

(k) Where any payment is to be made, any funds are to be applied or any calculation is to be made under this Agreement on a day that is not a Business Day, unless this Agreement otherwise provides, such payment shall be made, such funds shall be applied and such calculation shall be made on the immediately succeeding Business Day, and payments shall be adjusted accordingly.

(l) Notwithstanding the definition of “Knowledge,” “to the Knowledge of the Company” for purposes of Sections 4.10(h), 4.10(j), 4.10(l), 4.10(m), 4.10(n) and 4.10(q) shall mean, as of the Effective Date and as of the date of each Closing, as applicable, solely with respect to any IP Rights referenced in such sections that are owned by any member of the Company Group and exclusively licensed by such member to a Third Party and solely with respect to the scope of such exclusive licenses, the actual knowledge of the Company.

(m) Notwithstanding anything in this Agreement to the contrary, the representations and warranties in Section 4.10(d) and the first sentence of Section 4.10(k) shall not apply with respect to any Patent Rights to the extent that such Patent Rights are owned by any member of the Company Group and exclusively licensed by such member to a Third Party.

ARTICLE II REVENUE INTEREST FINANCING

Section 2.1 Investment Amount. Subject to the terms and conditions set forth herein, the Investor shall pay (or cause to be paid) to the Company, or the Company’s designee, the following:

(a) the sum of Thirty-Two Million Five Hundred Thousand Dollars (\$32,500,000) (the “Initial Investment Amount”) on the Initial Closing Date, subject to the satisfaction of the conditions set forth in Section 8.2 and the performance of the obligations set forth in Section 8.6(a) and (b), in immediately available funds, delivered by wire transfer to an account designated in writing by the Company to the Investor Representative prior to the Initial Closing Date, provided that, in connection with the funding of the Initial Investment Amount on the Initial Closing Date, the Investor shall have the right to, at its option, fund the amount due under this Section 2.1, on a net basis less the reimbursement owed by the Company pursuant to Section 8.6(b);

(b) the sum of Seven Million Five Hundred Thousand Dollars (\$7,500,000) (the “Second Investment Amount”) on the Second Closing Date, subject to the satisfaction of the conditions set forth in Section 8.3 and the performance of the obligations set forth in Section 8.6(c), in immediately available funds, by wire transfer to an account designated in writing by the Company to the Investor Representative prior to the Second Closing Date;

(c) the sum of Thirty-Five Million Dollars (\$35,000,000) (the “Third Investment Amount”) on the Third Closing Date, subject to the satisfaction of the conditions set forth in Section 8.4 and the performance of the obligations set forth in Section 8.6(d), in immediately available funds, by wire transfer to an account designated in writing by the Company to the Investor Representative prior to the Third Closing Date; and

(d) the sum of Twenty-Five Million Dollars (\$25,000,000) (the “Fourth Investment Amount”) on the Fourth Closing Date, subject to the satisfaction of the conditions set forth in Section 8.5 and the performance of the obligations set forth in Section 8.6(e), in immediately available funds by wire transfer to an account designated in writing by the Company to the Investor Representative prior to the Fourth Closing Date.

Section 2.2 No Assumed Obligations. Notwithstanding any provision in this Agreement or any other writing to the contrary, the Investor is not assuming any liability or obligation of the Company or any of the Company’s Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter (including as referenced in Section 2.3). All such liabilities and obligations shall be retained by and remain liabilities and obligations of the Company or the Company’s Affiliates, as the case may be (the “Excluded Liabilities and Obligations”).

Section 2.3 Excluded Assets. The Investor does not, pursuant to any of the Transaction Documents, purchase, acquire or accept any assets or contract rights of any member of the Company Group or any other assets of any Company Party, other than its rights with respect to the Revenue Interests and, to the extent provided in the Transaction Documents, the Collateral. As between the Parties, each member of the Company Group has sole authority and responsibility for the research, development and Commercialization of the Included Products.

ARTICLE III PAYMENTS ON ACCOUNT OF THE REVENUE INTEREST FINANCING

Section 3.1 Payments on Account of the Revenue Interest Financing.

(a) In consideration of the Investor paying the Investment Amount hereunder, the Company shall pay the following amounts to the Investor Representative as follows:

(i) On each Quarterly Payment Date, until the earlier of (A) subject to the proviso hereto, the date that the First Commercial Sale occurs and (B) the date on which the Investor Representative has received payments (including, without limitation, any amounts received by the Investor pursuant to the Insurance Policy, if any) equal to the Hard Cap, the Company shall pay the Quarterly Fixed Payments to the Investor Representative; provided that, if the First Commercial Sale has not occurred prior to June 30, 2025, then

the Company shall (1) continue the Quarterly Fixed Payments until such time as the Investor Representative has received payments (including, without limitation, any amounts received by the Investor pursuant to the Insurance Policy, if any) equal to the Hard Cap, and (2) make a one-time payment of [***] to Investor Representative no later than July 30, 2025 (the “One-Time Fixed Payment”).

(ii) Following the date that the First Commercial Sale occurs (subject to Section 3.1(a)(i)), on each Quarterly Payment Date, the Company shall pay the Included Product Payment Amount to the Investor Representative for the applicable Calendar Quarter until the earlier of (A) the date on which the Investor Representative has received payments (including, without limitation, any amounts received by the Investor pursuant to the Insurance Policy, if any) equal to the Hard Cap and (B) the Legal Maturity Date. If (1) the Investor Representative has not received payments (including, without limitation, any amounts received by the Investor pursuant to the Insurance Policy, if any) equal to the Hard Cap by the Legal Maturity Date (after giving effect to any payments made on the Legal Maturity Date) and (2) no Special Termination Event, Change of Control, Default or Event of Default has occurred or is continuing, the Company shall pay the Special Maturity Payment Amount on the Legal Maturity Date. The Company shall have the right, at any time and from time to time, to make voluntary prepayments to the Investor Representative, and such payments shall be credited against the Hard Cap and the Under Performance Payments set forth in Section 3.1(b). This Agreement shall be in full force and effect for the duration of the Payment Term.

(b)

(i) Following the date that the First Commercial Sale occurs, if the Investor Representative has not received the applicable Minimum Multiple of the Investment Amount set forth below by the corresponding Reference Date set forth below, the Company shall, within thirty (30) days of the applicable Reference Date, make a cash payment to the Investor Representative equal to (i) the Minimum Multiple times the then-current Investment Amount, minus (ii) the aggregate of all payments of the Company in respect of the Total Fixed Payments, the Total Included Product Payments (including any Under Performance Payment or Generic Product Payment paid on or prior to such Reference Date) and any amounts received by the Investor pursuant to the Insurance Policy, if any, made to the Investor prior to such date (each, an “Under Performance Payment”).

<u>A. Minimum Multiple</u>	<u>B. Reference Date</u>
0.60x	December 31, 2026
1.00x	December 31, 2028

(ii) Upon the occurrence of a Generic Product Payment Event, if the Investor Representative has not received the Minimum Multiple of the Investment Amount set forth below as of such occurrence, the Company shall, within thirty (30) days of such occurrence, make a cash payment to the Investor Representative equal to (i) the Minimum Multiple times the then-current Investment Amount, minus (ii) the aggregate of all payments of the Company in respect of the Total Fixed Payments, the Total Included Product Payments (including any Under Performance Payment paid on or prior to such date) and any amounts

received by the Investor pursuant to the Insurance Policy, if any, made to the Investor prior to such date (a "Generic Product Payment").

Minimum Multiple

1.00x

(c) Upon the occurrence of a Change of Control, the Company shall promptly pay to the Investor Representative the Change of Control Payment, whereupon this Agreement shall terminate on the date such payment is received by the Investor Representative.

(d) If a Special Termination Event has occurred and is continuing, the Investor Representative may, in its sole discretion, terminate this Agreement and notify the Company of its election to terminate this Agreement. In consideration for such termination, the Company shall pay the Special Termination Amount and any other unpaid Obligations to the Investor Representative within, in the case of clause (i) of the definition of Special Termination Event, [***], and, in the case of clause (ii) of the definition of Special Termination Event, [***], in each case, following receipt of such notice of the election to terminate this Agreement. The remedy set forth in this Section 3.1(d) shall be the Investor's and the Investor Representative's sole and exclusive remedy in the event of a Special Termination Event; provided, however, that to the extent the Special Termination Amount is not paid as aforesaid in full within such applicable period, for the avoidance of doubt, the failure to make such payment shall constitute an Event of Default.

(e) Within thirty (30) days following the date that Investor Representative has received aggregate payments under Section 3.1(a) and Section 3.1(b) equal to the Hard Cap, the Company shall pay to Investor Representative the sum of the IRR True-Up Payment Amount, if any.

(f) Once the Investor Representative has received (i) aggregate payments under Section 3.1(a), Section 3.1(b) and Section 3.1(e) or (ii) the amounts due pursuant to Section 3.1(c), Section 3.1(d) or Section 11.2, in either case, along with all of the other Obligations owed by the Company Parties under this Agreement and the other Transaction Documents, (A) the Company shall have no further obligations to the Investor with respect to the Revenue Interests, and Investor Representative will not be entitled to any additional payments in respect of Revenue Interests and (B) each of the Transaction Documents shall terminate immediately and automatically. Immediately upon termination of this Agreement pursuant to this Section 3.1(f) (1) all Liens on the Collateral granted to the Investor Representative pursuant to this Agreement and the other Transaction Documents shall immediately and automatically be released, without the delivery of any instrument or performance of any act by any Person, (2) the Company (or its designee) shall be permitted, and is hereby authorized to terminate any financing statement which has been filed pursuant to the Transaction Documents, and (3) the Investor and the Investor Representative shall execute and deliver to, or at the direction of, the Company, at the Company's sole cost and expense, all other releases and other documents as the Company shall reasonably request to evidence any such release.

(g) Notwithstanding the foregoing, if any Event of Default under Section 11.1(a) or Section 11.1(d) has occurred and is continuing, any overdue amount owed to the Investor shall bear interest at a rate of [***] percent ([***]%) per month from the due date until paid in full

or, if less, the maximum interest rate permitted by Applicable Law. In addition, in the event that an Event of Default has occurred, and for so long as it is continuing, interest shall accrue on the amount of the Event of Default Payment that remains unpaid at a rate of [***] percent ([***]%) per month from the date on which Company receives notice from the Investor Representative of such Event of Default until the Event of Default Payment is paid in full or, if less, the maximum interest rate permitted by Applicable Law. Any such overdue payment shall, when made, be accompanied by, and credited first to, all interest so accrued.

(h) The Company shall deposit all amounts payable by the Company to the Investor Representative under this Agreement into the Investor Account, unless otherwise instructed by the Investor Representative.

(i) For all purposes of this Section 3.1, the amount of payments deemed received by the Investor shall (i) include any additional amounts payable to the Investor pursuant to Section 6.22(c) (“Additional Amounts”) and (ii) be computed net of any applicable Tax withholding (including any Tax withholding in respect of any Additional Amounts), other than any withholding in respect of Excluded Taxes.

Section 3.2 [Reserved].

Section 3.3 Mode of Payment/Currency Exchange. All payments made by a Party hereunder shall be made by deposit of U.S. Dollars by wire transfer in immediately available funds into the applicable account. With respect to sales outside the United States, for the purpose of calculating Net Revenues for the purposes of determining the Included Product Payment Amount payable under Section 3.1, Net Revenues shall be calculated, if pursuant to a License Agreement, in the currency set forth therein, or otherwise in the currency of sale, and then such amounts shall be converted into U.S. Dollars at the rate of exchange utilized by the Parent Company for purposes of preparing its financial statements in accordance with GAAP fairly applied and as employed on a consistent basis throughout the Company’s operations. Should the Company change its foreign currency translation methodology, the new methodology will be disclosed in writing to the Investor Representative prior to its implementation. For clarity, to the extent that the Company receives a payment from a Third Party in U.S. Dollars included within the Revenue Interests, the foregoing currency exchange rates shall not apply to such amount, and in particular the Company will have no obligation to re-calculate any currency conversion that was employed in connection with such Third Party payment.

Section 3.4 Included Product Payment Reports and Record Retention. On or prior to each Quarterly Payment Date occurring after the Initial Closing Date, the Company shall deliver to the Investor Representative (i) copies of any Third Party Report for the applicable Calendar Quarter, so long as the Company is able to obtain the prior written consent of the relevant Third Party to disclose such information to the Investor Representative, (ii) following the First Commercial Sale, a written report of the amount of gross sales of the Included Product in each country during the applicable Calendar Quarter, an itemized calculation of Net Sales and Other Royalty Payments on a country-by-country basis and a calculation of the amount of the Included Product Payment Amount due under Section 3.1(a)(ii) in respect of the applicable Calendar Quarter, showing the Applicable Tiered Percentage applied thereto (if applicable) and a calculation of the Under Performance Payment and Generic Product Payment (if any) pursuant

to Section 3.1(b), (iii) copies of the most recent quarterly statements for each Deposit Account, Securities Account, Commodities Account and other Deposit Account, Securities Account or Commodities Account of the Company and each other Company Party, and (iv) a Compliance Certificate relating to each of the items described in clauses (i), (ii) and (iii) of this sentence. For five years after each sale of the Included Product made by the Company or any of its Affiliates, the Company shall keep (and shall ensure that its Affiliates shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the applicable Included Product Payment Amount paid pursuant to Section 3.1(a)(ii). The Company shall use commercially reasonable efforts to include, in each contract of the Company or any of its Affiliates for the distribution, marketing or selling of Included Products entered into on or after the Initial Closing 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 3.4 and calculate the Included Product Payment Amounts that are payable as set forth in this Agreement. The Company shall use commercially reasonable efforts to, within ninety (90) days of the Effective Date, obtain the consent of the relevant Third Party to share the Third Party Reports and the Third Party Information with the Investor Representative and the Investor.

Section 3.5 Audits.

(a) Upon the written request of the Investor Representative following the Initial Closing Date (which shall not be more than once each Calendar Year so long as no Default or Event of Default has occurred and is continuing), the Company shall permit an independent certified public accounting firm of national prominence selected by the Investor Representative, and reasonably acceptable to the Company, to have access to and to review, during normal business hours and upon not less than [***] days' prior written notice, the relevant documents and records of each member of the Company Group as may reasonably be necessary to verify Net Revenues and the accuracy and timeliness of the reports and payments (including calculation and payment of any Quarterly Fixed Payment and any Included Product Payment Amount) made by the Company under this Agreement and compliance by each member of the Company Group with the covenants under this Agreement. Such review may cover the records for sales or other Dispositions of the Included Products, Net Revenues, Other Royalty Payments, Quarterly Fixed Payments and the One-Time Fixed Payment in any Calendar Year ending no earlier than the first day of the previous Calendar Year; provided, however, that each period may be audited only once.

The accounting firm shall be permitted to prepare and disclose to the Investor Representative a written report stating only whether the Quarterly Fixed Payments, One-Time Fixed Payment, Included Product Payment Amounts, Under Performance Payments and Generic Product Payment paid to the Investor Representative hereunder and the reports provided by the Company relating to such Quarterly Fixed Payments, One-Time Fixed Payment, Included Product Payment Amounts, Under Performance Payments and Generic Product Payment required hereunder are correct or incorrect and the specific details concerning any discrepancies, or whether the Company has complied with its covenants under this Agreement, and if not, the specific details concerning such non-compliance. Notwithstanding the foregoing, after the occurrence and during the continuance of a Special Termination Event, Change of Control, Default or Event of Default, the Investor Representative shall have the right, as often, at such times and with such prior notice, as the Investor Representative shall determine, in its reasonable discretion, to have an independent certified public accounting firm of national prominence selected by the Investor Representative

review the relevant documents and records of each member of the Company Group for compliance with this Agreement.

(b) If such accounting firm reasonably concludes that any Quarterly Fixed Payments, One-Time Fixed Payment, Included Product Payment Amounts, Under Performance Payments or Generic Product Payment were owed and were not paid when due during such period pursuant to the provisions of this Agreement, the Company shall pay any late or unpaid Quarterly Fixed Payments, One-Time Fixed Payment, Included Product Payment Amounts, Under Performance Payments or Generic Product Payment within five (5) days after the date the Investor Representative delivers to the Company a notice including the accounting firm's written report and requesting such payment. If the amount of the underpayment (exclusive of interest accrued thereon pursuant to Section 3.1(a)) is greater than the lesser of (i) [***] percent ([***]%) of the total amount actually owed for the period audited or (ii) [***] Dollars (\$[***]), then the Company shall in addition (w) reimburse the Investor Representative for all reasonable costs and fees of the accounting firm related to such audit and (x) pay interest accrued on such amount of the underpayment at a rate of [***] percent ([***]%) per month from the initial due date until paid in full or, if less, the maximum interest rate permitted by Applicable Law. In the event of overpayment, any amount of such overpayment shall be fully creditable against the Included Product Payment Amount payable for the immediately succeeding Calendar Quarter(s). If the overpayment is not fully applied prior to the final quarterly Included Product Payment Amount payment due hereunder, the Investor shall promptly refund an amount equal to any such remaining overpayment. The Investor Representative shall (y) treat all information that it receives under this Section 3.5 or under any License Agreement of the Company in accordance with the provisions of ARTICLE IX and (z) cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with the Company obligating such firm to retain all such information in confidence pursuant to such confidentiality agreement, in each case except to the extent necessary for the Investor Representative to enforce its rights under this Agreement.

ARTICLE IV REPRESENTATIONS AND WARRANTIES OF THE COMPANY

Except as set forth in the disclosure schedules attached hereto (the "Disclosure Schedule"), the Company hereby represents and warrants to the Investor Representative as of the Effective Date and as of the date of each Closing as follows:

Section 4.1 Organization. Each member of the Company Group is duly organized, validly existing and in good standing under the Laws of its jurisdiction of organization and has all powers and authority, and all licenses, Permits, franchises, authorizations, consents and approvals of all Governmental Authorities, required to own its property and conduct its business as now conducted. Each member of the Company Group is duly qualified to transact business and is in good standing in every jurisdiction in which such qualification or good standing is required by Applicable Law (except where the failure to be so qualified or in good standing could not reasonably be expected to result in a Material Adverse Effect).

Section 4.2 No Conflicts.

(a) None of the execution and delivery by any Company Party of any of the Transaction Documents to which it is party, the performance by any Company Party of the obligations contemplated hereby or thereby or the consummation of the transactions contemplated hereby or thereby will: (i) contravene, conflict with, result in a breach, violation, cancellation or termination of, constitute a default (with or without notice or lapse of time, or both) under, require prepayment under, give any Person the right to exercise any remedy (including termination, cancellation or acceleration) or obtain any additional rights under, or accelerate the maturity or performance of or payment under, in any respect, (A) any Applicable Law or any judgment, order, writ, decree, Permit or license of any Governmental Authority to which any member of the Company Group or any of their respective assets or properties may be subject or bound, (B) any term or provision of any contract, agreement, indenture, lease, license, deed, commitment, obligation or instrument to which any member of the Company Group is a party or by which any member of the Company Group or any of their respective assets or properties is bound or committed (other than a Material Contract), (C) any Material Contract or (D) any term or provision of any of the organizational documents of any member of the Company Group, except in the case of clause (A) or (B) where any such event would not reasonably be expected to result in a Material Adverse Effect; or (ii) except as provided in any of the Transaction Documents to which it is party, result in or require the creation or imposition of any Lien on the Collateral (in each case other than Permitted Liens).

(b) No Company Party has granted, nor does there exist, any Lien on (i) the Transaction Documents or (ii) the Collateral (other than Permitted Liens).

Section 4.3 Authorization. Each Company Party has all powers and authority to execute and deliver, and perform its obligations under, the Transaction Documents to which it is party and to consummate the transactions contemplated hereby and thereby. The execution and delivery of each of the Transaction Documents to which any Company Party is party and the performance by each Company Party of its obligations hereunder and thereunder have been duly authorized by each Company Party. Each of the Transaction Documents to which each Company Party is party has been duly executed and delivered by each such Company Party. Each of the Transaction Documents to which any Company Party is party constitutes the legal, valid and binding obligation of each such Company Party, enforceable against each such Company Party in accordance with its respective terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or similar Applicable Laws affecting creditors' rights generally, general equitable principles and principles of public policy.

Section 4.4 Ownership. The Company Parties are the exclusive owners of the entire right, title (legal and equitable) and interest in, to and under the Collateral, free and clear of all Liens, other than Permitted Liens, and the Company Parties own their respective assets relating to the Included Products, free and clear of all Liens, other than Permitted Liens. The Revenue Interests sold, assigned, transferred, conveyed and granted to the Investor on the Closing Date have not been pledged, sold, assigned, transferred, conveyed or granted by any Company Party to any other Person. The Company Parties have full right to sell, assign, transfer, convey and grant the Revenue Interests to the Investor. Upon the sale, assignment, transfer, conveyance and granting by each Company Party of the Revenue Interests owned by it to the Investor Representative, the Investor shall acquire good and marketable title to the Revenue Interests free and clear of all Liens (other than Liens permitted pursuant to clauses (a), (b), (f), and (g) of the

definition of Permitted Liens), and shall be the exclusive owner of the Revenue Interests. No Company Party has caused, and to the Knowledge of the Company Party no other Person has caused, the claims and rights of Investor created by any Transaction Document in and to the Revenue Interests and the Collateral, in each case, to be subordinated to any creditor or any other Person.

Section 4.5 Governmental and Third Party Authorizations. The execution and delivery by each Company Party of the Transaction Documents to which each such Company Party is party, the performance by each Company Party of its obligations hereunder and thereunder and the consummation of any of the transactions contemplated hereunder and thereunder (including the sale, assignment, transfer, conveyance and granting of the Revenue Interests to the Investor) do not require any consent, approval, license, order, authorization or declaration from, notice to, action or registration by or filing with any Governmental Authority or any other Person, except for applicable filings under United States securities laws, the filing of UCC financing statements and those previously obtained or made or to be obtained or made on the Closing Date.

Section 4.6 No Litigation. There is no action, suit, arbitration proceeding, claim, citation, summons, subpoena, investigation or other proceeding (whether civil, criminal, administrative, regulatory, investigative or informal, and including by or before a Governmental Authority) pending or, to the Knowledge of any Company Party, threatened by or against any member of the Company Group, at law or in equity, that (i) if adversely determined, could reasonably be expected to result in a material liability to any member of the Company Group, or (ii) challenges or seeks to prevent or delay the consummation of any of the transactions contemplated by any of the Transaction Documents to which any Company Party is party.

Section 4.7 Solvency. The Company has determined that, and by virtue of the Company Parties entering into the transactions contemplated by the Transaction Documents to which such Company Party is party and its authorization, execution and delivery of the Transaction Documents to which such Company Party is party, such Company Party's incurrence of any liability hereunder or thereunder or contemplated hereby or thereby is in its own best interests. Upon consummation of the transactions contemplated by the Transaction Documents and the application of the proceeds therefrom, (a) the fair saleable value of the consolidated assets of the Company Parties will be greater than the sum of their debts, liabilities and other obligations, including known contingent liabilities, (b) the present fair saleable value of the consolidated assets of the Company Parties will be greater than the amount that would be required to pay their probable liabilities on its existing debts, liabilities and other obligations, including known contingent liabilities, as they become absolute and matured, (c) each Company Party will be able to realize upon its assets and pay its debts, liabilities and other obligations, including known contingent obligations, as they mature, (d) each Company Party will not have unreasonably small capital with which to engage in its business and will not be unable to pay its debts as they mature, (e) the Company Parties have not incurred, will not incur and do not have any present plans or intentions to incur debts or other obligations or liabilities beyond their ability to pay such debts or other obligations or liabilities as they become absolute and matured, (f) no Company Party will have become subject to any Bankruptcy Event and (g) no Company Party will have been rendered insolvent within the meaning of any Applicable Law. No step has been taken or is intended by

any Company Party or, to such Company Party's Knowledge, any other Person to make any Company Party subject to a Bankruptcy Event.

Section 4.8 No Brokers' Fees. No Company Party has taken any action that could entitle any Person or entity to any commission or broker's fee in connection with the transactions contemplated by this Agreement.

Section 4.9 Compliance with Laws. No member of the Company Group (a) has during the last three (3) years violated or is in violation of, or, to the Knowledge of the Company, is under investigation by a Governmental Authority with respect to or has been threatened by a Governmental Authority to be charged with or been given notice of any violation of, any Applicable Law or any judgment, order, writ, decree, injunction, stipulation, consent order, or Permit, issued or entered by any Governmental Authority or (b) is subject to any judgment, order, writ, decree, injunction, stipulation, consent order, or Permit granted, issued or entered by any Governmental Authority, in each case, that could reasonably be expected to result in a material liability to any Company Party. Each Subsidiary of the Parent Company is in compliance in all material respects with the requirements of all Applicable Laws.

Section 4.10 Intellectual Property Matters.

(a) Schedule 4.10(a) sets forth an accurate and complete list of the Patent Rights owned by or exclusively licensed to any Company Party, including the complete and accurate list of the Yutrepia Patent Rights. For each Patent Right set forth on Schedule 4.10(a) the Company has indicated: (i) the application number; (ii) the patent or registration number, if any; (iii) the country or other jurisdiction where the Patent Right was issued, registered, or filed; (iv) the scheduled expiration date of any issued Patent Right, including a notation if such scheduled expiration date includes a term extension or supplementary protection certificate; and (v) the registered owner thereof.

(b) The Company (or the Company Party indicated on Schedule 4.10(a)) is the sole and exclusive owner of the entire right, title and interest in each of the Owned Patent Rights. The Owned Patent Rights are not subject to any encumbrance, Lien or claim of ownership by any Third Party, other than a Permitted License, and to the Knowledge of the Company, there are no facts that would preclude the relevant Company Party from having unencumbered title to the Owned Patent Rights. No Company Party has received any written notice of any claim by any Third Party challenging the ownership of the rights of the Company Parties in and to the Owned Patent Rights.

(c) To the Knowledge of the Company, each Person who has or has had any rights in or to the Patent Rights, including each inventor named on such Patent Rights, has executed a Contract assigning their entire right, title and interest in and to such Patent Rights and the inventions embodied, described and/or claimed therein, to the owner thereof, and each such Contract has been duly recorded at the United States Patent and Trademark Office.

(d) To the Knowledge of the Company, no issued Patent Right has lapsed, expired or otherwise been terminated. No patent applications included in the Patent Rights have lapsed, expired, been abandoned or otherwise been terminated, in each case other than (i) by

operation of law, (ii) in the course of patent prosecution under the ordinary course of business, or (iii) due to strategic abandonment, expiration, or termination.

(e) There are no unpaid maintenance fees, annuities or other like payments that are overdue with respect to the Patent Rights as of the Effective Date for which any Company Party is responsible for payment.

(f) To the Knowledge of the Company, each of the Patent Rights correctly identifies each and every inventor of the claims thereof as determined in accordance with the Laws of the jurisdiction in which such Patent Right was issued or is pending. To the Knowledge of the Company, there is not any Person who is or claims to be an inventor of any of the Patent Rights who is not a named inventor thereof. No Company Party has received any notice from any Person who is or claims to be an inventor of any of the Patent Rights who is not a named inventor thereof.

(g) To the Knowledge of the Company, each of the Patent Rights and claims therein is valid, enforceable and subsisting. No Company Party has received any opinion of counsel that any of the Patent Rights is invalid or unenforceable. No Company Party has received any notice of any claim by any Third Party challenging the validity or enforceability of any of the Patent Rights.

(h) To the Knowledge of the Company, each individual associated with the filing and prosecution of the Patent Rights has complied in all material respects with all applicable duties of candor and good faith in dealing with any Patent Office, including any duty to disclose to any Patent Office all information known by such individual to be material to patentability of each such Patent Right, in those jurisdictions where such duties exist.

(i) There is at least one valid claim in each of the Patent Rights set forth on Schedule 4.10(i) that would be infringed by any member of the Company Group's Commercialization of the Included Products (other than the Sandoz Product) but for such member of the Company Group's rights in such Patent Rights.

(j) To the Knowledge of the Company, except for information disclosed to the applicable Patent Office during prosecution of the Patent Rights, there are no patents, published patent applications, articles, abstracts or other prior art deemed material to patentability of any of the inventions claimed in such Patent Rights, or that would otherwise reasonably be expected to materially adversely affect the validity or enforceability of any of the claims of such Patent Rights.

(k) There is no pending or, to the Knowledge of the Company, threatened opposition, interference, reexamination, injunction, claim, suit, action, citation, summons, subpoena, hearing, inquiry, investigation (by the International Trade Commission or otherwise), complaint, arbitration, mediation, demand, decree or other dispute, disagreement, proceeding, claim or inter partes review (other than standard patent prosecution before a Patent Office) (collectively, "Disputes") challenging the legality, validity, enforceability or ownership of any of the Patent Rights or that could result in any Set-off against the payments due to the Investor Representative under this Agreement. To the Knowledge of the Company, there are no Disputes by or with any Third Party against any Company Party involving the Included Product. The Patent

Rights are not subject to any outstanding injunction, judgment, order, decree, ruling, change, settlement or other disposition of a Dispute.

(l) To the Knowledge of the Company, and except as separately disclosed to Investor Representative, there is no pending or threatened, and no event has occurred or circumstance exists 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, and none of the Company Group members have received any written notice of the foregoing, that claims that the manufacture, use, marketing, sale, offer for sale, importation or distribution of the Included Product as currently contemplated infringes on any Patent or other intellectual property rights of any other Person or constitutes misappropriation of any other Person's Trade Secrets or other intellectual property rights.

(m) To the Knowledge of the Company, none of the conception, development and reduction to practice of the inventions claimed in the Patent Rights has constituted or involved the misappropriation of Trade Secrets or other rights or property of any Third Party.

(n) No Company Party has filed any disclaimer, other than a terminal disclaimer, or made or permitted any other voluntary reduction in the scope of any Patent Right.

(o) To the Knowledge of the Company, no Third Party Patent has been, or will be, or are, infringed by any member of the Company Group's Commercialization of the Included Products as the Commercialization of such Included Products is currently contemplated as of the date the representation is made. Except with respect to the Asserted Patents, none of the Company Group members have received any notice of any claim by any Third Party asserting that any member of the Company Group's Commercialization of any Included Product infringes such Third Party's Patent. Except with respect to the Asserted Patents, none of the Company Group members have received any opinion of counsel regarding infringement or non-infringement of any Third Party Patents by any member of the Company Group's Commercialization of any Included Product.

(p) To the Knowledge of the Company, there are no pending, published patent applications owned by any Third Party, which the Company Group members do not have the right to use, and which, if issued in their current form, could limit or prohibit in any material respect any member of the Company Group's Commercialization of any Included Product.

(q) To the Knowledge of the Company, no Third Party is infringing any of the issued Patent Rights. No Company Party has put any Third Party on notice of infringement of any of such Patent Rights.

(r) Schedule 4.10(r) sets forth Copyrights, Trademarks and Domain Names owned or exclusively licensed to any Company Party and material to any member of the Company Group's Commercialization of any Included Product.

(s) To the Knowledge of the Company, the Patent Rights set forth on Schedule 4.10(a) include all of the Patents owned or exclusively licensed and controlled by any member of the Company Group or any of the Company Group's Affiliates that are necessary for the sale of the Included Products in the United States.

Section 4.11 Margin Stock. No member of the Company Group is engaged in the business of extending credit for the purpose of buying or carrying margin stock, and no portion of the Investment Amount shall be used by any member of the Company Group for a purpose that violates Regulation T, U or X promulgated by the Board of Governors of the Federal Reserve System from time to time.

Section 4.12 Material Contracts.

(a) Schedule 4.12(a) hereto contains a list of the Material Contracts. As of the date hereof, the Company has provided a true and complete copy of each Material Contract to the Investor Representative.

(b) Neither any member of the Company Group nor, to the Knowledge of the Company, any Material Contract Counterparty is in breach or default of any Material Contract and no circumstances or grounds exist that would, upon the giving of notice, the passage of time or both, give rise (i) to a claim by any member of the Company Group or any Material Contract Counterparty of a breach or default of any Material Contract, or (ii) to a right of rescission, termination, revision, or Set-off, by any Person, in, to or under any Material Contract. No member of the Company Group has received from, or delivered to, any Material Contract Counterparty, any written notice alleging a breach or default under any Material Contract, which breach or default has not been cured as of the Closing Date.

(c) Each Material Contract is a valid and binding obligation of each member of the Company Group, as applicable and, to the Knowledge of the Company, of the applicable Material Contract Counterparty, enforceable against each of the relevant Company Group members and, to the Knowledge of the Company, each applicable Material Contract Counterparty in accordance with its terms, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, moratorium and other similar laws of general application relating to or affecting creditors' rights generally. No Company Group members have received any notice from any Material Contract Counterparty or any other Person challenging the validity or enforceability of any Material Contract. No member of the Company Group, nor to the Knowledge of the Company, any other Person, has delivered or intends to deliver any written notice to any member of the Company Group or a Material Contract Counterparty challenging the validity or enforceability of any Material Contract.

(d) There are no settlements, covenants not to sue, consents, judgements, orders or similar obligations which: (i) restrict the rights of any member of the Company Group from using any Product Rights relating to the research, development, manufacture, production, use, Commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Included Products (in order to accommodate any Third Party intellectual property or otherwise), or (ii) permit any Third Parties to use any Product Rights of any member of the Company Group, in each case, that would give rise to a Material Adverse Effect.

Section 4.13 Bankruptcy. No member of the Company Group nor, to the Knowledge of the Company, any Material Contract Counterparty is contemplating or planning to

commence any case, proceeding or other action relating to such Material Contract Counterparty's bankruptcy, insolvency, liquidation or dissolution or reorganization.

Section 4.14 Office Locations; Names; Bank Accounts.

(a) The chief place of business, the chief executive office and each office where each Company Party keeps its records regarding the Collateral are, as of the date hereof, each located at 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560.

(b) Except as set forth on Schedule 4.14(b), no Company Party (or any predecessor by merger or otherwise) has, within the five (5) year period preceding the date hereof, had a name that differs from its name as of the date hereof.

(c) No Company Party has any Deposit Accounts, Securities Accounts or Commodities Accounts except as set forth on Schedule 4.14(c) (such accounts constituting all Deposit Accounts, Securities Accounts or other similar accounts maintained by each Company Party as of the Initial Closing Date).

Section 4.15 Permitted Debt. There is no Indebtedness incurred by any member of the Company Group other than the Permitted Debt, including the Indebtedness as of the Effective Date, which is listed on Schedule 4.15 hereto.

Section 4.16 Financial Statements; No Material Adverse Effect.

(a) The Audited Financial Statements (i) were prepared in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the financial condition of each member of the Company Group as of the date thereof and their results of operations for the period covered thereby in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, and (iii) show all material Indebtedness and other liabilities, direct or contingent, of each member of the Company Group as of the date thereof, including material liabilities for Taxes, commitments and Indebtedness to the extent required by GAAP.

(b) The Interim Financial Statements (i) were prepared in accordance with GAAP consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the financial condition of each member of the Company Group as of the date thereof and their results of operations for the period covered thereby, and (iii) show all material Indebtedness and other liabilities, direct or contingent, of each member of the Company Group as of the date thereof, including material liabilities for Taxes, material commitments and Indebtedness to the extent required by GAAP, subject, in the case of clauses (i), (ii) and (iii) of this sentence, to the absence of footnotes and to normal year-end audit adjustments.

(c) From the date of the Audited Financial Statements to and including the applicable Closing Date, there has been no Disposition or any Involuntary Disposition of any material part of the business or property of any member of the Company Group, and no purchase or other acquisition by any of them of any business or property (including any Equity Interests of

any other Person) material to any Company Party or any Subsidiary, in each case, which is not reflected in the Financial Statements or in the notes thereto and has not otherwise been disclosed in writing to the Investor Representative on or prior to the applicable Closing Date.

(d) Since the date of the Audited Financial Statements, there has been no event or circumstance, either individually or in the aggregate, that has had or could reasonably be expected to result in a Material Adverse Effect.

Section 4.17 No Default; No Special Termination Event.

(a) Neither any Company Party nor any Subsidiary is in default (with or without notice or lapse of time, or both) under or with respect to any Contractual Obligation that could reasonably be expected to result in a Material Adverse Effect.

(b) No Change of Control, Special Termination Event, Default or Event of Default has occurred and is continuing.

Section 4.18 Insurance. The properties of each member of the Company Group are insured with financially sound and reputable insurance companies which are not Affiliates of such Persons, in such amounts, with such deductibles and covering such risks as are customarily carried by companies engaged in similar businesses and owning similar properties in localities where the applicable Company Group entity operates.

Section 4.19 ERISA Compliance.

(a) Except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (i) each Plan is in compliance with the applicable provisions of ERISA, the Internal Revenue Code and other federal or state Laws, and (ii) each Pension Plan that is intended to be a qualified plan under Section 401(a) of the Internal Revenue Code has received a favorable determination letter from the IRS to the effect that the form of such Plan is qualified under Section 401(a) of the Internal Revenue Code, an application for such a letter is currently being processed by the IRS or is entitled to rely on the opinion or advisory letter issued by the IRS to the sponsor of a preapproved plan document and, to the Knowledge of the Company, nothing has occurred that would prevent, or cause the loss of, such tax-qualified status.

(b) There are no pending or, to the Knowledge of the Company, threatened claims, actions or lawsuits, or action by any Governmental Authority, with respect to any Plan that would reasonably be expected to result in a Material Adverse Effect. Neither Company nor any ERISA Affiliate has engaged in any prohibited transaction or violation of the fiduciary responsibility rules with respect to any Plan, in any case, that would reasonably be expected to result in a Material Adverse Effect.

(c) Except as would not reasonably be expected to result in a Material Adverse Effect, (i) no ERISA Event has occurred with respect to any Pension Plan, (ii) the Company and each ERISA Affiliate has met all applicable requirements under the applicable pension funding rules in respect of each Pension Plan, and no waiver of the minimum funding standards under the applicable pension funding rules has been applied for or obtained, and (iii) neither the Company

nor any ERISA Affiliate has incurred any liability to the PBGC other than for the payment of premiums due but not delinquent under Section 4007 of ERISA.

Section 4.20 Subsidiaries. Set forth on Schedule 4.20 is a complete and accurate list of each Subsidiary of the Parent Company, together with (a) such Subsidiary's jurisdiction of organization and (b) the percentage of the Equity Interests in such Subsidiary owned by the Company.

Section 4.21 Perfection of Security Interests in the Collateral. The Collateral Documents create valid security interests in, and Liens on, the Collateral purported to be covered thereby to the extent such security interests may be created pursuant to Article 9 of the UCC, which security interests and Liens will be, upon the timely and proper filings, deliveries, notations and other actions contemplated in the Collateral Documents perfected security interests and Liens (to the extent that such security interests and Liens can be perfected by such filings, deliveries, notations and other actions), prior to (x) in the case of Revenue Interests all Liens other than Liens permitted pursuant to clauses (a), (b), (f), and (g) of the definition of Permitted Liens, and (y) in the case of all other Collateral, all Liens other than Permitted Liens.

Section 4.22 Disclosure. The Company has not failed to disclose to the Investor any data, documents, or other information, including any event or circumstance, that could reasonably be expected to result in a Material Adverse Effect. No report, financial statement, certificate or other information furnished (whether written or oral) by or on behalf of any Company Party to the Investor Representative in connection with the transactions contemplated hereby and the negotiation of this Agreement or delivered hereunder or under any other Transaction Document (in each case, as modified or supplemented by other information so furnished) contains any material misstatement of fact or omits to state any 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 financial projections, estimates, budgets or other forward-looking information, the Company Parties represent only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time such information was prepared (it being understood that such information is as to future events and is not to be viewed as facts, is subject to significant uncertainties and contingencies, many of which are beyond the control of the Company Group, that no assurance can be given that any particular projection, estimate, budget or forecast will be realized and that actual results during the period or periods covered by any such projections, estimate, budgets or forecasts may differ significantly from the projected results and such differences may be material).

Section 4.23 Sanctions Concerns; Anti-Corruption Laws; PATRIOT Act.

(a) Sanctions Concerns. None of the Company Group members, nor, to the Knowledge of the Company, any director, officer, employee, agent, Affiliate or representative thereof, is an individual or entity that is, or is owned or controlled by, any individual or entity that is (i) currently the subject or target of any Sanctions, (ii) included on OFAC's "List of Specially Designated Nationals", HMT's "Consolidated List of Financial Sanctions Targets and the Investment Ban List", or any similar list enforced by any other relevant sanctions authority or (iii) located, organized or resident in a Designated Jurisdiction.

(b) Anti-Corruption Laws. None of the Company Group members nor, to the Knowledge of the Company, any directors, officers, employees or agents of any member of the Company Group have, directly or indirectly, made, offered, promised or authorized any payment or gift of any money or anything of value to or for the benefit of any “foreign official” (as such term is defined in the U.S. Foreign Corrupt Practices Act (the “FCPA”)), foreign political party or official thereof or candidate for foreign political office for the purpose of (i) influencing any official act or decision of such official, party or candidate, (ii) inducing such official, party or candidate to use his, her or its influence to affect any act or decision of a foreign Governmental Authority or (iii) securing any improper advantage, in the case of (i), (ii) and (iii) above in order to assist the Parent Company or any of its Affiliates in obtaining or retaining business for or with, or directing business to, any “person” (as such term is defined in the FCPA). None of the Company Group members nor, to the Knowledge of the Company, any of its directors, officers, employees or agents have made or authorized any bribe, rebate, payoff, influence payment, kickback or other unlawful payment of funds or received or retained any funds in violation of any Law, rule or regulation. The Company further represents that it has maintained, and has caused each member of the Company Group and Affiliates to maintain, systems of internal controls (including accounting systems, purchasing systems and billing systems) to ensure compliance with all Anti-Corruption Laws. The Company Group members have conducted their business in compliance with all Anti-Corruption Laws and have instituted and maintained policies and procedures designed to promote and achieve compliance with such Laws.

(c) PATRIOT Act. To the extent applicable, each Company Group member complies, with the USA PATRIOT Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)), as amended from time to time.

Section 4.24 Data Security; Data Privacy.

(a) The Company Group members have not experienced any breach of security of unauthorized access by third parties of any Personal Information in its possession, custody, or control that could reasonably be expected to result in a Material Adverse Effect.

(b) In connection with its collection, storage, transfer (including, without limitation, any transfer across national borders) and/or use of any personally identifiable information from any individuals, including, without limitation, any customers, prospective customers employees and/or other Third Parties (collectively “Personal Information”), the Company Group members are and have been for the past three (3) years, to the Knowledge of Company, in compliance in all material respects with all Applicable Laws in all relevant jurisdictions, each Company Group member’s privacy policies and the requirements of any contracts or codes of conduct to which each Company Group member is a party, except for any such event that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect. The Company Group members have commercially reasonable physical, technical, organizational and administrative security measures and policies in place to protect all Personal Information collected by or on behalf of the Company Group members (as applicable) from and against unauthorized access, use and/or disclosure. The Company Group members are and have been for the past three (3) years, to the Knowledge of the Company, in compliance in all material respects with all Laws relating to data loss, theft and breach of security notification

obligations, except for any such event that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect.

Section 4.25 Compliance of Included Products.

(a) The Company Group members (and to the actual knowledge of the Company, Sandoz Inc., in the case of the Sandoz Product) possess all material Permits, including Regulatory Approvals from the FDA and other Governmental Authorities required for the conduct of their business as currently conducted, and all such Permits are in full force and effect;

(b) The Company Group members have not received any written communication from any Governmental Authority alleging any failure of any member of the Company Group to materially comply with any Laws, including any terms or requirements of any Regulatory Approval and, to the Knowledge of the Company, there are no facts or circumstances that are reasonably likely to give rise to any revocation, withdrawal, suspension, cancellation, material limitation, termination or adverse modification of any Regulatory Approval;

(c) None of the officers, directors, employees of any member of the Company Group or, to the Knowledge of the Company, Affiliates of the any member of Company Group or any agent or consultant involved in any Drug Application, has been convicted of any crime or engaged in any conduct for which debarment is authorized by 21 U.S.C. Section 335a nor, to the Knowledge of the Company, are any debarment proceedings or investigations pending or threatened against any member of the Company Group or any of their respective officers, employees or agents;

(d) None of the officers or directors of any member of the Company Group, or, to the Knowledge of the Company, employees or Affiliates of any member of the Company Group or any agent or consultant has (A) made an untrue statement of material fact or fraudulent statement to any Regulatory Agency or failed to disclose a material fact required to be disclosed to a Regulatory Agency; or (B) committed an act, made a statement, or failed to make a statement that would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Regulation 46191 (September 10, 1991);

(e) All applications, notifications, submissions, information, claims, reports and statistics and other data and conclusions derived therefrom, utilized as the basis for or submitted in connection with any and all requests for a Regulatory Approval from the FDA or other Governmental Authority relating to any member of the Company Group, their business operations and Included Products, when submitted to the FDA or other Governmental Authority were true, complete and correct in all material respects as of the date of submission or any necessary or required updates, changes, corrections or modifications to such applications, submissions, information and data have been submitted to the FDA or other Governmental Authority;

(f) All preclinical and clinical trials conducted by or on behalf of any member of the Company Group that have been submitted to any Governmental Authority, including the

FDA, in connection with any request for a Regulatory Approval, are being or have been conducted in compliance in all material respects with Applicable Laws;

(g) All Included Products have since January 1, 2021, been manufactured, transported, stored and handled in all material respects in accordance with all Permits and Applicable Laws, and since January 1, 2021, no Company Group (nor, to the Company's actual knowledge, Sandoz Inc. with respect to the Sandoz Product) has experienced any material delays or failures with respect to the manufacture of, or any member of the Company Group's ability to obtain, a supply of any Included Product or any device necessary to administer such Included Product that is sufficient to meet market demand in the United States;

(h) No member of the Company Group has received any written notice that any Governmental Authority, including without limitation the FDA, the Office of the Inspector General of the United States Department of Health and Human Services or the United States Department of Justice has (i) commenced or threatened to initiate any action to enjoin any member of the Company Group, its officers, directors, employees, agents and Affiliates, from conducting its business at any facility owned or used by it, (ii) commenced or threatened to initiate any action against any member of the Company Group or its officers, directors, employees, agents and Affiliates for any material civil penalty, injunction, seizure or criminal action that could reasonably be expected to result in a Material Adverse Effect, (iii) commenced any investigation or review of any member of the Company Group's (or any Third Party contractors for any member of the Company Group) manufacture, marketing or sale of any Included Product in the United States;

(i) No member of the Company Group has received (nor, to the Company's actual knowledge, has Sandoz Inc. received) from the FDA at any time since January 1, 2021, a "Warning Letter", Form FDA-483, "Untitled Letter", or similar written correspondence or notice alleging violations of Laws enforced by the FDA or any comparable correspondence from any other Governmental Authority with regard to any Included Product or the manufacture, processing, packaging or holding thereof, the subject of which communication is unresolved and if determined adversely to such Company Group entity (or, to the Company's actual knowledge, Sandoz Inc. with respect to the Sandoz Product) could reasonably be expected to result in a Material Adverse Effect; and

(j) Since January 1, 2021, (A) there have been no material Safety Notices, (B) to the Knowledge of the Company, there are no unresolved material product complaints with respect to Included Products, and (C) to the Knowledge of the Company, there are no facts that would result in (1) a material Safety Notice with respect to Included Products, (2) a material change in the labeling of Included Products, or (3) a termination or suspension of marketing of Included Products; and

(k) All of the Included Products that exist as of the applicable Closing Date are listed on Schedule 4.26(b).

Section 4.26 Labor Matters. There are no existing or, to the Knowledge of the Company, threatened strikes, lockouts or other labor Disputes involving any member of the Company Group that, individually or in the aggregate, would reasonably be expected to result in a Material Adverse Effect. Except as would not, individually or in the aggregate, reasonably be

expected to result in a Material Adverse Effect, hours worked by and payments of compensation made by each member of the Company Group to their respective employees are not in violation of the Fair Labor Standards Act or any other Applicable Law, rule or regulation dealing with such matters.

Section 4.27 EEA Financial Institution. No Company Group entity is an EEA Financial Institution.

Section 4.28 Taxes. Each member of the Company Group has (A) filed all Tax returns and reports required by to have been filed by it (including in its capacity as a withholding agent), (B) paid all Taxes required to have been paid by it (including in its capacity as a withholding agent), and (C) provided adequate accruals, charges and reserves in accordance with GAAP in their applicable financial statements in respect of all Taxes not yet due and payable, except, in each case, (i) any such Taxes that are being diligently contested in good faith by appropriate proceedings and for which adequate reserves have been provided in accordance with GAAP or (ii) any failure that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

ARTICLE V REPRESENTATIONS AND WARRANTIES OF THE INVESTOR

Each Investor hereby represents and warrants separately (and not jointly) to the Company as of the Effective Date and the date of each Closing as follows:

Section 5.1 Organization. Such entity is duly formed, validly existing and in good standing under the Laws of its state of formation and has all powers and authority, and all licenses, Permits, franchises, authorizations, consents and approvals of all Governmental Authorities, required to own its property and conduct its business as now conducted.

Section 5.2 No Conflicts. None of the execution and delivery by such entity of any of the Transaction Documents to which it is party, the performance by it of the obligations contemplated hereby or thereby or the consummation of the transactions contemplated hereby or thereby will contravene, conflict with, result in a breach, violation, cancellation or termination of, constitute a default (with or without notice or lapse of time, or both) under, require prepayment under, give any Person the right to exercise any remedy (including termination, cancellation or acceleration) or obtain any additional rights under, or accelerate the maturity or performance of or payment under, in any respect, (i) any Applicable Law or any judgment, order, writ, decree, Permit or license of any Governmental Authority to which such entity or any of its assets or properties may be subject or bound, (ii) any term or provision of any contract, agreement, indenture, lease, license, deed, commitment, obligation or instrument to which such entity is a party or by which such entity or any of its assets or properties is bound or committed or (iii) any term or provision of any of the organizational documents of such entity, except in the case of clause (i) where any such event would not result in a material adverse effect on the ability of such entity to consummate the transactions contemplated by the Transaction Documents.

Section 5.3 Authorization. Such entity has all powers and authority to execute and deliver, and perform its obligations under, the Transaction Documents to which it is party

and to consummate the transactions contemplated hereby and thereby. The execution and delivery of each of the Transaction Documents to which such entity is party, and the performance by it of its obligations hereunder and thereunder, have been duly authorized by it. Each of the Transaction Documents to which such entity is party has been duly executed and delivered by it. Each of the Transaction Documents to which such entity is party constitutes the legal, valid and binding obligation of it, enforceable against it in accordance with its respective terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or similar Applicable Laws affecting creditors' rights generally, general equitable principles and principles of public policy.

Section 5.4 Governmental and Third Party Authorizations. The execution and delivery by such entity of the Transaction Documents to which it is party, the performance by it of its obligations hereunder and thereunder and the consummation of any of the transactions contemplated hereunder and thereunder do not require any consent, approval, license, order, authorization or declaration from, notice to, action or registration by or filing with any Governmental Authority or any other Person.

Section 5.5 No Litigation. There is no action, suit, arbitration proceeding, claim, citation, summons, subpoena, investigation or other proceeding (whether civil, criminal, administrative, regulatory, investigative or informal and including by or before a Governmental Authority) pending or, to the knowledge of such entity, threatened by or against such entity, at law or in equity, that challenges or seeks to prevent or delay or which, if adversely determined, would prevent or delay the consummation of any of the transactions contemplated by any of the Transaction Documents to which it is party.

Section 5.6 No Brokers' Fees. Such entity has not taken any action that would entitle any Person or entity to any commission or broker's fee in connection with the transactions contemplated by this Agreement.

Section 5.7 Funds Available. Such entity has sufficient funds on hand or under commitment for it to satisfy its obligations to pay the Investment Amount due and payable on the Initial Closing Date and has sufficient funds under commitment to it to satisfy its obligations to pay the Investment Amount due and payable on the Second Closing Date, Third Closing Date and the Fourth Closing Date. Such entity acknowledges and agrees that its obligations under this Agreement are not contingent on obtaining financing.

Section 5.8 Access to Information. Such entity acknowledges that it has (a) reviewed such documents and information relating to the Revenue Interests, the Collateral and the Included Products and (b) had the opportunity to ask such questions of, and to receive answers from, representatives of the Company, in each case, as it deemed necessary to make an informed decision to purchase, acquire and accept the Revenue Interests in accordance with the terms of this Agreement. Such entity has such knowledge, sophistication and experience in financial and business matters that it is capable of evaluating the risks and merits of purchasing, acquiring and accepting the Revenue Interests in accordance with the terms of this Agreement.

Section 5.9 Tax Status. Such entity is a "United States person" (as such term is defined in Section 7701(a)(30) of the Internal Revenue Code).

ARTICLE VI
AFFIRMATIVE COVENANTS

The Parties hereto covenant and agree as follows:

Section 6.1 Collateral Matters; Guarantors.

(a) On or prior to the Initial Closing Date, each of the Company and the Guarantors shall enter into the Collateral Documents, pursuant to which the Company and the Guarantors shall grant to the Investor Representative, a continuing security interest of first priority in all of their respective right, title and interest in, to and under the Collateral (subject to Permitted Liens, but which, in the case of the Revenue Interests, shall be prior to all Liens other than Liens permitted pursuant to clauses (a), (b), (f), and (g) of the definition of Permitted Liens), whether now owned or hereafter existing or hereafter acquired, possessing or arising, whether tangible or intangible, wherever located, in each case, for the benefit of the Investor as security for the prompt and complete payment and performance of the Obligations. Pursuant to the Security Agreement, the Company Parties shall pledge all of the Collateral, whether now owned or hereafter existing or hereafter acquired, possessing or arising, whether tangible or intangible, wherever located to the Investor Representative for the benefit of the Investor to secure the Obligations. In addition, each Guarantor shall enter into the Guaranty, pursuant to which each Guarantor shall guarantee the prompt performance of the Obligations. Within thirty (30) days (or such longer period as the Investor Representative may reasonably agree) after any Company Party forms or acquires any Subsidiary, the Company shall cause such Subsidiary to (i) enter into a Joinder Agreement to become a party to the Guaranty as Guarantor and to the Security Agreement as “Grantor” (as defined therein), (ii) if the respective Subsidiary required to comply with the requirements in this Section 6.1(a) owns registrations of or applications for patents, trademarks and/or copyrights, an intellectual property security agreement, (iii) UCC financing statements in appropriate form for filing in such jurisdictions as the Investor Representative may reasonably determine, (iv) all other documents, deliverables and related items that may otherwise be required pursuant to the terms of the Security Agreement, Guaranty or the other Collateral Documents and (v) each item of Collateral that such Subsidiary is required to execute and/or deliver under the Security Agreement and/or Guaranty, including any Deposit Account Control Agreement, Securities Account Control Agreement, and Commodities Account Control Agreement, in each case, other than with respect to Excluded Accounts.

(b) The Company authorizes and consents to the Investor Representative filing, including with the Secretary of State of the State of Delaware, one or more UCC financing statements (and continuation statements with respect to such financing statements when applicable) or other instruments and notices, in such manner and in such jurisdictions, as in the Investor Representative’s determination may be necessary or appropriate to evidence the purchase, acquisition and acceptance by the Investor Representative of its security interest hereunder and to perfect and maintain the perfection of each of the Investor’s security interest in the Collateral granted by each Company Party to the Investor Representative pursuant to the Security Agreement or any other Collateral Document; provided that the Investor Representative is authorized to file one or more financing or continuation statements, including any amendments thereto, relative to all or any part of the Collateral (including any financing statement indicating that it covers “all assets” or “all personal property” or “all assets of the Company Party, whether now existing or

hereinafter arising” of such Company Party, or words of similar effect) without the signature of any Company Party. For greater certainty, the Investor Representative will not file this Agreement in connection with the filing of any such financing statements (or similar documents) but may file a summary or memorandum of this Agreement if required under Applicable Laws providing for such filing. For sake of clarification, the foregoing statements in this Section 6.1 shall not bind either Party regarding the reporting of the transactions contemplated hereby for GAAP or SEC reporting purposes.

Section 6.2 Update Meetings. During the Payment Term, but subject to ARTICLE IX, the Investor Representative shall be entitled to an update call or meeting (at the Investor Representative’s election, in-person, via teleconference or videoconference or at a location reasonably designated by the Company) once per each fiscal quarter to discuss (i) the reports delivered by the Company pursuant to Section 3.4, (ii) the progress of the sales and product development and marketing efforts made by each member of the Company Group pursuant to the Product Plan, (iii) the status and the historical and potential performance of the Included Products, (iv) any material regulatory developments or material developments relating to the Patent Rights of which any member of the Company Group has actual knowledge and/or (v) such other matters that the Investor Representative reasonably deems necessary or appropriate. Any information disclosed by either Party during such update meetings or calls or provided to the Investor Representative pursuant to its request shall be considered “Confidential Information” of the disclosing Party subject to the terms of ARTICLE IX. Notwithstanding the foregoing, after the occurrence and during the continuance of a Special Termination Event, Change of Control, Default or an Event of Default, the Investor Representative shall have the right, as often, at such times and with such prior notice as the Investor Representative shall determine in its reasonable discretion, to have such update meetings at the Company’s headquarters or inspect any records and operations of the Company and its Affiliates.

Section 6.3 Notices.

(a) Subject to any confidentiality obligations to any Third Party, to the extent permitted by Applicable Law, promptly after receipt by the Company after the Effective Date of notice of any action, suit, claim, demand, Dispute, investigation, arbitration or other legal proceeding (commenced or threatened) involving or related to an Included Product or any Company Group member which owns any assets (including Product Rights) related to an Included Product, the transactions contemplated by any Transaction Document, or to the Revenue Interests, the Company shall, subject to any confidentiality obligations to any Third Party, (i) inform the Investor Representative in writing of the receipt of such notice and the substance thereof and (ii) if such notice is in writing, furnish the Investor Representative with a copy of such notice and any related materials with respect thereto reasonably requested by the Investor Representative, and if such notice is not in writing, furnish to the Investor Representative a written summary describing in reasonable detail the substance thereof.

(b) To the extent permitted by Applicable Law, promptly following receipt by any member of the Company Group after the Effective Date of any written notice, claim or demand challenging the legality, validity, enforceability or ownership of any of the Product Rights included in the Collateral, including the continued effectiveness of any Regulatory Approval relating to any Included Product, or pursuant to which any Third Party commences or threatens any action, suit

or other proceeding against any member of the Company Group and relating to any Included Product (including Product Rights related to any Included Product), the Company shall, subject to any confidentiality obligation to any Third Party, (i) inform the Investor Representative in writing of such receipt and (ii) furnish the Investor Representative with a copy of such notice, claim or demand, or if such notice is not in writing, furnish to the Investor Representative a written summary describing in reasonable detail the contents thereof.

(c) The Company shall promptly (and in any event within fifteen (15) Business Days) provide Investor Representative with copies of any material information, reports and notices if the contents of such information, report or notice could, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(d) The Company shall provide the Investor Representative with prompt written notice after the Company has Knowledge of any of the following: (i) the occurrence of a Bankruptcy Event in respect of any member of the Company Group or any Material Contract Counterparty to any Material Contract; (ii) any material breach or default (in each case, with or without notice or lapse of time, or both) by any Company Party of or under any covenant, agreement or other provision of any Transaction Document; (iii) any representation or warranty made by any Company Party in any of the Transaction Documents or in any certificate delivered to the Investor pursuant to this Agreement shall prove to be untrue, inaccurate or incomplete in any material respect on the date as of which made; or (iv) any change, effect, event, occurrence, state of facts, development or condition with respect to the assets of any member of the Company Group, taken as a whole, that could reasonably be expected to result in a Material Adverse Effect.

(e) The Company shall promptly notify the Investor Representative of the occurrence of a Change of Control.

(f) The Company shall notify the Investor Representative in writing not less than five (5) Business Days prior to any change in, or amendment or alteration of, any Company Party's (i) legal name, (ii) form of legal entity or (iii) jurisdiction of organization,

(g) The Company shall notify the Investor Representative of any ERISA Event promptly (and in any event, within ten (10) Business Days) following the Company becoming aware of such ERISA Event.

(h) The Company shall notify the Investor Representative of the occurrence of any material default or event of default (in each case, with or without notice or lapse of time, or both) related to any Permitted Convertible Notes promptly following the Company becoming aware of such default or event of default (and in any event, within five Business Days or within one (1) Business Day if any Indebtedness under such Permitted Convertible Notes has been accelerated).

(i) The Company shall promptly (and in any event, within ten (10) days) notify the Investor Representative of (i) the termination of any Material Contract other than upon its scheduled expiration date; (ii) the receipt by any Company Party or any of its Affiliates from a counterparty asserting a default by any member of the Company Group under any Material Contract where such alleged default, if accurate, would permit such counterparty to terminate such

Material Contract, and provide a copy of any related documentation to the Investor Representative; (iii) the entering into of any new Material Contract by a Company Party or any Affiliate, and provide a copy of such new Material Contract to the Investor Representative; or (iv) any material amendment to an Material Contract, and provide a copy of such amendment to the Investor Representative.

(j) The Company shall promptly notify the Investor Representative of the occurrence of a Change of Control, Special Termination Event, Default or Event of Default.

(k) The Company shall promptly notify the Investor Representative of the occurrence of any event with respect to the assets of the Company or any Affiliates of the Company that could reasonably be expected to result in a Material Adverse Effect.

Subject to any confidentiality obligations to any Third Party, each notice pursuant to clauses (a) through (k) of this Section 6.3 shall be accompanied by a statement of a Responsible Officer of the Company setting forth details of the occurrence referred to therein and stating what action the applicable Company Party has taken and proposes to take with respect thereto. Each notice pursuant to Section 6.3(g), Section 6.3(i) or Section 6.3(h) shall describe with particularity any and all provisions of this Agreement and any other Transaction Document that have been breached.

Section 6.4 Public Announcement.

(a) As soon as reasonably practicable following the date hereof, one or both of the Parties shall issue a mutually agreed to press release substantially in the applicable form attached hereto as Exhibit A. Except as required by Applicable Law (including disclosure requirements of the SEC, the Nasdaq Stock Market or any other stock exchange on which securities issued by a Party or its Affiliates are traded) or for statements that are materially consistent with all or any portion of a previously approved public disclosure, neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party (which in the case of the Investor, shall be the Investor Representative) with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

(b) The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including proposed redaction of certain provisions of this Agreement) with the SEC, the Nasdaq Stock Market or any other stock exchange or Governmental Authority on which securities issued by a Party or its Affiliate are traded, and each Party shall use reasonable efforts to seek confidential treatment for the terms of this Agreement proposed to be redacted, if any; provided that each Party shall ultimately retain control over what information to disclose to the SEC, the Nasdaq Stock Market or any other stock exchange or Governmental Authority, as the case may be, and provided further that the Parties shall use their reasonable efforts to file redacted versions with any Governmental Authorities which are consistent with redacted versions previously filed with any other Governmental Authorities. Other than such obligation, neither

Party (nor its Affiliates) shall be obligated to consult with or obtain approval from the other Party with respect to any filings with the SEC, the Nasdaq Stock Market or any other stock exchange or Governmental Authority. For clarity, once a public announcement or other disclosure is made by a Party in accordance with this Section 6.4, then no further consent or compliance with this Section 6.4 shall be required for any substantially similar disclosure thereafter.

Section 6.5 Further Assurances.

(a) Each Company Party shall, and shall cause its Subsidiaries to, promptly, upon the reasonable request of the Investor Representative, at the Company's sole cost and expense, (a) execute, acknowledge and deliver, or cause the execution, acknowledgment and delivery of, and thereafter register, file or record, or cause to be registered, filed or recorded, in an appropriate governmental office, any document or instrument supplemental to or confirmatory of the Transaction Documents or otherwise deemed by the Investor Representative reasonably necessary for the continued validity, perfection and priority of the Liens on the Collateral covered thereby subject to no other Liens except as permitted by the applicable Transaction Document, or obtain any consents or waivers as may be necessary in connection therewith; (b) deliver or cause to be delivered to the Investor Representative from time to time such other documentation, consents, authorizations, approvals and orders in form and substance reasonably satisfactory to the Investor Representative as the Investor Representative shall reasonably deem necessary to perfect or maintain the Liens on the Collateral pursuant to the Transaction Documents; and (c) upon the exercise by the Investor of any power, right, privilege or remedy pursuant to any Transaction Document which requires any consent, approval, registration, qualification or authorization of any Governmental Authority, execute and deliver all applications, certifications, instruments and other documents and papers that the Investor Representative may require. In addition, the Company shall promptly, at its sole cost and expense, execute and deliver to the Investor Representative such further instruments and documents, and take such further action as the Investor Representative may, at any time and from time to time, reasonably request in order to carry out the intent and purpose of this Agreement and the other Transaction Documents and to establish and protect the rights, interests and remedies created, or intended to be created, in favor of the Investor hereby and thereby.

(b) The Company and the Investor shall cooperate and provide assistance as reasonably requested by each of the Parties hereto, at the expense of the requesting Party (except as otherwise set forth herein), in connection with any litigation, arbitration, investigation or other proceeding (whether threatened, existing, initiated or contemplated prior to, on or after the date hereof) to which the requesting party, any of its Affiliates or controlling Persons or any of their respective officers, directors, equity holders, controlling Persons, managers, 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 interest, in each case relating to any Transaction Document, the transactions contemplated herein or therein, the Total Fixed Payments or the Revenue Interests, but in all cases excluding any litigation brought by the Company (for itself or on behalf of any Company Indemnified Party) against the Investor or brought by the Investor or Investor Representative (for itself or on behalf of any Investor Indemnified Party) against the Company.

(c) Each Party shall comply with all Applicable Laws with respect to the Transaction Documents and the Revenue Interests and the Total Fixed Payments except where any non-compliance could not reasonably be expected to result in a Material Adverse Effect.

Section 6.6 Included Product Patent Rights. Each Company Party shall, and shall cause its Subsidiaries to: (a) use commercially reasonable efforts to take any and all actions, and prepare, execute, deliver and file any and all agreements, documents and instruments, that are reasonably necessary or desirable to preserve and maintain the IP Rights related to the Included Products in the United States, including payment of maintenance fees or annuities, at the sole expense of the Company; (b) use commercially reasonable efforts to defend the IP Rights related to the Included Products in the United States against interference by any other Person, and against any claims of invalidity or unenforceability (including by defending any claim or counterclaim of invalidity or action of a Third Party in any United States forum), (c) use commercially reasonable efforts to enforce the IP Rights related to the Included Products in the United States against infringement by any other Person (including by bringing a legal action for infringement) to the extent that the Company determines that such enforcement is in the best interests of the business of the Company Group and would not give rise to a Material Adverse Effect, (d) use commercially reasonable efforts to defend against any material claim or action in the United States by any other Person that the manufacture, use, marketing, sale, offer for sale, importation or distribution of an Included Product as currently contemplated infringes on any Patent Rights or other intellectual property rights of any other Person or constitutes misappropriation of any other Person's Trade Secrets or other intellectual property rights; and (e) when available in respect of an Included Product and where applicable, use best efforts to obtain a patent listing in the Orange Book. The Company shall not exercise and enforce its applicable rights in any manner that would result in a breach of this Agreement.

Section 6.7 Existence. Each Company Party shall, and shall cause its Subsidiaries to, (a) preserve and maintain its existence, (b) preserve and maintain its rights, franchises and privileges unless failure to do any of the foregoing would not reasonably be expected to result in a Material Adverse Effect, (c) qualify and remain qualified in good standing in each jurisdiction where the failure to preserve and maintain such qualifications could reasonably be expected to result in a Material Adverse Effect, including appointing and employing such agents or attorneys in each jurisdiction where it shall be necessary to take action under this Agreement, and (d) comply in all material respects with its organizational documents.

Section 6.8 Commercialization of Included Products.

(a) After the receipt of a Favorable Determination, each Company Party shall, and shall cause its Subsidiaries to, use Commercially Reasonable and Diligent Efforts to prepare, execute, deliver and file any and all agreements, documents or instruments that are necessary or desirable to secure and maintain Marketing Authorization in the United States for the Existing Yutrepia Product. The Company shall not, without the prior consent of the Investor Representative, withdraw or abandon, or fail to take any action necessary to prevent the withdrawal or abandonment of, Marketing Authorization in the United States for the Existing Yutrepia Product. The Company shall (i) use Commercially Reasonable and Diligent Efforts, itself or through one or more Subsidiaries or Permitted Licensees, to Commercialize the Existing Yutrepia Product in the United States, and (ii) prior to the achievement of the Net Sales Threshold, perform,

itself or through one or more Subsidiaries, its obligations under the Sandoz Agreement and the Sandoz Device Agreement in all material respects.

(b) If any existing Material Contract (other than a Material Contract for a Permitted Foreign Transaction) terminates for any reason whatsoever and such Contract was, as of the time of termination, still a Material Contract, the Company shall use Commercially Reasonable and Diligent Efforts to enter into a replacement Material Contract as promptly as reasonably practicable.

(c) During the Payment Term, the Company shall, and shall cause the Company Parties to: (i) maintain in full force and effect, and shall not terminate, any Material Contract relating to an Included Product (including the Sandoz Agreement and the Sandoz Device Agreement following the achievement of the Net Sales Threshold to the extent that such agreements continue to be Material Contracts), except to the extent that the applicable Company Party determines that the termination of such Material Contract is in the best interests of the business of the Company Group and would not give rise to a Material Adverse Effect, and (ii) ensure a continuous and sufficient supply of the active pharmaceutical ingredient for Yutrepia and any device necessary to administer Yutrepia and, until the Net Sales Threshold is achieved, the Sandoz Product. During the Payment Term until the Net Sales Threshold is achieved, the Company shall, and shall cause the Company Parties to, maintain in full force and effect, and shall not terminate, the Sandoz Agreement or the Sandoz Device Agreement. Each member of the Company Group shall comply with all material terms and conditions of and fulfill all material obligations under each Material Contract for an Included Product to which any of them is party. Upon the occurrence of a material breach of any such Material Contract by any member of the Company Group, the Company shall use Commercially Reasonable and Diligent Efforts to cure (or cause its Subsidiary to cure) such material breach. Notwithstanding the foregoing, the Company shall have the right, by written notice to the Investor Representative, to amend Schedule 4.12(a) to replace the Mainbridge Agreement with a New Sandoz Device Agreement provided that such New Sandoz Device Agreement is not reasonably expected to result in a delay in the Regulatory Approval of a New Pump (as defined in the Product Plan) as compared to the corresponding timelines set forth in the Product Plan.

(d) If, prior to the achievement of the Net Sales Threshold, a material breach of the Sandoz Agreement by the counterparty thereto occurs that could result in a reduction in the amounts that are paid or payable to the applicable Company Party under the Sandoz Agreement, the Company shall notify the Investor Representative in writing, consult with the Investor Representative relating to such breach and any related enforcement action, and shall seek to enforce all of its (and cause its Affiliates to seek to enforce all of their) rights and remedies thereunder. Upon the occurrence of a material breach of any Material Contract (including the Sandoz Agreement and the Sandoz Device Agreement following the achievement of the Net Sales Threshold to the extent that such agreements continue to be Material Contracts) by any other party thereto, the Company shall seek to enforce all of its (and cause its Affiliates to seek to enforce all of their) rights and remedies thereunder, except to the extent that the applicable Company Party determines that not enforcing such rights and remedies is in the best interests of the business of such Company Party and would not give rise to a Material Adverse Effect.

Section 6.9 Financial Statements.

(a) Commencing with the fiscal year ending December 31, 2022, the Company shall deliver to the Investor Representative, in form and detail reasonably satisfactory to the Investor Representative as soon as available, and in any event within ninety (90) days after the end of each fiscal year of the Company (or, if earlier, when required to be filed with the SEC), a consolidated balance sheet of the Company Group as at the end of such fiscal year, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for such fiscal year, setting forth in each case in comparative form the figures for the previous fiscal year, all in reasonable detail and prepared in accordance with GAAP, or otherwise audited and accompanied by a report and opinion of an independent certified public accountant of nationally recognized standing and reasonably acceptable to the Investor Representative, which report and opinion shall be prepared in accordance with generally accepted auditing standards and shall not be subject to any qualification or exception as to the scope of such audit (except for a qualification or an exception to the extent related to the maturity or refinancing of borrowings under Permitted Debt or this Agreement); provided, that to the extent the components of such financial statements relating to a prior fiscal period are separately audited by different independent public accounting firms, the audit report of any such accounting firm may contain a qualification or exception as to scope of such financial statements as they relate to such components; provided, further, that, such financial statements shall be deemed to have been delivered to the Investor Representative on the date on which such financial statements are publicly available via EDGAR on the SEC's website at www.sec.gov; and

(b) The Company shall deliver to the Investor Representative, as soon as available, and in any event within forty-five (45) days after the end of each of the first three fiscal quarters of each fiscal year of the Company (or, if earlier, when required to be filed with the SEC), commencing with the first such fiscal quarter ending following the Closing Date, a consolidated balance sheet of the Company Group as at the end of such fiscal quarter, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for such fiscal quarter and for the portion of the Company's fiscal year then ended, setting forth, in each case in comparative form, the figures for the corresponding fiscal quarter of the previous fiscal year and the corresponding portion of the previous fiscal year, all in reasonable detail; provided, that, such financial statements shall be deemed to have been delivered to the Investor Representative on the date on which such financial statements are publicly available via EDGAR on the SEC's website at www.sec.gov.

Section 6.10 Certificates; Other Information; Bank Account Viewing Access.

(a) The Company shall deliver to the Investor Representative, in form and detail reasonably satisfactory to the Investor Representative:

(i) concurrently with the delivery of the financial statements referred to in Section 6.9(a) and Section 6.9(b), a duly completed Compliance Certificate signed by the chief executive officer, chief financial officer, treasurer or controller of the Company.

(ii) as soon as practicable upon the reasonable request of the Investor Representative, copies of the most recent quarterly statements for each Deposit Account, Securities Account, Commodities Account and other bank account or securities account of the Company and each other Company Party;

(iii) concurrently with the delivery of the financial statements referred to in Section 6.9(a) and Section 6.9(b), a certificate of a Responsible Officer of the Company listing (A) all applications by any Company Party, if any, for Copyrights, Patent Rights or Trademarks made since the date of the prior certificate (or, in the case of the first such certificate, the Initial Closing Date), (B) all issuances of registrations or letters on existing applications by any Company Party for Copyrights, Patent Rights and Trademarks received since the date of the prior certificate (or, in the case of the first such certificate, the Initial Closing Date), (C) all material Trademark Licenses, Copyright Licenses and Patent Licenses entered into by any Company Party since the date of the prior certificate (or, in the case of the first such certificate, the Initial Closing Date), (D) such supplements to Schedule 1.1-4, Schedule 4.10(a), Schedule 4.10(i), Schedule 4.10(r), Schedule 4.12(a), Schedule 4.14(c), and Schedule 4.20 (it being understood that notwithstanding anything to the contrary contained in this Agreement or any other Transaction Document, any updates to the Schedules pursuant to this Section 6.10(a)(iii) which contain updates outside of the information required by the Sections or clauses of this Agreement to which such Schedule is pertaining shall not qualify the representations and warranties, covenant or other terms of the Transaction Documents) as are (i) necessary to add items solely for events occurring between the last Closing Date and the date of such certificate in order to cause such schedule to be true and complete in all material respects as of the date of such certificate (it being understood that such supplements are not meant to cure inaccurate disclosure made as of the last Closing Date for purposes of the Investor's rights to indemnification hereunder) and (ii) reasonably acceptable to the Investor Representative.

(iv) concurrently with the delivery of the financial statements referred to in Section 6.9(a) and Section 6.9(b), to the extent necessary, updated versions of the Perfection Certificate and schedules to the Security Agreement showing information as of the date of such audit report (it being agreed and understood that this requirement shall be in addition to the notice and delivery requirements set forth in the Collateral Documents and shall not constitute a cure or waiver of any breach of such notice or delivery requirements).

(b) Documents required to be delivered pursuant to Section 6.9 or Section 6.10(a) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date (i) on which the Company posts such documents, or provides a link thereto on the Company's website, or (ii) on which such documents are posted on the Company's behalf on an internet or intranet website, if any, to which the Investor Representative has access (whether a commercial, third-party website or whether sponsored by the Investor); provided, that the Company shall notify the Investor Representative (by electronic mail) of the posting of any such documents and provide to the Investor Representative by electronic mail electronic versions (*i.e.*, soft copies) of such documents. The Investor Representative shall have no obligation to request the delivery of or to maintain paper copies of the documents referred to above, and in any event shall have no responsibility to monitor compliance by the Company with any such request for delivery by the Investor or the Investor Representative, and the Investor or the Investor Representative shall be solely responsible for requesting delivery to it or maintaining its copies of such documents.

(c) The Company shall at all times provide the Investor Representative with “view-only” online access enabling it to view all aggregate cash and Cash Equivalents, in each case, of the Company and each Company Party held in Deposit Accounts and Securities Accounts for which the Investor Representative shall have received a Deposit Account Control Agreement or Securities Account Control Agreement, as applicable.

Section 6.11 Payment of Obligations. Each Company Party shall pay and discharge (a) prior to the date on which penalties attach thereto, all federal and state and other Taxes imposed upon it or its properties or assets, unless the same are being contested in good faith by appropriate proceedings diligently conducted and adequate reserves in accordance with GAAP are being maintained by the Company Party, (b) as the same shall become due and payable, all other obligations, liabilities or lawful claims which, if unpaid, would by Law become a Lien (other than a Permitted Lien pursuant to clause (d) of the definition of Permitted Liens in Section 1.1) upon any Collateral, and (c) prior to the date on which such Indebtedness shall become delinquent or in default, all material Indebtedness, but subject to any subordination provisions contained in any instrument or agreement evidencing such Indebtedness.

Section 6.12 Maintenance of Properties. Each Company Group entity shall maintain, preserve and protect all of its material properties and equipment necessary in the operation of its business in good working order and condition (ordinary wear and tear and casualty and condemnation events excepted) except where the failure to do so would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, and shall make all necessary repairs thereto and renewals and replacements thereof, except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect.

Section 6.13 Maintenance of Insurance.

(a) Except as would not reasonably be expected to result in a Material Adverse Effect, each member of the Company Group shall maintain with financially sound and reputable insurance companies that are not Affiliates of the Company, insurance with respect to its properties and business against loss or damage of the kinds customarily insured against by Persons engaged in the same or similar business, of such types and in such amounts as are customarily carried under similar circumstances by such other Persons.

(b) Within thirty (30) days of the Initial Closing Date, (i) the Company shall provide the Investor Representative a schedule of the insurance coverage of each member of the Company Group as is then in effect, outlined as to carrier, policy number, expiration date, type, amount and deductibles, and (ii) each member of the Company Group members shall cause the Investor and its successors and/or assigns to be named as lender’s loss payee or mortgagee as its interest may appear, and/or additional insured with respect to any such insurance providing liability coverage or coverage in respect of any tangible Collateral.

Section 6.14 Books and Records. Each member of the Company Group shall maintain proper books of record and account, in which full, true and correct entries in conformity with GAAP consistently applied shall be made of all financial transactions and matters involving the assets and business of such Company Group entity, as the case may be. Each member of the Company Group members shall maintain such books of record and account in material conformity

with all applicable requirements of any Governmental Authority having regulatory jurisdiction over such Company Group entity, as the case may be.

Section 6.15 Use of Proceeds. The Company Group, taken as a whole, shall use substantially all of the Investment Amount to consummate the Payoff, support the development and Commercialization of Yutrepia, including the commercial launch of Yutrepia in accordance with the Product Plan, the Commercialization of the Sandoz Product, the development of a pump for the administration of the Sandoz Product, one or more Strategic Transactions, preclinical pipeline activities, the Commercialization of any products acquired or developed and for general corporate purposes. In no event, however, shall the Investment Amount be used to fund any activities of or business with any Person, or in any Designated Jurisdiction, that, at the time of such funding, is the subject of Sanctions, or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as Investor or otherwise) of Sanctions or otherwise in contravention of any Law or of any Transaction Document.

Section 6.16 ERISA Compliance. Each member of the Company Group shall do each of the following: (a) maintain each Plan in compliance with the applicable provisions of ERISA, the Internal Revenue Code and other federal or state Law, (b) cause each Pension Plan that is qualified under Section 401(a) of the Internal Revenue Code to maintain such qualification, and (c) make all contributions required to be made by each member of the Company Group to any Pension Plan subject to Section 412 or Section 430 of the Internal Revenue Code, in each case, except as would not reasonably be expected to result in a Material Adverse Effect.

Section 6.17 Compliance with Material Contracts. Without limitation of the Company's obligations under Section 6.8, each member of the Company Group shall comply in all respects with (a) the Product Plan and (b) each Contractual Obligation of such Person, except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

Section 6.18 Compliance with Laws. (a) Each member of the Company Group shall comply with all Applicable Laws (including any Law, rule or regulation with respect to the making or brokering of loans or financial accommodations), except, in each case, as would not, individually or in the aggregate, be expected to result in a Material Adverse Effect and (b) each Company Party shall, or cause its Subsidiaries to, obtain and maintain all required material Permits.

Section 6.19 Anti-Corruption Laws; Anti-Terrorism Laws.

(a) Neither any member of the Company Group, nor, to the Knowledge of the Company, any of their respective directors, officers, employees or agents shall, directly or indirectly, engage in any activity which would constitute a violation of the FCPA make, offer, promise or authorize any payment or gift of any money or anything of value to or for the benefit of any "foreign official" (as such term is defined in the FCPA), foreign political party or official thereof or candidate for foreign political office for the purpose of (i) influencing any official act or decision of such official, party or candidate, (ii) inducing such official, party or candidate to use his, her or its influence to affect any act or decision of a foreign Governmental Authority or

(iii) securing any improper advantage, in the case of (i), (ii) and (iii) above in order to assist the Company or any of its Affiliate in obtaining or retaining business for or with, or directing business to, any “person” (as such term is defined in the FCPA).

(b) The Company Group members shall not, nor shall any member of the Company Group permit any Affiliate controlled by any member of the Company Group to, directly or indirectly, knowingly enter into any documents, instruments, agreements or Contracts with any sanctioned Person. The Company Group members shall not, nor shall any member of the Company Group permit any Affiliate controlled by the Company to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any sanctioned Person, including, without limitation, the making or receiving of 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 Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, 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 Executive Order No. 13224 or other Anti-Terrorism Law.

Section 6.20 Data Privacy. In connection with its collection, storage, transfer (including, without limitation, any transfer across national borders) and/or use of any Personal Information, the Company Group members shall maintain compliance in all material respects with all Applicable Laws in all relevant jurisdictions, the Company Group member’s privacy policies and the requirements of any contracts or codes of conduct to which any member of the Company Group is a party, except for any such non-compliance that, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Effect. The Company shall maintain commercially reasonable physical, technical, organizational and administrative security measures and policies in place to protect all Personal Information collected by it or on its behalf from and against unauthorized access, use and/or disclosure. The Company Group members shall maintain compliance in all material respects with all Applicable Laws relating to data loss, theft and breach of security notification obligations, except for any such non-compliance that, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Effect.

Section 6.21 Included Products. In connection with the development, testing, manufacture, marketing or sale of each and any Included Product by any member of the Company Group, the Company Group members shall comply in all material respects with all material Permits.

Section 6.22 Tax.

(a) The Parties (i) agree that for U.S. federal and applicable state and local income Tax purposes, each of the Initial Investment Amount, the Second Investment Amount, the Third Investment Amount and the Fourth Investment Amount is intended to constitute a debt instrument that is subject to U.S. Treasury Regulations under Section 1.1275-4(b) governing contingent payment debt instruments. Within ninety (90) days after the date of this Agreement (and, if applicable, each of the Second Closing Date, the Third Closing Date and the Fourth Closing Date), the Company will prepare and deliver to the Investor Representative a determination of the

comparable yield and a projected payment schedule under Section 1.1275-4(b) (the “Comparable Yield”). Unless the Investor Representative objects to the Comparable Yield within fifteen (15) days after receipt thereof, the Comparable Yield shall become final and binding on the Parties. If the Investor Representative objects to the Comparable Yield within fifteen (15) days of receipt, then the Parties shall cooperate in good faith to agree on a revised Comparable Yield within twenty (20) days of the Investor’s objection. The Parties intend that the provisions of the U.S. Treasury Regulation Section 1.1275-2(a)(1) would apply, subject to the exceptions in the U.S. Treasury Regulation Section 1.1275-2(a)(2), to treat any non-contingent payments on the debt instrument and the projected amount of any contingent payments as first, a payment of any accrued and any unpaid original issue discount at such time and second, a payment of principal (including for purposes of the rules applicable to “applicable high yield discount obligations”). The Parties agree not to take and to not cause or permit their Affiliates to take, any position that is inconsistent with the provisions of this Section 6.22(a) on any U.S. federal, state or local income Tax return or for any other U.S. federal, state or local income Tax purpose, unless required by Applicable Law or the good faith resolution of a Tax audit or other Tax proceeding.

(b) On or prior to the Initial Closing Date, the Investor shall provide the Company with a duly completed and executed IRS Form W-9 certifying that such entity is a “United States person” (as such term is defined in Section 7701(a)(30) of the Internal Revenue Code) that is exempt from U.S. federal backup withholding with respect to all payments pursuant to this Agreement.

(c) Payments by or on account of any obligation of any Company Party under any Transaction Document shall be made without deduction or withholding for any Taxes, except as required by Applicable Law. If any Company Party is required by Applicable Law to deduct or withhold any Tax in respect of any amounts payable to an Investor pursuant to any Transaction Document, (1) such Company Party shall make such deduction or withholding and timely pay such amount to the applicable Governmental Authority, (2) such Company Party shall provide such Investor with a receipt evidencing such payment or other evidence of such payment reasonably satisfactory to such Investor and (3) if the Tax deducted or withheld was an Indemnified Tax, the sum payable by such Company Party shall be increased so that after all required deductions and withholdings for Indemnified Taxes have been made (including deductions and withholdings applicable to additional sums payable under this Section 6.22(c)), such Investor receives an amount equal to the sum it would have received had no such deductions or withholdings been made. The Company will promptly notify an Investor if any Company Party becomes required to deduct or withhold any Tax in respect of any payment to such Investor pursuant to any Transaction Document.

(d) If the Investor determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has received Additional Amounts pursuant to this Section 6.22, it shall pay to the Company an amount equal to such refund (but only to the extent of Additional Amounts paid under this Section 6.22 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of the Investor and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). The Company, upon the request of the Investor, shall repay to the Investor the amount paid over pursuant to this Section 6.22(d) (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that the Investor is required to repay such refund

to such Governmental Authority. Notwithstanding anything to the contrary in this Section 6.22(d), in no event will the Investor be required to pay any amount to the Company pursuant to this Section 6.22(d) the payment of which would place the Investor in a less favorable net after-Tax position than the Investor would have been in if the Tax for which the Company paid Additional Amounts and giving rise to such refund had not been deducted, withheld or otherwise imposed and the Additional Amounts with respect to such Tax had never been paid. This Section 6.22(d) shall not be construed to require the Investor to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the Company or any other Person other than a reasonably detailed explanation of any computation made pursuant to this Section 6.22(d).

(e) The Company shall timely pay to the applicable Governmental Authority in accordance with Applicable Law any Other Taxes.

(f) Without duplication of any amounts payable under Section 6.22(c) or Section 6.22(e), the Company shall indemnify the Investor with respect to any Indemnified Tax or Other Tax payable or paid by the Investor (including any Indemnified Tax or Other Tax payable or paid with respect to any amounts payable under this Section 6.22) and any reasonable expenses related thereto, in each case whether or not such Taxes were correctly or legally asserted by the applicable Governmental Authority. Any such indemnification shall be paid within fifteen (15) days after the Investor makes a written demand therefor. A certificate as to the amount of such payment or liability, accompanied by a reasonable explanation thereof, delivered to the Company by the Investor shall be conclusive absent manifest error.

(g) Each Party's obligations under this Section 6.22 shall survive the termination of this Agreement, any assignment by an Investor and the repayment, satisfaction or discharge of all obligations under this Agreement.

ARTICLE VII NEGATIVE COVENANTS

During the Payment Term, no Company Party shall, nor shall it permit any Subsidiary to, directly or indirectly:

Section 7.1 Liens. Create, incur, assume or suffer to exist any Lien upon any assets or property, whether now owned or hereafter acquired, other than the Permitted Liens.

Section 7.2 Indebtedness. Create, incur, assume or suffer to exist any Indebtedness without the prior written consent of the Investor Representative, except Permitted Debt.

Section 7.3 Dispositions. Make any Disposition (other than, for the avoidance of doubt, Permitted Transfers) unless:

(a) the consideration paid in connection therewith shall be in an amount not less than the fair market value of the property Disposed of;

(b) no Special Termination Event, Default or Event of Default shall have occurred and be continuing both immediately prior to and immediately after giving effect to such Disposition;

(c) such transaction does not involve the sale or other Disposition of a minority Equity Interest in any Subsidiary (other than to a Company Party);

(d) such transaction does not involve a sale, transfer, license or other Disposition of the Existing Yutrepia Product assets or rights included in the Collateral (or any Product Rights associated therewith) in the United States; and

(e) the aggregate net book value of all of the assets sold or otherwise Disposed of (including, for the avoidance of doubt, the assets sold or otherwise Disposed of in such Disposition) does not exceed [***] Dollars (\$[***]) in any fiscal year.

Section 7.4 Change in Nature of Business, Management, Control, or Business Location.

(a) Engage in any material line of business other than the discovery, development, manufacture or commercialization of biopharmaceutical products.

(b) Liquidate or dissolve or permit any of its Subsidiaries to liquidate or dissolve.

(c) Without at least thirty (30) days prior written notice to the Investor Representative, add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than [***] Dollars (\$[***]) in assets or property) or deliver any portion of the Collateral valued, individually or in the aggregate, in excess of [***] Dollars (\$[***]) to a bailee at a location other than to a bailee and at a location already disclosed in writing to the Investor Representative. If the Company intends to add any new offices or business locations, including warehouses, containing in excess of [***] Dollars (\$[***]) of the Company's assets or property, then the Company shall use reasonable efforts to cause the landlord of any such new offices or business locations, including warehouses, to execute and deliver a landlord consent in form and substance satisfactory to the Investor Representative in its commercially reasonable discretion. If the Company intends to deliver any portion of the Collateral valued, individually or in the aggregate, in excess of [***] Dollars (\$[***]) to a bailee, and the Investor Representative and such bailee are not already parties to a bailee agreement governing both the Collateral and the location to which the Company intends to deliver the Collateral, then the Company shall use reasonable efforts to cause such bailee to execute and deliver a bailee agreement in form and substance satisfactory to the Investor Representative in its commercially reasonable discretion.

Section 7.5 Prepayment of Other Indebtedness. Make (or give any notice with respect thereto) any voluntary or optional payment or prepayment or redemption, cash settlement or acquisition for value of (including without limitation, by way of depositing money or securities with the trustee with respect thereto before due for the purpose of paying when due), refund, refinance or exchange of any Indebtedness of the Company or any Subsidiary (other than exchanging any such Indebtedness for capital stock (other than Disqualified Capital Stock)) or

the proceeds from the sale of capital stock (other than Disqualified Capital Stock) or, with respect to the Indebtedness arising under the Transaction Documents, Permitted Debt and, in the case of the Permitted Convertible Notes, other than from using the proceeds from the sale of Permitted Convertible Notes or exchanging any such Indebtedness for Permitted Convertible Notes.

Section 7.6 Organization Documents; Fiscal Year; Legal Name, State of Formation and Form of Entity; Certain Amendments.

(a) Amend, modify or change its Organization Documents in a manner materially adverse to the rights or remedies of the Investor under the Transaction Documents.

(b) Without providing ten (10) days' prior notice to the Investor Representative, change its fiscal year.

(c) Without providing ten (10) days' prior notice to the Investor Representative, change its name, state of organization or form of organization or its Federal Taxpayer Indemnification Number or its organizational identification number.

(d) Amend, modify or change any of the terms or provisions of any Permitted Debt Facility Document in a manner materially adverse to the interests of the Investor and the Investor Representative.

(e) Amend, modify or change the Product Plan without the prior written consent of the Investor Representative.

(f) Amend, modify or change in any material respect or waive any of the terms or provisions of a Material Contract (other than any License Agreement outside the United States) in a manner materially adverse to the Investor. For clarity, any amendment, modification, change or waiver to the Sandoz Agreement that reduces the amounts payable thereunder to any Company Party shall be deemed to be materially adverse to the Investor.

Section 7.7 Restricted Payments. Declare or make, directly or indirectly, any Restricted Payment, or incur any obligation (contingent or otherwise) to do so, except that:

(a) each Subsidiary may make Restricted Payments to any other Company Party;

(b) each Company Party may make Restricted Payments to any Company Party;

(c) each Subsidiary may make Restricted Payments to the holders of its Equity Interests on a *pro rata* basis;

(d) each Subsidiary that is not a Company Party may make Restricted Payments to any other Subsidiary;

(e) the Company Group may declare and make dividend payments or other distributions payable solely in the Equity Interests (other than Disqualified Capital Stock) of the Company Group member, as applicable;

(f) the Company may make scheduled payments to the Permitted Debt Creditors so long as (i) no Default or Event of Default (in each case, with or without notice or lapse of time, or both) exists under the Permitted Debt Facility Documents and (ii) such payments are made in accordance with the terms of the Permitted Debt Facility Documents;

(g) the Company may make Restricted Payments to the Permitted Convertible Notes Creditors in each case in accordance with the Permitted Debt Facility Documents related thereto;

(h) the Company may make any Restricted Payment in exchange for, or out of the net cash proceeds of a contribution to the common equity of the Company or a substantially concurrent sale (other than to a Subsidiary of the Company Group) of, Equity Interests (other than Disqualified Capital Stock) of the Company;

(i) the Company Group may repurchase Equity Interests (i) deemed to occur upon the exercise of options, warrants or other convertible securities to the extent that such Equity Interests represent all or a portion of the exercise price thereof or (ii) deemed to occur upon the withholding of a portion of Equity Interests granted or awarded to any current or former officer, director, manager, employee or consultant (or permitted transferees, assigns, estates, trusts or heirs of any of the foregoing) to pay for Taxes payable by such Person in connection with such grant or award (or the vesting thereof);

(j) any member of the Company Group may make payments of cash in lieu of fractional Equity Interests pursuant to the exchange or conversion of any exchangeable or convertible securities; and

(k) any member of the Company Group may repurchase, redeem or otherwise acquire or retire for value any Equity Interests of such member of the Company Group held by any current or former employee, director, manager, consultant or director (or permitted transferees, assigns, estates, trusts or heirs of any of the foregoing) of such member of the Company Group pursuant to the terms of any employee equity subscription agreement, stock option agreement or similar agreement; provided that the aggregate price paid under this clause (k) in any Calendar Year, commencing with the Calendar Year ended December 31, 2023, will not exceed [***] Dollars (\$[***]) (with unused amounts in any such Calendar Year being referred to as “Unused Amounts”); provided, further, that such amount may be increased by an amount not to exceed:

(A) the net cash proceeds from the sale of Equity Interests (other than Disqualified Capital Stock) of the Company to any current or former employee, director, manager, consultant or director of any member of the Company Group that occurs after the date of this Agreement; and

(B) the cash proceeds of life insurance policies received by any member of the Company Group after the date of this Agreement; and

(C) the aggregate Unused Amounts for the prior two (2) year period which aggregate amount will be reduced to the extent used to repurchase, redeem or otherwise acquire or retire for value any Equity Interests pursuant to this clause (k).

(l) any member of the Company Group may make payments or distributions to dissenting stockholders pursuant to Applicable Law in connection with any merger, amalgamation or consolidation with, or other acquisition of, another Person;

(m) to the extent constituting Restricted Payments, may make payments of contingent liabilities in respect of any adjustment of purchase price, earn outs, deferred compensation and similar obligations of the Company Group may make any other Restricted Payments in an aggregate amount not to exceed [***] Dollars (\$[***]).

Notwithstanding the foregoing, and for the avoidance of doubt, conversion by holders of (including any cash payment upon conversion), or required payment of any principal or premium on, or required payment of any interest with respect to, any Permitted Convertible Notes, in each case, in accordance with the terms of the indenture governing such Permitted Convertible Notes, shall not constitute a Restricted Payment.

Notwithstanding the foregoing, the Company may repurchase, exchange or induce the conversion of Permitted Convertible Notes by delivery of shares of the Company's common stock and/or a different series of Permitted Convertible Note (any such series of Permitted Convertible Notes, "Refinancing Convertible Notes") and/or by payment of cash in an amount that does not exceed the proceeds received by the Company from the substantially concurrent issuance of shares of the Company's common stock and/or Refinancing Convertible Notes.

Section 7.8 Minimum Cash. During the Payment Term, permit aggregate cash and Cash Equivalents, in each case, of the Company or any Company Party held in Deposit Accounts and Securities Accounts, in each case, for which the Investor Representative shall have received an effective Deposit Account Control Agreement or Securities Account Control Agreement, as applicable (collectively, the "Minimum Cash Accounts" and each, a "Minimum Cash Account"), to be less than the following amounts in the aggregate: (a) during the Calendar Year beginning on January 1, 2024, [***] Dollars (\$[***]), and (b) for the remainder of the Payment Term after the Calendar Year ended December 31, 2024, [***] Dollars (\$[***]).

Section 7.9 Burdensome Actions.

(a) Each member of the Company Group shall not enter into any Contract, or grant any right to any other Person, in any case that would conflict with the Transaction Documents or serve or operate to limit or circumscribe any of the Investor's rights under the Transaction Documents (or the Investor's ability to exercise any such rights) or create, incur, assume or suffer to exist any Lien upon any property or assets of any member of the Company Group to secure the Obligations (other than Permitted Liens which relate solely to the property secured thereby), or agree to do or suffer to exist any of the foregoing. Without limiting the generality of the foregoing, the Company shall not enter into, or permit to exist, any Contractual Obligation that encumbers or restricts the ability of any Company Party (other than Permitted Liens) to (i) pledge its property

pursuant to the Transaction Documents or (ii) perform any of its obligations under the Transaction Documents or any Material Contract in any material respect. Notwithstanding anything to the contrary in this Agreement, the Company shall not take any action or abstain from taking any action, directly or indirectly, which action or abstinence would have the effect of altering the terms and conditions of this Agreement or the other Transaction Documents (or any ancillary documents thereto) in a manner that could reasonably be expected to result in a Material Adverse Effect.

(b) Each member of the Company Group shall not enter into any Contract, grant any right to any other Person with respect to the Existing Yutrepia Product or amend or waive any requirements under any agreement with respect to the Existing Yutrepia Product that would reasonably be expected to result in a Material Adverse Effect.

(c) Prior to the achievement of the Net Sales Threshold, each member of the Company Group shall not terminate or amend or waive any requirements under the Sandoz Agreement or the Sandoz Device Agreement without the consent of the Investor Representative (such consent not to be unreasonably withheld, conditioned or delayed).

Section 7.10 Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of a Company Party, except for (a) transactions that are in the ordinary course of such Company Party's business, upon fair and reasonable terms that are no less favorable to such Company Party than would be obtained in an arm's length transaction with a non-affiliated Person, (b) transactions of the type described in and permitted by Section 7.3 and Section 7.11 hereof, and (c) unsecured debt financings with the Company Party's existing investors, so long as all such Indebtedness is subordinated.

Section 7.11 Investments. Directly or indirectly make any Investment (including, without limitation, by the formation of any Subsidiary or in any Foreign Subsidiary) other than Permitted Investments or in connection with a Permitted Foreign Transaction.

Section 7.12 Bank Accounts. Not, and not permit any other Company Party, to maintain or establish any Deposit Accounts, Securities Accounts, or Commodities Accounts (other than (x) Excluded Accounts and (y) the Deposit Accounts, Securities Accounts, or Commodities Accounts set forth on Schedule 4.14(c) (which accounts constitute all of the Deposit Accounts, Securities Accounts, Commodities Accounts or other similar accounts maintained by the Company Parties as of the Closing Date), without prior written notice to Investor Representative and unless (other than with respect to Excluded Accounts) Investor Representative, the applicable Company Party and any other relevant Company Party (if applicable) and the bank, securities intermediary, commodities intermediary, broker, clearing corporation or other Person at which any Deposit Account, Securities Account or Commodities Account is to be opened enter into a Deposit Account Control Agreement, Securities Account Control Agreement and/or Commodities Account Control Agreement regarding such account. It is agreed and understood that the foregoing requirement to deliver a Deposit Account Control Agreement, Securities Account Control Agreement and/or Commodities Account Control Agreement shall not apply to Excluded Accounts. Notwithstanding anything to the contrary contained in Section 6.5 and this Section 7.12, it is hereby acknowledged and agreed by Investor Representative that the Company Parties shall have sixty (60) days (or such longer time period as agreed to by Investor Representative in its sole discretion) from the closing date of any Permitted

Acquisition to enter into a Deposit Account Control Agreement, Securities Account Control Agreement and/or Commodities Account Control Agreement with respect to any Deposit Account, Securities Account or Commodities Account (in each case, other than Excluded Accounts) of a target acquired, or otherwise established, by any member of the Company Party in connection with a Permitted Acquisition.

Section 7.13 Negative Pledge. Not, and not permit any other Company Party to enter into, any Contract restricting the creation of Liens on the property of any Company Party for the benefit of the Investor Representative to secure the Obligations, in each case other than in respect to Permitted Liens (and solely with respect to the property covered thereby).

ARTICLE VIII THE CLOSINGS

Section 8.1 Closing. Subject to the terms of this Agreement, the closings of the transactions contemplated hereby (each, a “Closing”) shall each take place on the corresponding date set forth below, or such other date as the Parties may mutually agree:

(a) for the initial Closing (the “Initial Closing”), subject to the satisfaction of the conditions set forth in Section 8.2, on the date that is fifteen (15) Business Days following the Effective Date (the “Initial Closing Date”) following the satisfaction of the conditions set forth in Section 8.6(a) and Section 8.6(b);

(b) for the second Closing (the “Second Closing”), subject to the satisfaction of the conditions set forth Section 8.3 and Investor Representative’s receipt of the Second Closing Notice on or prior to December 31, 2023, on the date that is fifteen (15) Business Days following the satisfaction of the conditions set forth in Section 8.3 and Section 8.6(c) (the “Second Closing Date”);

(c) for the third Closing (the “Third Closing”), subject to the satisfaction of the conditions set forth in Section 8.4 and Investor Representative’s receipt of the Third Closing Notice, on the date that is fifteen (15) Business Days following the satisfaction of the conditions set forth in and Section 8.4 and Section 8.6(d) (the “Third Closing Date”); and

(d) for the fourth Closing (the “Fourth Closing”), subject to the satisfaction of the conditions set forth in Section 8.5 and Investor Representative’s receipt of written notices from the Company and the Investor that Company has elected to receive, and Investor has elected to pay, the Fourth Investment Amount, on the date that is fifteen (15) Business Days following the satisfaction of the conditions set forth in Section 8.5 and Section 8.6(e) (the “Fourth Closing Date”), provided that the Fourth Closing Date must occur, if at all, no later than fifteen (15) Business Days before the Legal Maturity Date.

Section 8.2 Conditions to Initial Closing. The obligations of the Investor relating to the Initial Closing shall be conditional upon no Bankruptcy Event with respect to any member of the Company Group or no Special Termination Event, Change of Control, Default or Event of Default having occurred and be continuing (and the Investor Representative’s receipt of the certification from a Responsible Officer to that effect).

Section 8.3 Conditions to Second Closing. The obligations of the Investor relating to the Second Closing shall be conditional upon (a) no Bankruptcy Event with respect to any member of the Company Group or no Special Termination Event, Change of Control, Default or Event of Default having occurred and be continuing (and the Investor Representative's receipt of the certification from a Responsible Officer to that effect), and (b) Company providing written notice to Investor Representative of: (i) its election to receive the Second Investment Amount; and (ii) a written description of the Strategic Transaction for which such funds will be used (the "Second Closing Notice"). For clarity, the Investor shall have no obligation to pay the Second Investment Amount to Company (x) for any transaction other than a Strategic Transaction, or (y) if the Second Closing Notice is delivered to the Investor Representative after December 31, 2023.

Section 8.4 Conditions to Third Closing. The obligations of the Investor relating to the Third Closing shall be conditional upon: (a) no Bankruptcy Event with respect to any member of the Company Group or no Special Termination Event, Change of Control, Default or Event of Default having occurred and be continuing (and the Investor Representative's receipt of the certification from a Responsible Officer to that effect), and (b) the occurrence of one of the following: (i) the Favorable Determination; (ii) Investor's receipt of an insurance policy in a form and substance reasonably satisfactory to Investor Representative and the Company, whereby Investor would receive an amount equal to or greater than the Third Investment Amount if an Other Determination occurs ("Insurance Policy"); or (iii) the mutual written agreement of the Parties that Company has elected to receive, and the Investor has elected to pay, the Third Investment Amount. The Company shall provide written notice to the Investor Representative within ten (10) Business Days after the occurrence of any event in clause (b) of this Section 8.4, together with documentation reasonably sufficient to evidence the occurrence of such event (the "Third Closing Notice"). At the option of the Investor Representative, the Investor Representative may use a portion of the proceeds of the Third Closing to fund the payment of the premium of the Insurance Policy and, in such case, the proceeds of the Third Closing shall be funded net of such expense; provided, that (x) the Insurance Policy is the sole condition under clause (b) above which triggers the obligation of the Investor to pay the Third Investment Amount and (y) the Investor obtained the prior written consent of the Company to authorize the effectiveness of the Insurance Policy.

Section 8.5 Conditions to Fourth Closing. The obligations of the Investor relating to the Fourth Closing shall be subject to (a) the Company's election to receive, and the Investor's election to pay, the Fourth Investment Amount, and (b) no Bankruptcy Event with respect to any member of the Company Group or no Special Termination Event, Change of Control, Default or Event of Default having occurred and be continuing (and the Investor Representative's receipt of the certification from a Responsible Officer to that effect).

Section 8.6 Closing Deliverables of the Company.

(a) On Effective Date, the Company shall deliver or cause to be delivered to the Investor Representative the following:

(i) Transaction Documents. (A) Receipt by the Investor Representative of executed counterparts (including by electronic means) of this Agreement, executed by the

parties thereto (in a manner reasonably acceptable to the Investor Representative), in form and substance satisfactory to the Investor Representative and (B) the Investor Representative and the Company shall have agreed to the form of the Security Agreement and the Guaranty, including all schedules, annexes and exhibits thereto).

(ii) Organization Documents, Resolutions, Etc. Receipt by the Investor Representative of the following (to the extent not previously provided to the Investor Representative), each of which shall be originals or electronic copies, in form and substance reasonably satisfactory to the Investor Representative and its legal counsel:

(A) copies of the certificate of incorporation or organization, as applicable, of each Company Party certified to be true and complete as of a recent date by the appropriate Governmental Authority of the state or other jurisdiction of its incorporation or organization, where applicable, and the other Organization Documents, in each case certified by a secretary or assistant secretary (or, if such entity does not have a secretary or assistant secretary, a Responsible Officer with equivalent responsibilities) of such Company Party to be true and correct as of the Effective Date;

(B) such certificates of resolutions or other action, incumbency certificates and/or other certificates of Responsible Officers of each Company Party as the Investor Representative may reasonably require evidencing the identity, authority and capacity of each Responsible Officer thereof authorized to act as a Responsible Officer in connection with this Agreement and the other Transaction Documents to which such Company Party is a party; and

(C) such documents and certifications as the Investor Representative may reasonably require to evidence that each Company Party is duly organized or formed, and is validly existing, in good standing and qualified to engage in business in its state of organization or formation.

(iii) Form of Opinions of Counsel. Receipt by the Investor Representative of a form of written legal opinion of DLA Piper LLP (US), in form and substance reasonably acceptable to the Investor Representative.

(iv) Responsible Officer's Certificate. Receipt by the Investor Representative of a certificate of a Responsible Officer of each Company Party certifying that (i) the representations and warranties set forth in ARTICLE IV or any other Transaction Document (other than the Fundamental Representations) are true and correct in all material respects on and as of the Effective Date (or, if made as of a specific date, as of such date); provided, that to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Effective Date or such other date, as applicable, (ii) the Fundamental Representations are true and correct in all respects on and as of the Effective Date (or, if made as of a specific date, as of such date) and (iii) no Bankruptcy Event with respect to any member

of the Company Group and no Special Termination Event, Change of Control, Default or Event of Default has occurred and is continuing, in each case on the Effective Date.

(v) Other. Such other documents, instruments, reports, statements and information as may be reasonably requested by the Investor Representative.

(b) On the Initial Closing Date, the Company shall deliver or cause to be delivered to the Investor Representative the following:

(i) Transaction Documents. Receipt by the Investor Representative of executed counterparts (including by electronic means) of the Guaranty and the Security Agreement, executed by the parties thereto (in a manner reasonably acceptable to the Investor Representative), in each case in form and substance previously agreed between the Company and the Investor Representative prior to the Effective Date.

(ii) A certificate of a Responsible Officer of each Company Party (the statements made in which shall be true and correct on and as of the Initial Closing Date): (A) attaching copies, certified by such officer as true and complete, of (x) the Organization Documents of the Company Party and (y) confirming that resolutions of the governing body of the Company Party authorizing and approving the execution, delivery and performance by the Company Party of the Transaction Documents and the transactions contemplated herein and therein remain in full force and effect; and (B) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of the Company Party's jurisdiction of organization, stating that the Company Party is in good standing under the Applicable Laws of such jurisdiction.

(iii) A certificate of a Responsible Officer of each Company Party certifying that (a) the representations and warranties set forth in ARTICLE IV or any other Transaction Document (other than the Fundamental Representations) are true and correct in all material respects on and as of the Initial Closing Date (or, if made as of a specific date, as of such date); provided, that to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Initial Closing Date or such other date, as applicable, (b) that the Fundamental Representations are true and correct in all respects on and as of the Initial Closing Date (or, if made as of a specific date, as of such date), subject to any additions that the Company may make to the Disclosure Schedule with respect to Section 4.10 and Section 4.12 (provided that any such additions to Section 4.12 of the Disclosure must be reasonably satisfactory to the Investor Representative (and could not be reasonably expected to have a Material Adverse Effect)) as of the Initial Closing Date and (c) that each Company Party has complied in all material respects with its covenants, agreements and other obligations under this Agreement and the other Transaction Documents.

(iv) Opinions of Counsel. Receipt by the Investor Representative of a written legal opinion of DLA Piper LLP (US), addressed to the Investor Representative, dated as

of the Initial Closing Date and in form and substance previously agreed between the Company and the Investor Representative.

(v) Perfection and Priority of Liens. Receipt by the Investor Representative of the following:

(A) Certified copies, as of a recent date, of customary Lien searches in the jurisdictions where a filing would need to be made in order to perfect the Investor's security interest in the Collateral, copies of the financing statements on file in such jurisdictions (including UCC termination statements) and evidence showing that no Liens exist on the Collateral (other than such Liens that will be terminated or released prior to or simultaneously with the Initial Closing);

(B) UCC financing statements for each appropriate jurisdiction as is necessary, in the Investor's sole discretion, to perfect the Investor's security interest in the Collateral;

(C) all certificates evidencing any certificated Equity Interests pledged to the Investor (if any), together with duly executed in blank and undated stock powers attached thereto;

(D) a duly executed Perfection Certificate of each Company Party; and

(E) searches of ownership of, and Liens on, the Yutrepia Patent Rights of each Company Party in the appropriate U.S. governmental offices.

(vi) Attorney Costs; Due Diligence Expenses. The Company shall have paid all reasonable and documented fees, charges and disbursements of counsel to the Investor and all reasonable and documented due diligence expenses of the Investor, in each case, incurred prior to or at the Initial Closing Date; provided that the condition set forth in this clause (vi) will be satisfied by the transfer by the Investor of an amount equal to the Initial Investment Amount minus the amount owed by the Company under this clause (vi).

(vii) Payoff. The Payoff shall have been consummated, and the Investor Representative shall have received (A) a payoff letter with respect to the Payoff, duly executed by the Company Parties and Silicon Valley Bank, as lender and (B) confirmation that the UCC-3 termination statements for all UCC-1 financing statements have been filed by the collateral agent party thereto covering any portion of the Collateral, in each case in form and substance reasonably satisfactory to the Investor Representative and its legal counsel.

(viii) Other. Such other documents, instruments, reports, statements and information as may be reasonably requested by the Investor Representative.

(c) At the Second Closing (should the Second Closing occur), the Company shall deliver or cause to be delivered to the Investor Representative the following:

(i) A certificate of a Responsible Officer of each Company Party (the statements made in which shall be true and correct on and as of the Second Closing Date): (A) attaching copies, certified by such officer as true and complete, of (x) the Organization Documents of the Company Party and (y) confirming that resolutions of the governing body of the Company Party authorizing and approving the execution, delivery and performance by the Company Party of the Transaction Documents and the transactions contemplated herein and therein remain in full force and effect; and (B) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of the Company Party's jurisdiction of organization, stating that the Company Party is in good standing under the Applicable Laws of such jurisdiction;

(ii) A certificate of a Responsible Officer of the Company (A) certifying that, (1) the information and documents provided to the Investor Representative with the Second Closing Notice are true and correct and (2) as applicable, (x) the Favorable Determination has occurred, (y) the Insurance Policy is in effect, or (z) the Parties have mutually agreed to the Third Investment Amount; (B) attaching copies, certified by such officer as true and complete, of documents sufficient to evidence that the event indicated with respect to clause (A) has occurred; and (B) no Bankruptcy Event with respect to any member of the Company Group and no Special Termination Event, Change of Control, Default or Event of Default has occurred and is continuing; and

(iii) A certificate of a Responsible Officer of each Company Party certifying that (a) the representations and warranties set forth in ARTICLE IV or any other Transaction Document (other than the Fundamental Representations) are true and correct in all material respects on and as of the Second Closing Date (or, if made as of a specific date, as of such date); provided, that to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Second Closing Date or such other date, as applicable, (b) that the Fundamental Representations are true and correct in all respects on and as of the Second Closing Date (or, if made as of a specific date, as of such date), subject to any additions that the Company may make to the Disclosure Schedule with respect to Section 4.10 and Section 4.12 (provided that any such additions to Section 4.12 of the Disclosure must be reasonably satisfactory to the Investor Representative (it being acknowledged that any addition that would not be reasonably expected to have a Material Adverse Effect shall be conclusively deemed satisfactory)) as of the Second Closing Date and (c) that each Company Party has complied in all material respects with its covenants, agreements and other obligations under this Agreement and the other Transaction Documents.

(d) At the Third Closing (should the Third Closing occur), the Company shall deliver or cause to be delivered the following:

(i) A certificate of a Responsible Officer of each Company Party (the statements made in which shall be true and correct on and as of the Third Closing Date): (A) attaching copies, certified by such officer as true and complete, of (x) the Organization

Documents of the Company Party and (y) confirming that resolutions of the governing body of the Company Party authorizing and approving the execution, delivery and performance by the Company Party of the Transaction Documents and the transactions contemplated herein and therein remain in full force and effect; and (B) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of the Company Party's jurisdiction of organization, stating that the Company Party is in good standing under the Applicable Laws of such jurisdiction;

(ii) A certificate of a Responsible Officer of each member of the Company Group (A) certifying that, (1) the information and documents provided to the Investor Representative with the Third Closing Notice are true and correct; and (B) certifying that no Bankruptcy Event with respect of its Subsidiaries and no Special Termination Event, Change of Control, Default or Event of Default has occurred and is continuing;

(iii) A certificate of a Responsible Officer of each Company Party certifying that (A) the representations and warranties set forth in ARTICLE IV (other than the Fundamental Representations) are true and correct in all material respects on and as of the Third Closing Date (or, if made as of a specific date, as of such date); provided, that to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Third Closing Date or such other date, as applicable, (B) that the Fundamental Representations are true and correct in all respects on and as of the Third Closing Date (or, if made as of a specific date, as of such date), subject to any additions that the Company may make to the Disclosure Schedule with respect to Section 4.10 and Section 4.12 (provided that any such additions to Section 4.12 must be reasonably satisfactory to the Investor Representative (it being acknowledged that any addition that would not be reasonably expected to have a Material Adverse Effect shall be conclusively deemed satisfactory)) as of the Third Closing Date and (C) that the Company Party has complied in all material respects with its covenants, agreements and other obligations under this Agreement and the other Transaction Documents;

(iv) To the extent the Insurance Policy is to be issued as a condition to the Third Investment Amount, delivery of written instructions of the Company to authorize the effectiveness of the Insurance Policy; and

(v) Such other documents, instruments, reports, statements and information as may be reasonably requested by the Investor Representative.

(e) At the Fourth Closing (should the Fourth Closing occur), the Company shall deliver or cause to be delivered to the Investor Representative the following:

(i) A certificate of a Responsible Officer of each Company Party (the statements made in which shall be true and correct on and as of the Fourth Closing Date): (A) attaching copies, certified by such officer as true and complete, of (x) the organizational

documents of the Company Party and (y) confirming that resolutions of the governing body of the Company Party authorizing and approving the execution, delivery and performance by the Company Party of the Transaction Documents and the transactions contemplated herein and therein remain in full force and effect; and (B) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of the Company Party's jurisdiction of organization, stating that the Company Party is in good standing under the Applicable Laws of such jurisdiction.

(ii) A certificate of a Responsible Officer of the Company Party certifying that (a) the representations and warranties set forth in ARTICLE IV (other than the Fundamental Representations) are true and correct in all material respects on and as of the Fourth Closing Date (or, if made as of a specific date, as of such date); provided, that to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Fourth Closing Date or such other date, as applicable, (b) that the Fundamental Representations are true and correct in all respects on and as of the Fourth Closing Date (or, if made as of a specific date, as of such date), subject to any additions that the Company Party may make to the Disclosure Schedule with respect to Section 4.10 and Section 4.12 (provided that any such additions to Section 4.12 must be reasonably satisfactory to the Investor Representative (it being acknowledged that any addition that would not be reasonably expected to have a Material Adverse Effect shall be conclusively deemed satisfactory)) as of the Fourth Closing Date and (c) that the Company Party has complied in all material respects with its covenants, agreements and other obligations under this Agreement and the other Transaction Documents.

ARTICLE IX CONFIDENTIALITY

Section 9.1 Confidentiality; Permitted Use. During the Payment Term and for a period of five (5) years thereafter, each Party shall maintain in strict confidence all Confidential Information and materials disclosed or provided to it by the other Party, except as approved in writing in advance by the disclosing Party, and shall not use or reproduce the disclosing Party's Confidential Information for any purpose other than as required to carry out its obligations and exercise its rights pursuant to this Agreement (the "Purpose"). The Party receiving such Confidential Information (the "Recipient") agrees to institute measures to protect the Confidential Information in a manner consistent with the measures it uses to protect its own most sensitive proprietary and confidential information, which must not be less than a reasonable standard of care. Notwithstanding the foregoing, the Recipient may permit access to the disclosing Party's Confidential Information to those of its employees or authorized representatives having a need to know such information for the Purpose and who have signed confidentiality agreements or are otherwise bound by confidentiality obligations at least as restrictive as those contained herein. Each Party shall be responsible for the breach of this Agreement by its employees or authorized representatives. Each Party shall immediately notify the other Party upon discovery of any loss or unauthorized disclosure of the other Party's Confidential Information.

Section 9.2 Exceptions. The obligations of confidentiality and non-use set forth in Section 9.1 shall not apply to any portion of Confidential Information that the Recipient or its Affiliates can demonstrate was: (a) known to the general public at the time of its disclosure to the Recipient or its Affiliates, or thereafter became generally known to the general public, other than as a result of actions or omissions of the Recipient, its Affiliates, or anyone to whom the Recipient or its Affiliates disclosed such portion; (b) known by the Recipient or its Affiliates, prior to the date of disclosure by the disclosing Party; (c) disclosed to the Recipient or its Affiliates on an unrestricted basis from a source unrelated to the disclosing Party and not known by the Recipient or its Affiliates to be under a duty of confidentiality to the disclosing Party; or (d) independently developed by the Recipient or its Affiliates by personnel that did not use or make reference to the Confidential Information of the disclosing Party in connection with such development.

Section 9.3 Permitted Disclosures. The obligations of confidentiality and non-use set forth in Section 9.1 shall not apply to the extent that the receiving Party or its Affiliates:

(a) Subject to Section 6.4, is required to disclose Confidential Information pursuant to: (i) an order of a court of competent jurisdiction; (ii) Applicable Laws (including disclosure requirements of the SEC, Nasdaq, or any other stock exchange on which securities issued by a Party or its Affiliates are traded); (iii) regulations or rules of a securities exchange; (iv) requirement of a Governmental Authority for purposes related to development or Commercialization of an Included Product, or (v) the exercise by each Party of its rights granted to it under this Agreement or its retained rights or as required to perfect Investor's rights under the Transaction Documents;

(b) discloses such Confidential Information solely on a "need to know basis" to Affiliates, potential or actual acquirers, merger partners, licensees, permitted assignees, collaborators (including Licensees), subcontractors, investment bankers, limited partners, lenders, or other financial partners, and their respective directors, employees, contractors and agents; provided, that, the Investor and its Affiliates shall not disclose Confidential Information to any Competitive Party;

(c) provides a copy of this Agreement or any of the other Transaction Documents to the extent requested by an authorized representative of a U.S. or foreign Tax authority; or

(d) discloses Confidential Information in response to a routine audit or examination by, or a blanket document request from, a Governmental Authority;

provided that (A) such Third Party or Person or entity in clause (b) agrees to confidentiality and non-use obligations with respect thereto at least as stringent as those specified for in this ARTICLE IX; and (B) in the case of clauses (a)(i) through (iv) and clause (c), to the extent permitted by Applicable Law, the Recipient shall provide prior written notice thereof to the disclosing Party and provide the opportunity for the disclosing Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefor; and provided, further that the Recipient will use reasonable efforts to secure confidential treatment of such information and the Confidential Information disclosed shall be limited to that information which is legally required to be disclosed.

Notwithstanding anything set forth in this Agreement, prior to any foreclosure on the Collateral, the Investor and the Investor Representative shall not file any patent application based upon or using the Confidential Information of the Company provided hereunder.

Section 9.4 Return of Confidential Information. Each Party shall return or destroy, at the other Party's instruction, all Confidential Information of the other Party in its possession upon termination or expiration of this Agreement; provided, however, that each Party shall be entitled to retain one (1) copy of such Confidential Information of the other Party for legal archival purposes and/or as may be required by Applicable Law and neither Party shall be required to return, delete or destroy Confidential Information or any electronic files or any information prepared by such Party that have been backed-up or archived in the ordinary course of business consistent with past practice. Any Confidential Information that is retained pursuant to this Section 9.4 shall remain subject to the terms of this ARTICLE IX Confidential Information is retained notwithstanding the earlier termination or expiration of this Agreement or the period referenced in Section 9.1.

ARTICLE X INDEMNIFICATION

Section 10.1 Indemnification by the Company. The Company agrees to indemnify and hold each of the Investor and their respective Affiliates and any and all of their respective partners, directors, managers, members, officers, employees, agents and controlling Persons (each, a "Investor Indemnified Party") harmless from and against, and will pay to each Investor Indemnified Party the amount of, any and all Losses awarded against or incurred or suffered by such Investor Indemnified Party arising out of (a) any breach of any representation, warranty or certification made by the Company in any of the Transaction Documents or certificates given by the Company to the Investor Representative in writing pursuant to this Agreement or any other Transaction Document, (b) any breach of or default under any covenant or agreement by the Company to the Investor Representative pursuant to any Transaction Document, (c) any Excluded Liabilities and Obligations and (d) any fees, expenses, costs, liabilities or other amounts incurred or owed by the Company to any brokers, financial advisors or comparable other Persons retained or employed by it in connection with the transactions contemplated by this Agreement (collectively, the "Company Indemnification Obligations"); provided, however, that the foregoing shall exclude any indemnification to any Investor Indemnified Party (i) that results from the fraud, gross negligence, bad faith or willful misconduct of such Investor Indemnified Party, (ii) to the extent resulting from acts or omissions of the Company based upon the written instructions from any Investor Indemnified Party or (iii) for any matter to the extent of, and in respect of, which any Company Indemnified Party would be entitled to indemnification under Section 10.2.

Section 10.2 Indemnification by the Investor. The Investor jointly and severally agree to indemnify and hold each of the Company, its Affiliates and any and all of their respective partners, directors, managers, members, officers, employees, agents and controlling Persons (each, a "Company Indemnified Party") harmless from and against, and will pay to each Company Indemnified Party the amount of, any and all Losses awarded against or incurred or suffered by such Company Indemnified Party arising out of (a) any breach of any representation, warranty or certification made by the Investor in any of the Transaction Documents or certificates given by

the Investor in writing pursuant hereto or thereto, (b) any breach of or default under any covenant or agreement by the Investor pursuant to any Transaction Document, and (c) any fees, expenses, costs, liabilities or other amounts incurred or owed by the Investor to any brokers, financial advisors or comparable other Persons retained or employed by it in connection with the transactions contemplated by this Agreement (collectively, the “Investor Indemnification Obligations”); provided, however, that the foregoing shall exclude any indemnification to any Company Indemnified Party (i) that results from the fraud, gross negligence, bad faith or willful misconduct of such Company Indemnified Party, (ii) to the extent resulting from acts or omissions of the Investor based upon the written instructions from any Company Indemnified Party or (iii) for any matter to the extent of, and in respect of, which any Investor Indemnified Party would be entitled to indemnification under Section 10.1.

Section 10.3 Procedures. If any Third Party Claim shall be brought or alleged against an indemnified party in respect of which indemnity is to be sought against an indemnifying party pursuant to Section 10.1 or Section 10.2, the indemnified party shall, promptly after receipt of notice of the commencement of any such Third Party Claim, notify the indemnifying party in writing of the commencement thereof, enclosing a copy of all papers served, if any; provided, that the omission to so notify such indemnifying party promptly will not relieve the indemnifying party from any liability that it may have to any indemnified party under Section 10.1 or Section 10.2 unless, and only to the extent that, the indemnifying party is actually prejudiced by such omission. In the event that any Third Party Claim is brought against an indemnified party and it notifies the indemnifying party of the commencement thereof in accordance with this Section 10.3, the indemnifying party will be entitled, at the indemnifying party’s sole cost and expense, to participate therein. In any such Third Party Claim, 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 sole cost and expense of such indemnified party unless (a) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel, (b) the indemnifying party has failed within a reasonable time to retain counsel reasonably satisfactory to such indemnified party or (c) the named parties to any such Third Party Claim (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 counsel to the indemnifying party. It is agreed that the indemnifying party shall not, in connection with any Third Party Claim or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate law firm (in addition to local counsel where necessary) for all such indemnified parties. The indemnifying party shall not be liable for any settlement of any Third Party Claim effected without its written consent, but, if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any Loss by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or discharge of any pending or threatened Third Party Claim in respect of which any indemnified party is or would have been a party and indemnity would have been sought hereunder by such indemnified party, unless such settlement, compromise or discharge, as the case may be, (i) includes an unconditional written release of such indemnified party, in form and substance reasonably satisfactory to the indemnified party, from all liability on claims that are the subject matter of such claim or proceeding, (ii) does not include any statement as to an admission of fault,

culpability or failure to act by or on behalf of any indemnified party and (iii) does not impose any continuing material obligation or restrictions on such indemnified party.

Section 10.4 Other Claims. A claim by an indemnified party under this ARTICLE X for any matter not involving a Third Party Claim and in respect of which such indemnified party seeks indemnification hereunder may be made by delivering, in good faith, a written notice of demand to the indemnifying party, which notice shall contain (a) a description and the amount of any Losses incurred or suffered by the indemnified party (and the method of computation of such Losses), (b) a statement that the indemnified party is entitled to indemnification under this ARTICLE X for such Losses and a reasonable explanation of the basis therefor, and (c) a demand for payment in the amount of such Losses. For all purposes of this Section 10.4, the Company shall be entitled to deliver such notice of demand to the Investor Representative on behalf of the Company Indemnified Parties, and the Investor Representative shall be entitled to deliver such notice of demand to the Company on behalf of the Investor Indemnified Parties. Within thirty (30) days after receipt by the indemnifying party of any such notice, the indemnifying party may deliver to the indemnified party that delivered the notice a written response in which the indemnifying party (a) agrees that the indemnified party is entitled to the full amount of the Losses claimed in the notice from the indemnified party; (b) agrees that the indemnified party is entitled to part, but not all, of the amount of the Losses claimed in the notice from the indemnified party; or (c) indicates that the indemnifying party disputes the entire amount of the Losses claimed in the notice from the indemnified party. If the indemnified party does not receive such a response from the indemnifying party within such thirty (30)-day period, then the indemnifying party shall be conclusively deemed to have agreed that the indemnified party is entitled to the full amount. If the indemnifying party and the indemnified party are unable to resolve any Dispute relating to any amount of the Losses claimed in the notice from the indemnified party within thirty (30) days after the delivery of the response to such notice from the indemnifying party, then the parties shall be entitled to resort to any legal remedy available to such party to resolve such Dispute that is provided for in this Agreement, subject to all the terms, conditions and limitations of this Agreement.

Section 10.5 Exclusive Remedies. The indemnification afforded by this ARTICLE X shall be the sole and exclusive remedy for any and all Losses awarded against or incurred or suffered by the Investor Indemnified Parties against the Company in connection with the Company Indemnification Obligations and the Company Indemnified Parties against the Investor in connection with the Investor Indemnification Obligations under Section 10.1 or Section 10.2, as applicable, in each case other than any Company Indemnification Obligations or Investor Indemnification Obligations, as applicable, resulting from (a) the fraud, bad faith or willful misconduct of the other Party or (b) acts or omissions based upon the written instructions from the other Party; provided that nothing in this Section 10.5 shall alter or affect the rights of the either Party to specific performance by the other Party under the Transaction Documents or the rights of the Investor to exercise remedies under the Transaction Documents after an Event of Default or other rights of creditors under the UCC or any other Applicable Law.

Section 10.6 Certain Limitations. The indemnification afforded by this ARTICLE X shall be subject to the following limitations:

(a) With respect to indemnification by the Company pursuant to Section 10.1(a), the Company's maximum liability for any Loss suffered by an Investor Indemnified Party (other than any Loss resulting from a Third Party Claim) shall not exceed an amount (the "Company Indemnification Cap") equal to:

(i) the Hard Cap plus the IRR True-Up Payment Amount, if any, and the amount of all of the other Obligations owed by the Company Parties to the Investor under this Agreement and the other Transaction Documents (other than the indemnification amounts payable under Section 10.1(a)) as of the date of determination, *minus*

(ii) the aggregate amount of all of the payments (including any amounts received by the Investor pursuant to the Insurance Policy, if any) collected or received by the Investor Representative (and any direct or indirect transferee of the Investor Representative to whom any interest in the Revenue Interests is transferred) hereunder as of such date of determination (other than (A) any payments collected or received as a reimbursement of expenses incurred by any Investor Indemnified Party (including attorney's fees) and (B) any indemnification payments collected or received pursuant to Section 10.1(a)), *minus*

(iii) the aggregate amount collected or received by the Investor Representative (and any direct or indirect transferee of the Investor Representative to whom any interest in the Revenue Interests is transferred) pursuant to the exercise of its rights under Section 10.1(a) (without duplication of any amounts collected or received pursuant to clause (ii)) prior to such date of determination to the extent such amount was not collected or received in connection with a Third Party Claim.

Notwithstanding the foregoing, the Company Indemnification Cap shall not apply to any Loss suffered by any Investor Indemnified Party in connection with a Third Party Claim.

(b) With respect to indemnification by the Investor pursuant to Section 10.2, the Investor's maximum liability shall not exceed an amount equal to the excess (if any) of (a) the aggregate amount of all of the payments collected or received by the Investor from the Company prior to the date of determination (excluding any amounts collected or received as a reimbursement of expenses incurred by the Investor or any indemnification amounts collected or received in connection with a Third Party Claim) over (b) the Investment Amount.

ARTICLE XI EVENTS OF DEFAULT AND REMEDIES

Section 11.1 Events of Default. Any of the events set forth below shall constitute an Event of Default.

(a) Non-Payment. The Company or any Guarantor (if any) fails to pay any amounts to the Investor Representative when and as required to be paid herein, including, without limitation, the Company's failure to (i) pay the Quarterly Fixed Payments, the Under Performance Payment, the Generic Product Payment, the One-Time Fixed Payment or the Included Product Payment Amount on any Quarterly Payment Date and such failure continues for more than five

Business Days (unless such failure was as a result of accounting errors made by the Company in good faith without gross negligence in calculating the Quarterly Net Revenues and the Included Product Payment Amount for such Quarterly Payment Date) or pay any late or unpaid Quarterly Fixed Payments, Under Performance Payment, Generic Product Payment, One-Time Fixed Payment or any Included Product Payment Amount and any interest accrued thereto and reimburse the Investor Representative for audit expenses pursuant to Section 3.5(b), (ii) pay the Change of Control Payment pursuant to Section 3.1(c); (iii) pay the Special Termination Amount pursuant to Section 3.1(d); or (iv) pay any other amounts due under any Transaction Document (not contested by the Company in good faith), including the Special Maturity Payment Amount on the Legal Maturity Date and any required IRR True-Up Payment Amount, in each case to the extent due under any Transaction Document, in each case, within ten (10) Business Days of the date upon which the Company is notified in writing by the Investor Representative that such amounts are due and payable hereunder; or

(b) Specific Covenants. Any Company Party, or any Subsidiary thereof, fails to perform or observe any term, covenant or agreement contained in Section 6.6 (Included Product Patent Rights), Section 6.7 (Existence), Section 6.8 (Commercialization of Included Products), Section 6.9 (Financial Statements), Section 6.19 (Anti-Corruption Laws; Anti-Terrorism Laws) and ARTICLE VII (Negative Covenants) provided that in the case of any such Default is susceptible to cure and can be cured within ten (10) Business Days after the earlier of the date on which (i) a Responsible Officer of any Company Party has actual knowledge of such failure or (ii) written notice thereof shall have been given to the Company by the Investor Representative, the Company shall have such ten Business Day period to cure such Default; or

(c) Other Defaults. Any Company Party fails to perform or observe any other covenant or agreement (not specified in Section 11.1(a) and Section 11.1(b)) and contained in any Transaction Document on its part to be performed or observed, and

(i) such failure continues for thirty (30) days after the earlier of the date on which (a) a Responsible Officer of any Company Party has actual knowledge of such Default or (b) written notice thereof shall have been given to the Company by the Investor Representative; and

(ii) such failure (without giving effect to any qualifications as to “materiality” “Material Adverse Effect” or any words of similar meaning) would reasonably be expected to have a Material Adverse Effect.

(d) Insolvency Proceedings, Etc. Any member of the Company Group institutes or consents to the institution of any proceeding under any Debtor Relief Law, or makes an assignment for the benefit of creditors; or applies for or consents to the appointment of any receiver, trustee, custodian, conservator, liquidator, rehabilitator or similar officer for it or for all or any material part of its property; or any receiver, trustee, custodian, conservator, liquidator, rehabilitator or similar officer is appointed without the application or consent of such Person and the appointment continues undischarged or unstayed for sixty (60) days; or any proceeding under any Debtor Relief Law relating to any such Person or to all or any material part of its property is instituted without the consent of such Person and continues undischarged or unstayed for sixty (60) days, or an order for relief is entered in any such proceeding; or

(e) Inability to Pay Debts; Attachment. (i) Any member of the Company Group becomes unable or admits in writing its inability or fails generally to pay its debts as they become due, or (ii) any writ or warrant of attachment or execution or similar process is issued or levied against all or any material part of the property of any such Person and is not released, vacated or fully bonded within thirty (30) days after its issue or levy; or

(f) Judgments. There is entered against any member of the Company Group one or more final judgments or orders for the payment of money in an aggregate amount exceeding [***] Dollars (\$[***) (to the extent not covered by independent third-party insurance as to which the insurer does not dispute coverage) or any one or more non-monetary final judgments that could reasonably be expected to result in a Material Adverse Effect and (i) enforcement proceedings are commenced by any creditor upon such judgment or order or (ii) there is a period of ninety (90) consecutive days during which a stay of enforcement of such judgment, by reason of a pending appeal or otherwise, is not in effect; or

(g) Indebtedness. Any Company Party or any Subsidiary thereto (i) fails to pay when due beyond any grace period provided with respect thereto (whether by scheduled maturity, required prepayment, acceleration, demand or otherwise) any Indebtedness (other than the Obligations hereunder) in excess of [***] Dollars (\$[***) (or its foreign currency equivalent) or (ii) fails to perform or observe any covenant or agreement to be performed or observed by it contained in agreement or in any instrument evidencing any of its Indebtedness (other than Obligations hereunder) of [***] Dollars (\$[***) or more and, as a result of such failure, any other party to that agreement or instrument is entitled to exercise the right to accelerate the maturity of any Indebtedness thereunder; or

(h) ERISA. (i) An ERISA Event occurs with respect to a Pension Plan or Multiemployer Plan which has resulted or would result in liability of any Company Party or any Subsidiary under Title IV of ERISA to the Pension Plan, Multiemployer Plan or the PBGC in an aggregate amount in excess of [***] Dollars (\$[***)], or (ii) the Company or any ERISA Affiliate fails to pay when due, after the expiration of any applicable grace period, any installment payment with respect to its withdrawal liability under Section 4201 of ERISA under a Multiemployer Plan that has resulted or would result in liability of any Company Party in an aggregate amount in excess of [***] Dollars (\$[***)]; or

(i) Invalidity of Transaction Documents. Any Transaction Document, at any time after its execution and delivery and for any reason other than as expressly permitted hereunder or thereunder or satisfaction in full of all Obligations, ceases to be in full force and effect; or any Company Party or any other Person contests in any manner the validity or enforceability of any Transaction Document; or any Company Party denies that it has any or further liability or obligation under any Transaction Document, or purports to revoke, terminate or rescind any Transaction Document; or

(j) Security Interest. Any security interest in portion of the Collateral with a fair market value in excess of [***] Dollars (\$[***) purported to be created by the Security Agreement shall cease to be in full force and effect, or shall cease to give the rights, powers and privileges purported to be created and granted hereunder or thereunder (including a perfected first priority security interest in and Lien on substantially all of the Collateral (except as otherwise

expressly provided herein and therein)) in favor of the Investor pursuant hereto or thereto (other than as a result of the failure by any Investor to take any action required to maintain the perfection of such security interests), or shall be asserted by any member of the Company Group not to be a valid, perfected, first priority (except as otherwise expressly provided in this Agreement or such Transaction Document) security interest in the Collateral.

Section 11.2 Remedies Upon Event of Default. If any Event of Default occurs and is continuing, the Company shall promptly following written notice from the Investor Representative pay the Event of Default Payment to the Investor Representative. In addition, the Investor Representative may exercise on behalf of itself and the Investor all rights and remedies available to it and the Investor under the Transaction Documents and Applicable Law; provided, however, that upon the occurrence of an actual or deemed entry of an order for relief with respect to the Company under the Bankruptcy Code of the United States or under any other Debtor Relief Law, the obligation of each of the Investor to pay or advance any funds shall automatically terminate, and the Event of Default Payment shall automatically become due and payable, in each case without further act of the Investor.

ARTICLE XII MISCELLANEOUS

Section 12.1 Survival. All representations, warranties and covenants made herein and in any other Transaction Document or any certificate delivered pursuant to this Agreement shall survive the execution and delivery of this Agreement and the Closing. The rights hereunder to indemnification and payment of Losses under ARTICLE X or to seek specific performance under Section 12.2 based on such representations, warranties and covenants shall not be affected by any investigation conducted with respect to, or any knowledge acquired (or capable of being acquired) at any time (whether before or after the execution and delivery of this Agreement or the Closing) in respect of the accuracy or inaccuracy of or compliance with, any such representation, warranty or covenant.

Section 12.2 Specific Performance. Each of the Parties hereto acknowledges that the other Party hereto may not have adequate remedy at law if the other Party fails to perform any of its obligations under any of the Transaction Documents. In such event, each of the Parties hereto agrees that the other Party hereto shall have the right, in addition to any other rights it may have (whether at law or in equity), to seek specific performance of this Agreement without the necessity of posting a bond or proving the inadequacy of monetary damages as a remedy and to seek injunctive relief against any breach or threatened breach of the Transaction Documents. The Parties further agree not to assert that a remedy of specific performance is unenforceable, invalid, contrary to Applicable Law or inequitable for any reason.

Section 12.3 Notices. All notices, consents, waivers and other communications hereunder shall be in writing and shall be effective (a) upon receipt when sent through the mails, registered or certified mail, return receipt requested, postage prepaid, with such receipt to be effective the date of delivery indicated on the return receipt, (b) upon receipt when sent by an overnight courier (costs prepaid and receipt requested), (c) on the date personally delivered to an authorized officer of the party to which sent or (d) on the date transmitted by electronic

transmission with a confirmation of receipt, in all cases, with a copy emailed to the recipient at the applicable address, addressed to the recipient as follows:

if to the Company, to:

Liquidia Technologies, Inc.
419 Davis Drive, Suite 100
Morrisville, North Carolina
Attention: General Counsel
Email: legal@liquidia.com

with a copy to (which shall not constitute notice):

DLA Piper LLP (US)
51 John F. Kennedy Parkway, Suite 120
Short Hills, New Jersey 07078
Attention: Andrew P. Gilbert, Esq. and Lauren Murdza, Esq.
Email: andrew.gilbert@us.dlapiper.com and lauren.murdza@us.dlapiper.com

if to the Investor, to:

HealthCare Royalty Management, LLC
300 Atlantic Street, Suite 600
Stamford, CT 06901
Attention: Anthony Rapsomanikis, Managing Director
Email: Anthony.Rapsomanikis@hcrx.com

with a copy (which shall not constitute notice) to:

HealthCare Royalty Management, LLC
300 Atlantic Street, Suite 600
Stamford, CT 06901
Attention: Tim Bryant, General Counsel
Email: Tim.Bryant@hcrx.com

with a copy (which shall not constitute notice) to:

Sidley Austin LLP
2850 Quarry Lake Drive, Suite 280
Baltimore, MD 21209
Attn: Asher Rubin, Adriana Tibbitts and Angela Fontana
E-mail: arubin@sidley.com, atibbitts@sidley.com and angela.fontana@sidley.com

Each Party hereto may, by notice given in accordance herewith to the other Party hereto, designate any further or different address to which subsequent notices, consents, waivers and other communications shall be sent.

Section 12.4 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 permitted assigns. The Company shall not be entitled to assign any of its obligations and rights under this Agreement without the prior written consent of the Investor Representative. The Investor may assign any of its obligations (other than those arising under Section 2.1, unless the assignee is an Affiliate of the Investor and has provided the Company with the representations and warranties set forth in ARTICLE V) and rights hereunder to any Person without the consent of the Company; provided that, the Investor may not assign any of its rights and obligations hereunder to any Person that is a Competitive Party. The Investor Representative shall give notice of any such assignment by the Investor to the Company promptly after the occurrence thereof. The Company shall maintain a “register” for the recordation of the names and addresses of, and the amounts owing to, each Investor from time to time. Notwithstanding anything to the contrary contained in this Agreement, no assignment of any interest of any Investor shall be effective until such assignment is recorded in the register and, consistent with the foregoing, the Company shall treat any Investor recorded in the register as an Investor under this Agreement, notwithstanding notice to the contrary. The Company shall be under no obligation to reaffirm any representations, warranties or covenants made in this Agreement or any of the other Transaction Documents in connection with any such assignment. Any purported assignment of rights or obligations in violation of this Section 12.4 will be void.

Section 12.5 Independent Nature of Relationship. The relationship between the Company and the Investor is solely that of lender and borrower, and neither the Company nor any of the Investor has any fiduciary or other special relationship with the any of the Investor and its Affiliates on the one hand, or the Company and its Affiliates on the other hand. Nothing contained herein or in any other Transaction Document shall be deemed to constitute the Company and the Investor as a partnership, an association, a joint venture or any other kind of entity or legal form. The Parties agree that they shall not take any inconsistent position with respect to such treatment in a filing with any Governmental Authority.

Section 12.6 Entire Agreement. This Agreement, together with the Exhibits hereto (which are incorporated herein by reference) and the other Transaction Documents, constitute the entire agreement between the Parties hereto with respect to the subject matter hereof and supersede all prior agreements, understandings and negotiations, both written and oral, between the Parties hereto 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 hereto or the other Transaction Documents) has been made or relied upon by either Party hereto.

Section 12.7 Governing Law.

(a) THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL SUBSTANTIVE LAWS OF THE STATE OF NEW YORK WITHOUT REFERENCE TO THE RULES THEREOF RELATING TO CONFLICTS OF LAW OR CHOICE OF FORUM OTHER THAN SECTIONS 5-1401 AND 5-1402 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK, AND THE OBLIGATIONS, RIGHTS AND REMEDIES OF THE PARTIES HEREUNDER SHALL BE DETERMINED IN ACCORDANCE WITH SUCH LAWS.

(b) Each of the Parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the exclusive jurisdiction of the Supreme Court of the State of New York sitting in New York County and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Agreement, or for recognition or enforcement of any judgment, and each of the Parties hereto hereby irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such New York State court or, to the extent permitted by Applicable Law, in such federal court. Each of the Parties hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Applicable Law.

(c) Each of the Parties hereto hereby irrevocably and unconditionally waives, to the fullest extent it may legally and effectively do so, any objection that it may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Agreement in any court referred to in Section 12.7(b). Each of the Parties hereto hereby irrevocably waives, to the fullest extent permitted by Applicable Law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court.

(d) Each of the Parties hereto irrevocably consents to service of process in the manner provided for notices in Section 12.3. Nothing in this Agreement will affect the right of any Party hereto to serve process in any other manner permitted by Applicable Law. Each of the Parties hereto waives personal service of any summons, complaint or other process, which may be made by any other means permitted by New York laws.

Section 12.8 Waiver of Jury Trial. EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER PARTY HERETO HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE OTHER PARTY HERETO WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS Section 12.8.

Section 12.9 Severability. If one or more provisions of this Agreement are held to be invalid, illegal or unenforceable by a court of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, which shall remain in full force and effect, and the Parties hereto shall replace such invalid, illegal or unenforceable provision with a new provision permitted by Applicable Law and having an economic effect as close as possible to the invalid, illegal or unenforceable provision. Any provision of this Agreement held invalid, illegal or unenforceable only in part or degree by a court of competent jurisdiction shall remain in full force and effect to the extent not held invalid, illegal or unenforceable.

Section 12.10 Counterparts. This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement shall become effective when each Party hereto shall have received a counterpart hereof signed by the other Party hereto. Any counterpart may be executed by electronic transmission, and such electronic transmission shall be deemed an original.

Section 12.11 Amendments; No Waivers. Neither this Agreement nor any term or provision hereof may be amended, restated, amended and restated, supplemented, waived, changed or modified or terminated except with the written consent of the Company and the Investor Representative. No failure or delay by either Party hereto 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. No notice to or demand on either Party hereto in any case shall entitle it to any notice or demand in similar or other circumstances. No waiver or approval hereunder shall, except as may otherwise be stated in such waiver or approval, be applicable to subsequent transactions. No waiver or approval hereunder shall require any similar or dissimilar waiver or approval thereafter to be granted hereunder. Except as set forth in Section 10.5, the rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by Applicable Law.

Section 12.12 No Third Party Rights. Other than the Parties, no Person will have any legal or equitable right, remedy or claim under or with respect to this Agreement. This Agreement may be amended, restated, amended and restated, supplemented, waived, changed or modified or terminated, and any provision of this Agreement may be waived, without the consent of any Person who is not a Party. The Company shall enforce any legal or equitable right, remedy or claim under or with respect to this Agreement for the benefit of the Company Indemnified Parties and the Investor Representative shall enforce any legal or equitable right, remedy or claim under or with respect to this Agreement for the benefit of the Investor Indemnified Parties.

Section 12.13 Table of Contents and Headings. The Table of Contents and headings of the Articles and Sections of this Agreement have been inserted for convenience of reference only, are not to be considered a part hereof and shall in no way modify or restrict any of the terms or provisions hereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the Effective Date.

LIQUIDIA TECHNOLOGIES, INC.

By: _____

Name:

Title:

[Signature Page to Revenue Interest Financing Agreement]

LEGAL 4875-0317-8306v.49

**HEALTHCARE ROYALTY PARTNERS IV,
L.P.**

By: HealthCare Royalty GP IV, LLC,
its general partner

By: _____
Name:
Title:

INVESTOR REPRESENTATIVE:

HCR COLLATERAL MANAGEMENT, LLC

By: _____
Name:
Title:

[Signature Page to Revenue Interest Financing Agreement]

LEGAL 4875-0317-8306v.49

DISCLOSURE SCHEDULES
of
LIQUIDIA TECHNOLOGIES, INC.

pursuant to that certain
REVENUE INTEREST FINANCING AGREEMENT

dated as of January 9, 2023

by and among

LIQUIDIA TECHNOLOGIES, INC.,

HEALTHCARE ROYALTY PARTNERS IV, L.P.,

and

HCR COLLATERAL MANAGEMENT, LLC

The following schedules are delivered pursuant to that certain Revenue Interest Financing Agreement (the “Agreement”), dated as of January 9, 2023, by and among LIQUIDIA TECHNOLOGIES, INC., a Delaware corporation (the “Company”), HEALTHCARE ROYALTY PARTNERS IV, L.P., a Delaware limited partnership (the “Investor”), and HCR COLLATERAL MANAGEMENT, LLC, a Delaware limited liability company (the “Investor Representative”), solely in its capacity as agent for, and representative of, the Investor. Nothing contained in these schedules is intended to broaden the scope of any representation or warranty contained in the Agreement or to create any covenant unless clearly and explicitly specified in the contrary herein.

The information set forth in these schedules shall be deemed to be disclosed for purposes of all Sections or subsections of the Agreement.

Notwithstanding any materiality qualifications in any representations or warranties in the Agreement, for administrative ease, certain items have been included herein which are not considered by the Company to be material to its business, assets (including intangible assets), financial condition, prospects or results of operations. No reference to or disclosure of any item or other matter in these schedules shall be construed as an admission or indication that such item or other matter is material (nor shall it establish a standard of materiality for any purpose whatsoever) or that such item or other matter is required to be referred to or disclosed herein.

The information set forth in these schedules is disclosed solely for the purposes of the Agreement, and nothing in these schedules constitute an admission by any party hereto of any liability or obligation of the Company to any third party of any matter whatsoever, or an admission against the Company interests. The inclusion of any matters not required by the Agreement to be reflected in these schedules is set forth for informational purposes and does not necessarily include

other matters of a similar informational nature. In disclosing the information in these schedules, the Company expressly does not waive any attorney-client privilege associated with such information or any protection afforded by the work-product doctrine with respect to any of the matters disclosed or discussed herein.

The information contained in these schedules is in all respects subject to ARTICLE IX of the Agreement. These schedules and the information, descriptions and disclosures included herein are intended to qualify and limit the representations, warranties, and covenants of the Company contained in the Agreement. The headings used in these schedules are inserted for convenience only and shall not create a different standard for disclosure than the language set forth in the Agreement. Capitalized terms used herein but not otherwise defined herein shall have the meanings ascribed thereto in the Agreement.

SCHEDULE 1.1-1
APPLICABLE TIERED PERCENTAGES

[***]

SCH. 1.1-1

LEGAL 4875-0317-8306v.49

SCHEDULE 1.1-2

COMPETITIVE PARTY

“Competitive Party” means any Person that is engaged in developing, marketing, manufacturing, and/or commercializing any clinical therapeutic product candidates and/or products that are or could reasonably be expected to be competitive with business of a member of the Company Group and listed below, as the same may be updated, by written notice to the Investor Representative from time to time, which notice shall not apply retroactively. For clarity, no Royalty Company may be included as a Competitive Party.

[***]

SCH. 1.1-2

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SCHEDULE 1.1-3

KNOWLEDGE PERSONS AND RESPONSIBLE OFFICERS

Chief Executive Officer

Chief Financial Officer

General Counsel

Chief Medical Officer (solely with respect to Section 4.25)

SCH. 1.1-3

LEGAL 4875-0317-8306v.49

SCHEDULE 1.1-4
LICENSE AGREEMENTS

1. None.

SCH. 1.1-4

LEGAL 4875-0317-8306v.49

SCHEDULE 1.1-5

PERMITTED INVESTMENTS

1. Ownership of Equity Interests in the Company by Parent Company.
2. Ownership of Equity Interests in Liquidia PAH, LLC by the Company.

SCH. 1.1-5

LEGAL 4875-0317-8306v.49

SCHEDULE 1.1-6

PERMITTED LICENSES

1. Inhaled Collaboration and Option Agreement, dated as of June 15, 2012, by and between Liquidia Technologies, Inc., and Glaxo Group Limited, as amended by Amendment 1 to the Inhaled Collaboration and Option Agreement, dated as of May 13, 2015, Second Amendment to the Inhaled Collaboration and Option Agreement, dated as of November 19, 2015, and Amendment No. 3 to the Inhaled Collaboration and Option Agreement, dated as of June 24, 2019 (the “GSK ICO Agreement”).
2. License Agreement, dated as of November 8, 2013, by and between Liquidia Technologies, Inc., and Envisia Therapeutics, Inc., as amended by Amendment to License Agreement, dated as of March 6, 2014, 2nd Amendment to License Agreement, dated September 15, 2014, 3rd Amendment to License Agreement, dated as of May 6, 2015, 4th Amendment to License Agreement, dated as of July 20, 2015, 5th Amendment to License Agreement, dated as of March 29, 2017, 6th Amendment to License Agreement, dated as of March 29, 2017, and 7th Amendment to License Agreement, dated as of October 4, 2017 (the “Envisia License Agreement”).

SCH. 1.1-6

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SCHEDULE 1.1-7

PRODUCT PLAN

[***]

SCH. 1.1-7

LEGAL 4875-0317-8306v.49

SCHEDULE 1.1-8

NET SALES THRESHOLD

The Net Sales Threshold is achieved if aggregate Net Sales of the Existing Yutrepia Product in any period of four consecutive Calendar Quarters exceed \$[***].

SCH. 1.1-8

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SCHEDULE 1.1-9

SPECIAL TERMINATION AMOUNT / SPECIAL TERMINATION EVENT

“Special Termination Amount” means as of any date of payment, the lesser of (a) the sum of (i) the Hard Cap less the aggregate of (A) all of the payments of the Company in respect of the Total Fixed Payments and the Total Included Product Payments (including any Under Performance Payment or Generic Product Payment) made to the Investor prior to such date and (B) any amounts received by the Investor pursuant to the Insurance Policy, if any, plus (ii) any other Obligations (other than inchoate Obligations) payable by the Company Parties under this Agreement or the other Transaction Documents (if any), and (b) the sum of (i) the Investment Amount minus the aggregate of all of the payments received by the Investor in respect of the Total Fixed Payments and the Total Included Product Payments (including any Under Performance Payment or Generic Product Payment), plus (ii) after taking into account the Total Fixed Payments, the Total Included Product Payments, the Under Performance Payment and the Generic Product Payment received by the Investor Representative under this Agreement, the IRR True-Up Payment Amount.

“Special Termination Event” means any of the following events:

(i) Material Adverse Effect. There occurs any circumstance or circumstances that could reasonably be expected, either individually or in the aggregate, to have the occurrence and a continuance of a Material Adverse Effect;

(ii) Representations and Warranties. Any representation, warranty, certification or statement of fact made or deemed made by or on behalf of the Company or any other Company Party in Section 4.4 (Ownership), Section 4.7 (Solvency), Section 4.10 (Intellectual Property Matters), Section 4.12 (Material Contracts), Section 4.13 (Bankruptcy), Section 4.16 (Financial Statements; No Material Adverse Effect), Section 4.17 (No Default; No Special Termination Event), Section 4.21 (Perfection of Security Interests in the Collateral), or Section 4.25 (Compliance of Included Products) of this Agreement shall be materially incorrect or materially misleading when made or deemed made and, if susceptible to cure, such inaccuracy continues for thirty (30) days after the earlier of the date on which (A) a Responsible Officer of any Company Party has knowledge of such inaccuracy or (B) written notice thereof shall have been given to the Company by the Investor Representative (it being understood and agreed that the representations and warranties set forth in Section 4.7 and Section 4.13, are not susceptible to cure and shall not be subject to a cure period);

(iii) Specified Covenants. Any Company Party fails to perform or observe any term, covenant or agreement contained in Section 6.8(a) or Section 6.8(c) and such failure continues for sixty (60) days after the earlier of the date on which (A) a Responsible Officer of any Company Party has knowledge of such breach or (B) written notice thereof shall have been given to the Company by the Investor Representative;

(iv) Yutrepia; Sandoz Product.

(A) Following receipt of Regulatory Approval for the Existing Yutrepia Product in the United States, there occurs any revocation, withdrawal, suspension or

SCH. 1.1-9

cancellation of such Regulatory Approval which results in any member of the Company Group being prevented from marketing or selling the Existing Yutrepia Product in the United States, and such revocation, withdrawal, suspension or cancellation continues for sixty (60) days or more; and

(B) Prior to the achievement of the Net Sales Threshold, (a) the Sandoz Agreement is assigned or terminated, or any provision of the Sandoz Agreement is modified or waived in a manner that materially reduces the amounts payable to the applicable Company Party thereunder, (b) the Sandoz Device Agreement is assigned, terminated or modified in a manner that would have an adverse effect on the commercialization of the Sandoz Product in the United States, or (c) there occurs any revocation, withdrawal, suspension or cancellation of the Regulatory Approval for the Sandoz Product which prevents the Company or any other Company Party from marketing the Sandoz Product in the United States and receiving payments from Sandoz under the Sandoz Agreement with respect thereto, and such revocation, withdrawal, suspension or cancellation continues for sixty (60) days or more.

(v) Commercialization. Prior to the achievement of the Net Sales Threshold, no member of the Company Group has the right to Commercialize the Sandoz Product or to receive payments related thereto, whether under the terms of the Sandoz Agreement or otherwise, equivalent to the payments set forth in the Sandoz Agreement as of the Effective Date.

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SCHEDULE 1.1-10

PERMITTED LIENS

Debtor	Secured Party	UCC File No.	Filing Jurisdiction
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20182080022	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20183016710	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20183016728	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20183018971	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20183654619	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20186960039	DE
Liquidia Technologies, Inc.	U.S. Bank Equipment Finance, a Division of U.S. Bank National Association	20190662606	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20192774292	DE
Liquidia Technologies, Inc.	Corporation Service	20193213944	DE

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Debtor	Secured Party	UCC File No.	Filing Jurisdiction
	Company, as Representative		
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20195818872	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20196331016	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20196374776	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20197181709	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20197181691	DE
Liquidia Technologies, Inc.	Thermo Fisher Financial Services, Inc.	20197414423	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20197940005	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20222018174	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20223808664	DE
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20223808698	DE

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Debtor	Secured Party	UCC File No.	Filing Jurisdiction
Liquidia Technologies, Inc.	Corporation Service Company, as Representative	20223808706	DE

SCH. 1.1-10

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SCHEDULE 1.1-11

GENERIC PRODUCT PAYMENT EVENT

“Generic Product Payment Event” means the FDA grants final approval to an inhaled treprostinil product Therapeutically Equivalent to the Existing Yutrepia Product.

“Therapeutically Equivalent” means the product in question is (a) a pharmaceutical equivalent of the Existing Yutrepia Product for which bioequivalence or other accepted regulatory standard has been demonstrated, and can be expected to have the same clinical effect and safety profile as the Existing Yutrepia Product when administered to patients under the conditions specified in the labeling, and (b) is classified by the FDA as an A rated product in relation to the Existing Yutrepia Product due to meeting the following criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.

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SCHEDULE 3.4

THIRD PARTY REPORTS AND INFORMATION

“Third Party Reports” means the reports under Sections 4.2.3(b), 4.2.3(c) and 6.6 of the Sandoz Agreement, or any similar report under the Sandoz Agreement, in each case that has been received by any Company Party from Sandoz Inc. under the Sandoz Agreement relating to any payments to any Company Party thereunder.

“Third Party Information” means any “Confidential Information” (as defined in the Sandoz Agreement) of Sandoz Inc. that is provided by Sandoz Inc. to any Company Party under the Sandoz Agreement that is responsive to any disclosure or reporting obligations of the Company Group under the Transaction Documents.

SCH. 3.4

LEGAL 4875-0317-8306v.49

SCHEDULE 4.2(b)

NO CONFLICTS

Parent Company, the Company and Liquidia PAH have granted Liens in the “Collateral” (as defined in the SVB Loan Agreement), pursuant to that certain Amended and Restated Loan and Security Agreement dated as of January 7, 2022, by and among Silicon Valley Bank, as lender, administrative agent, and collateral agent, SVB Innovation Credit Fund VIII, L.P., the Company, the Parent Company, and Liquidia PAH (the “SVB Loan Agreement”). Each member of the Company Group’s Indebtedness under the SVB Loan Agreement will be satisfied in full and retired as of the Initial Closing Date, and all Liens securing such Indebtedness will be released.

SCH. 4.2(b)

LEGAL 4875-0317-8306v.49

SCHEDULE 4.4

OWNERSHIP

The disclosure under Schedule 4.2(b) of this Disclosure Schedule is incorporated herein by reference.

SCH. 4.4

LEGAL 4875-0317-8306v.49

SCHEDULE 4.6

LITIGATION

The following disclosures are made under subsection (i) of Section 4.6:

1. Liquidia Technologies, Inc. is party to the following proceedings related to the Asserted Patents that, if adversely determined, could have an adverse effect on the Company Group:
 - a. Hatch-Waxman lawsuit before U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA) (the "Hatch-Waxman Litigation")
 - b. *Inter partes* review before the Patent Trial and Appeal Board of the United States Patent and Trademark Office (IPR2021-00406) (the "IPR")
2. United Therapeutics Corporation has filed a lawsuit against Liquidia Technologies, Inc. in the North Carolina Business Court (Case No. 2021CVS4094), alleging that Liquidia Technologies, Inc. and a former employee misappropriated certain trade secrets of United Therapeutics Corporation (the "Trade Secret Case").

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SCHEDULE 4.10(a)

PATENT RIGHTS

[***]

SCH. 4.10(a)

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SCHEDULE 4.10(i)

PATENT RIGHTS COVERING INCLUDED PRODUCTS

[***]

SCH. 4.10(i)

LEGAL 4875-0317-8306v.49

SCHEDULE 4.10(r)

COPYRIGHTS, TRADEMARKS AND DOMAIN NAMES

Owned Copyrights

None that are owned or exclusively licensed to any Company Party and material to any member of the Company Group's Commercialization of any Included Product.

Owned Trademarks

1. RareGen, LLC owns (or has an ownership interest in) the following issued United States trademark:

RAREGEN (Registration No. 5836188)

2. Liquidia Technologies, Inc. owns (or has an ownership interest in) the following issued United States trademarks:

PRINT (Registration No. 5541277)
LIQUIDIA TECHNOLOGIES (Registration No. 5443598)
PRINT (Registration No. 3694178)
PRINT (Registration No. 3346353)
LIQUIDIA TECHNOLOGIES (Registration No. 3321419)
FLUOROCUR (Registration No. 6646535)

3. Liquidia Technologies, Inc. owns (or has an ownership interest in) the following issued United States trademarks and United States trademark applications:

LIQUIDIA (Application No. 90218085)
YUTREPIA (Application No. 88749075)
YUTREPIA (Application No. 88899379)
ZENLIFIA (Application No. 88403824)
LIQUIDIA (Application No. 88403819)
PAHVIMY (Application No. 88403738)
TREPLIFI (Application No. 88403720)
LIQUIDIA (Application No. 88403710)

Owned Domain Names

All of the following domain names are held by Liquidia Technologies, Inc. and are registered through GoDaddy:

raregenllc.com
genericpah.com
genericpah.net

SCH. 4.10(r)

genericrepij.com
genericrepij.net
genericreprostiniil.com
genericreprostiniil.net
genericreprostiniilinjection.com
genericreprostiniilinjection.net
trepinj.com
trepinj.net
trepinjection.com
trepinjection.net
treprostiniilinjection.com
treprostiniilinjection.net
pahvimy.com
treplifi.com
wispia.com
zenlafia.com
dryvaso.com
inhaledmed.com
inhaledrx.com
inhaledtrep.com
inhaledtrep.net
printparticle.com
inhaledtrep.org
inhaledtreprostiniil.com
liquidiabiopharma.com
liquidiabiopharma.net
liquidiabiopharma.org
pahvimy.net
pahvimy.org
treplifi.net
treplifi.org
wispia.net
wispia.org
zenlifi.net
zenlafia.org
yutrepia.net
yutrepia.org
yutrepia.com
liquidia.com
yutrepia.co
yutrepia.info
yutrepia.life
yutrepia.live
yutrepia.me
yutrepia.today
yutrepia.us

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liquidia.co
liquidia.info
liquidia.net
liquidia.org
liquidiacorp.com
liquidiacorporation.com
liquidiainc.com
liquidiainc.net
youtrepia.co
youtrepia.com
youtrepia.info
youtrepia.net
youtrepia.org

Licensed Copyrights, Trademarks, and Domain Names

1. Sandoz possesses certain Trademarks, Trade Secrets and Domain Names that are material to the Commercialization of the Sandoz Product. Pursuant to the Sandoz Agreement, Liquidia PAH, LLC has a non-exclusive license to use the “Sandoz Trademarks and Copyrights” as such term is defined in the Sandoz Agreement. ■

SCH. 4.10(r)

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SCHEDULE 4.10

DISCLOSURES

[***]

SCH. 4.10

LEGAL 4875-0317-8306v.49

SCHEDULE 4.12(a)

MATERIAL CONTRACTS

(a) List of Material Contracts

1. Sandoz Agreement.
2. Joint Development Agreement, dated as of May 6, 2019, by and between RareGen, LLC, and Carelife USA Inc.
3. Mainbridge Agreement.
4. Amended and Restated License Agreement, dated as of December 15, 2008, by and between Liquidia Technologies, Inc., and The University of North Carolina at Chapel Hill, as amended by First Amendment to Amended and Restated License Agreement, dated as of June 8, 2009, Second Amendment to Amended and Restated License Agreement, dated as of June 1, 2012, Third Amendment to Amended and Restated License Agreement, dated as of October 7, 2014, 4th Amendment to Amended and Restated License Agreement, dated as of July 22, 2015, 5th Amendment to Amended and Restated License Agreement, dated as of November 12, 2015, 6th Amendment to Amended and Restated License Agreement, dated as of June 10, 2016, and 7th Amendment to Amended and Restated License Agreement, dated as of March 23, 2018.
5. Manufacturing Development and Scale-Up Agreement, dated as of March 19, 2012, by and between Liquidia Technologies, Inc., and Chasm Technologies, Inc., as amended by 1st Amendment to Manufacturing Development and Scale-Up Agreement, dated as of May 25, 2017.
6. Lease Agreement, dated June 29, 2007, by and between Liquidia Technologies, Inc. and GRE Keystone Technologies One LLC, as amended by Lease Modification Agreement No. 1, dated January 12, 2009, Lease Modification Agreement No. 2, dated December 17, 2010, Third Amendment to Lease Agreement, dated June 25, 2014, Fourth Amendment to Lease Agreement, dated November 17, 2015, Fifth Amendment to Lease Agreement, dated January 23, 2017, Sixth Amendment to Lease Agreement, dated June 9, 2017, and Seventh Amendment to Lease Agreement, dated November 1, 2018.
7. The Litigation Financing Agreements.
8. LIQ861 API Supply Agreement, dated as of January 10, 2020, by and among Liquidia Technologies, Inc., LGM Pharma LLC and Yonsung Fine Chemicals Co., Ltd., as modified by LIQ861 Liquidia-LGM Pricing Agreement, dated as of January 10, 2020, by and between Liquidia Technologies, Inc., and LGM Pharma LLC.

SCH. 4.12(a)

9. Commercial Manufacturing Services and Supply Agreement, dated as of November 12, 2020, by and between Liquidia Technologies, Inc., and Xcelience, LLC
10. The GSK ICO Agreement.
11. The Envisia License Agreement.

SCH. 4.12(a)

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SCHEDULE 4.12

DISCLOSURES

[***]

SCH. 4.14(b)

SCHEDULE 4.14(b)

ADDITIONAL NAMES

1. Liquidia PAH was formerly known as RareGen, LLC. Its name was changed on February 24, 2021.
2. In connection with the acquisition of Liquidia PAH by Parent Company, Gemini Merger Sub I, Inc. and Gemini Merger Sub II, LLC were formed as wholly owned subsidiaries of the Parent Company. Gemini Merger Sub I, Inc. was merged with and into the Company. Gemini Merger Sub II, LLC was merged with and into Liquidia PAH.

SCH. 4.14(b)

SCHEDULE 4.14(c)
DEPOSIT ACCOUNTS AND SECURITY ACCOUNTS

[***]

SCH. 4.14(b)

SCHEDULE 4.15

PERMITTED DEBT

1. Indebtedness secured by the Liens described in Schedule 1.1-10.
2. Royalty obligations under the agreements identified in Items 4 and 5 in part (a) of Schedule 4.12.
3. Payment obligations with respect to the development of a new pump pursuant to the agreement identified in Item 3 in part (a) of Schedule 4.12.
4. Obligations to reimburse patent costs pursuant to the agreement identified in Item 4 in part (a) of Schedule 4.12.
5. Any Indebtedness underlying the Litigation Finance Agreements
6. The Indebtedness of each member of the Company Group with respect to the SVB Loan Agreement referenced in Schedule 4.2(b), which will be satisfied in full and retired as of the Initial Closing Date, and all Liens securing such Indebtedness will be released.

SCH. 4.15

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SCHEDULE 4.16(d)
MATERIAL ADVERSE EFFECT

[***]

SCH. 4.16(d)

LEGAL 4875-0317-8306v.49

SCHEDULE 4.20

SUBSIDIARIES

<u>Subsidiary</u>	<u>Jurisdiction of Organization</u>	<u>Percentage of Equity Interests</u>
Liquidia Technologies, Inc	Delaware	100%
Liquidia PAH, LLC	Delaware	100%

SCH. 4.20

LEGAL 4875-0317-8306v.49

SCHEDULE 4.21

PERFECTION OF SECURITY INTERESTS IN THE COLLATERAL

Schedule 4.2(b) of this Disclosure Schedule is incorporated herein by reference. Each member of the Company Group's Indebtedness with respect to the SVB Loan Agreement referenced in Schedule 4.2(b) will be satisfied in full and retired as of the Initial Closing Date, and all Liens securing such Indebtedness will be released.

SCH. 4.21

LEGAL 4856-5560-1223v.12

SCHEDULE 4.25(b)
LIMITATIONS ON REGULATORY APPROVAL

[***]

SCH. 4.25(b)

LEGAL 4856-5560-1223v.12

SCHEDULE 4.26(b)
INCLUDED PRODUCTS

1. Sandoz Product.
2. Existing Yutrepia Product.

SCH. 4.26(b)

LEGAL 4875-0317-8306v.49

SCHEDULE 6.2
ADDITIONAL INFORMATION

1. None.

SCH. 6.2

EXHIBIT A
FORM OF PRESS RELEASE
CONFIDENTIAL DRAFT

[Attached]

EX. A

LEGAL 4875-0317-8306v.49

EXHIBIT B

FORM OF COMPLIANCE CERTIFICATE

Financial Statement Date: _____, 20__ (the “Financial Statement Date”)

To: HCR Collateral Management, LLC, as Investor Representative

Re: Revenue Interest Financing Agreement dated as of January 9, 2023 (as amended, restated, amended and restated, supplemented or otherwise modified or extended from time to time, the “Revenue Interest Financing Agreement”) among Liquidia Technologies, Inc., a Delaware corporation (the “Company”), the entities listed on the signature pages thereto and HCR Collateral Management, LLC, a Delaware limited liability company, solely in its capacity as agent for, and representative of, the Investor. Capitalized terms used but not otherwise defined herein have the meanings provided in the Revenue Interest Financing Agreement.

Ladies and Gentlemen:

The undersigned [chief executive officer / chief financial officer / treasurer / controller] hereby certifies as of the date hereof that [he/she] is the _____ of the Company, and that, in [his/her] capacity as such, [he/she] is authorized to execute and deliver this Compliance Certificate to the Investor Representative on the behalf of the Company, and that:

[Use following paragraph 1 for fiscal year-end financial statements that are not previously filed with the SEC:]

[1. Attached hereto as Schedule 1 are the year-end audited financial statements required by Section 6.9(a) of the Revenue Interest Financing Agreement for the fiscal year of the Parent Company ended as of the Financial Statement Date, together with the report and opinion of an independent certified public accountant required by such Section.]

[Use following paragraph 1 for fiscal quarter-end financial statements:]

[1. [Attached hereto as Schedule 1 are the unaudited financial statements required by Section 6.9(b) of the Revenue Interest Financing Agreement for the fiscal quarter of the Parent Company ended as of the Financial Statement Date. Such financial statements] ¹ [The financial statements for the fiscal quarter of the Parent Company filed with the SEC] ² fairly present in all material respects the financial condition, results of operations, stockholders’ equity and cash flows of the Parent Company and its Subsidiaries in accordance with GAAP, subject only to normal year-end audit adjustments and the absence of footnotes.]

2. The undersigned has reviewed and is familiar with the terms of the Revenue Interest Financing Agreement and has made, or has caused to be made, a reasonably detailed review of the

_____ ¹ To be included if the fiscal quarter-end financial statements have not previously been filed with the SEC.

² To be included if the financial statements have been filed with the SEC.

EX. B

transactions and condition (financial or otherwise) of the Company Group during the past fiscal quarter.

3. A review of the activities of the Company Group during such fiscal period has been made under the supervision of the undersigned with a view to determining whether during such fiscal period the Company Group performed and observed all of its Obligations, and

[select one:]

[to the knowledge of the undersigned during such fiscal period, the Company Group performed and observed each covenant and condition of the Transaction Documents applicable to it, and no Change of Control, Special Termination Event, Default or Event of Default has occurred and is continuing.]

[or:]

[the following covenants or conditions have not been performed or observed and the following is a list of each such Special Termination Event, Change of Control, Default and/or Event of Default and its nature and status:]

[4.] [Attached hereto as Schedule [1] [2] are copies of any Sales and Inventory Report (as defined in the Sandoz Agreement) or similar report received by any Company Party from Sandoz under the Sandoz Agreement relating to any payments to any Company Party thereunder for the applicable Calendar Quarter, including reports under Section 6.6 of the Sandoz Agreement.]³

[5.] [Attached hereto as Schedule [2][3] are calculations showing the amount of gross sales of the Included Product in each country, (ii) the amount of Other Royalty Payments in each country, (iii) the amount of the Net Revenues and a calculation thereof, and (iv) a calculation of the Included Product Payment Amount for each Quarterly Payment Date, showing the Applicable Tiered Percentage applied thereto and a calculation of Under Performance Payments or the Generic Product Payment (if applicable), in each case, for each fiscal quarter period covered by such Compliance Certificate.]⁴

[5.][6.]. Attached are updates required by Section 6.3(l) and Section 6.10(a)(iii).

[Signature Page Follows]

³ To be included only upon the receipt of Sandoz's consent.

⁴ To be included following the First Commercial Sale.

EX. B

IN WITNESS WHEREOF, the undersigned has executed this Compliance Certificate as of _____, 20__.

Liquidia Technologies, Inc.,
a Delaware corporation

By: _____
Name:
Title:

EX. B

LEGAL 4875-0317-8306v.49

EXHIBIT C

EXAMPLE OF CALCULATION OF INCLUDED PRODUCT PAYMENT AMOUNT

	Total Calendar Year Revenue			
	<i>(\$ millions)</i>			
	<u>Q1</u>	<u>Q2</u>	<u>Q3</u>	<u>Q4</u>
Period's Net Revenue				
Cumulative Annual Net Revenue				
A. Portion of Annual Net Revenue less than or equal to \$[***]				
B. Portion of Annual Net Revenue greater than \$[***] and less than \$[***]				
C. Portion of Annual Net Revenue greater than or equal to \$[***]				
Investment Amount				\$[●]
Applicable Tiered Percentage for A				[●]%
Applicable Tiered Percentage for B				[●]%
Applicable Tiered Percentage for C				[●]%
Payment for each Calendar Quarter				

EXAMPLE OF CALCULATION OF QUARTERLY FIXED PAYMENTS

[To be provided by Investor]

EX. C

EXHIBIT D

FORM OF JOINDER AGREEMENT

THIS JOINDER AGREEMENT (this “Agreement”) dated as of [●] [●], 20[●] is by and between [NAME OF NEW GUARANTOR] (the “New Subsidiary”) and [HEALTHCARE ROYALTY PARTNERS IV, L.P.], each as secured party (in such capacities, collectively, the “Secured Party”). Capitalized terms used herein and not otherwise defined herein shall have the meanings assigned to such terms in the Revenue Interest Financing Agreement, dated as of January 9, 2023 (the “Revenue Interest Financing Agreement”), by and among LIQUIDIA TECHNOLOGIES, INC. (the “Company”), the Secured Party, as Investor, and HCR COLLATERAL MANAGEMENT, LLC, a Delaware limited liability company, solely in its capacity as agent for, and representative of, the Investor.

The New Subsidiary is required by Section 6.1(a) of the Revenue Interest Financing Agreement to become a “Grantor” under the Security Agreement and a “Guarantor” under the Guaranty. Accordingly, and as of the date hereof, the New Subsidiary hereby agrees as follows with the Secured Party:

1. The New Subsidiary hereby acknowledges, agrees and confirms that, by its execution of this Agreement, the New Subsidiary will be deemed to be a party to the Security Agreement and a “Grantor” for all purposes of the Security Agreement, and shall have all the obligations of a Grantor thereunder as if it had executed the Security Agreement. The New Subsidiary hereby ratifies, as of the date hereof, and agrees to be bound by, all of the terms, provisions and conditions contained in the Security Agreement (subject to the information set forth on the schedules to this Agreement). Without limiting the generality of the foregoing terms of this Section 1, the New Subsidiary hereby grants to the Secured Party, a continuing security interest in any and all right, title and interest of the New Subsidiary in and to the Collateral of the New Subsidiary to secure the prompt payment and performance in full when due, whether by lapse of time, acceleration, mandatory prepayment or otherwise, of the Secured Obligations (as defined in the Security Agreement).

2. The New Subsidiary hereby acknowledges, agrees and confirms that, by its execution of this Agreement, the New Subsidiary will be deemed to be a party to the Guaranty and a “Guarantor” for all purposes of the Guaranty, and shall have all of the obligations of a Guarantor thereunder as if it had executed the Guaranty. The New Subsidiary hereby ratifies, as of the date hereof, and agrees to be bound by, all of the terms, provisions and conditions applicable to the Guarantors contained in the Guaranty. Without limiting the generality of the foregoing terms of this Section 1, the New Subsidiary hereby jointly and severally, irrevocably, and unconditionally, together with the other Guarantors, guarantees to the Secured Party as primary obligor and not as surety, the prompt payment and performance of the Guaranteed Obligations (as defined in the Guaranty) in full when due (including amounts that would become due but for the operation of the automatic stay under Section 362(a) of the Bankruptcy Code of the United States of America) strictly in accordance with the terms thereof.

3. The New Subsidiary hereby represents and warrants to the Secured Party that:

EX. D

(a) The New Subsidiary's exact legal name and state of organization are as set forth on the signature pages hereto.

(b) The New Subsidiary's taxpayer identification number and organizational identification number are set forth on Schedule 1 hereto.

(c) Other than as set forth on Schedule 2 hereto, the New Subsidiary has not changed its legal name, changed its state of organization, or been party to a merger, consolidation or other change in structure in the five years preceding the date hereof.

(d) Schedule 3 hereto sets forth a complete and accurate list of the Collateral of the New Subsidiary as of the date hereof, in form and substance substantially similar to the original scheduling requirements of the Collateral by the Company under the Revenue Interest Financing Agreement

(e) Schedule 4 hereto is a complete and accurate list as of the date hereof of each Subsidiary of the New Subsidiary, together with (i) jurisdiction of organization, (ii) number of shares of each class of Equity Interests outstanding, (iii) number and percentage of outstanding shares of each class owned (directly or indirectly) by the New Subsidiary and (iv) number and effect, if exercised, of all outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto.

(f) Without limiting the generality of the terms of Section 1, to the extent applicable to it, the New Subsidiary represents and warrants that the representations and warranties in the ARTICLE IV of the Revenue Interest Financing Agreement applicable to the New Subsidiary are true and correct in all material respects as of the date hereof (or, if made as of a specific date, as of such date) subject to any additions that the Company may make to the Disclosure Schedule; (which additions must be acceptable to the Investor Representative it being acknowledged that any addition that would not be reasonably expected to have a Material Adverse Effect shall be conclusively deemed acceptable); provided, that to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Closing Date or such other date, as applicable.

4. The address of the New Subsidiary for purposes of all notices and other communications is the address designated for the Company Parties or such other address as the New Subsidiary may from time to time notify the Secured Party in writing.

5. The New Subsidiary waives acceptance and notice of acceptance by the Secured Party of the guaranty by the New Subsidiary upon the execution of this Agreement by the New Subsidiary.

6. This Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. Delivery of an executed counterpart of a signature page of this Agreement by electronic imaging means (e.g., "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Agreement.

EX. D

7. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

[Signature Page Follows]

EX. D

LEGAL 4875-0317-8306v.49

IN WITNESS WHEREOF, the New Subsidiary has caused this Joinder Agreement to be duly executed by their authorized officers, and the Secured Party has caused the same to be accepted by its authorized officer, as of the day and year first above written.

[NAME OF NEW SUBSIDIARY]

By: _____

Name:

Title:

Acknowledged and accepted:

HEALTHCARE ROYALTY PARTNERS IV, L.P.

By: HealthCare Royalty GP IV, LLC,
its general partner

By: _____

Name:

Title:

EX. D

LEGAL 4875-0317-8306v.49

EXHIBIT E

EXAMPLE OF IRR TRUE-UP PAYMENT AMOUNT

[***]

EX. E

LEGAL 4875-0317-8306v.49

THIRD AMENDMENT TO PROMOTION AGREEMENT

This Third Amendment to Promotion Agreement (this “**Third Amendment**”), is entered into as of November 18, 2022 (the “**Third Amendment Effective Date**”) by and between Sandoz Inc. (“Sandoz”) and Liquidia PAH, LLC, formerly known as RareGen, LLC (“**RareGen**”).

BACKGROUND

WHEREAS, Sandoz and RareGen are parties to that certain Promotion Agreement, dated as of August 1, 2018 (the “Original Agreement”), as amended by that certain First Amendment to Promotion Agreement, dated as of May 8, 2020 (the “**First Amendment**”) and that certain Second Amendment to Promotion Agreement, dated as of September 4, 2020 (the “**Second Amendment**”) and, collectively with the Original Agreement and First Amendment, as they may be amended from time to time, the “**Agreement**”); and

WHEREAS, Sandoz and RareGen plan to enter into an agreement with Mainbridge Health Partners LLC regarding the development and supply of Pumps suitable to be used with the Product in substantially the form attached hereto as Exhibit A (the “Mainbridge Development Agreement”);

WHEREAS, Sandoz and RareGen desire to amend the terms of the Agreement to, among other things, extend the term of the Agreement and allocate responsibility for the costs agreed to in the Mainbridge Development Agreement;

NOW, THEREFORE, in consideration of the mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Sandoz and RareGen agree as follows:

AGREEMENT

1. **Definitions.** All capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings assigned to them in the Agreement.

2. **Amendments.**

a. Article I of the Agreement is hereby amended by adding the following sections:

“1.93 ‘**Pump**’ means an infusion pump that is suitable for the parenteral administration of the Product.

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- b. A new Section 2.4.5 is hereby added to the Agreement to read as follows:

“2.4.5 Development of Pump.

(a) Sandoz and RareGen agree to enter into the Mainbridge Agreement in substantially the form attached hereto, with only such changes as may be approved by both Sandoz and RareGen.

(b) Sandoz and RareGen agree to split equally the Milestone Payments set forth in Article 6 of the Mainbridge Development Agreement (“Pump Milestone Payments”). Sandoz will pay the full amount of each Pump Milestone Payment in full directly to Mainbridge in accordance with the terms of the Mainbridge Development Agreement. Following each such payment, Sandoz will deduct [***] of each Pump Milestone Payment from RareGen’s portion of the Net Profits under this Agreement until the full [***] has been recouped by Sandoz.

(c) To the extent any additional costs are needed toward the development of the Pump beyond those enumerated in the Mainbridge Development Agreement, Sandoz and RareGen shall negotiate in good faith to agree upon a budget for such costs, which shall be split equally between Sandoz and RareGen in the same manner Pump Milestone Payment are paid and reimbursed in accordance with Section 2.4.5(a).”

- c. A new Section 3.4.10 is hereby added to the Agreement to read as follows:

“3.4.10 discuss and review the status of the development of the Pumps and any associated costs.”

- d. Section 6.3 of the Agreement is hereby deleted and restated in its entirety to read as follows:

“6.3 Profit Sharing. The terms and conditions of this Section 6.3 shall govern each Party’s rights and obligations with respect to Net Profits during the Term: (i) for that portion of aggregate Net Profits in the Territory during the Term less than or equal to [***], Sandoz shall receive [***] of all such Net Profits, and RareGen shall receive [***] of all such Net Profits; (ii) except as otherwise set forth in clause (iii), for that portion of aggregate Net Profits in the Territory during the Term greater than [***], Sandoz shall receive [***] of all such Net Profits, and RareGen shall receive [***] of all such Net Profits; and (iii) if aggregate Net Profits in the Territory reach [***] prior to December 31, 2028, Sandoz shall

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receive [***] for that portion of aggregate Net Profits greater than [***] and RareGen shall receive seventy-five percent (75%) of all such Net Profits. For clarity, the tiers set forth in this Section 6.3 shall be with respect to the aggregate of all Net Profits in the Territory during the Term except for the tier starting at [***], which shall only be triggered if that tier is reached by December 31, 2028.

If that tier is not reached by that date, Net Profits shall remain split [***] to Sandoz and [***] to RareGen for the remainder of the Term.”

e. Section 12.1 of the Agreement is hereby deleted and restated in its entirety to read as follows:

“12.1 **Term.** This Agreement shall become effective as of the Effective Date and, unless earlier terminated as provided in this ARTICLE 12, shall initially extend until December 31, 2032 (the ‘**Initial Term**’). After the Initial Term, this Agreement shall automatically renew for successive two (2) year terms under the same terms of this Agreement, unless the Initial Term or any renewal period is earlier terminated as provided in this ARTICLE 12 or a Party provides notice of non-renewal in writing not less than twelve (12) months prior to the expiration of the then-current Term. The Initial Term, together with each such renewal period is referred to as the ‘**Term**’.”

f. Section 11.1 of the Agreement is amended and restated as follows:

11.1 **Indemnification by Sandoz.** Sandoz shall defend, indemnify and hold harmless RareGen and its Affiliates and its and their respective officers, directors, employees, agents, representatives, successors and assigns from and against all Claims, and all associated Losses, to the extent incurred or suffered by any of them to the extent resulting from or arising out of (a) any misrepresentation or breach of any representations, warranties, or covenants (or any of its Affiliates or its or their respective officers, directors, employees, agents or representatives) of Sandoz under this Agreement, (b) the negligence, willful misconduct or violation of Applicable Laws by Sandoz (or any of its Affiliates or its or their respective officers, directors, employees, agents or representatives), (c) the infringement of the intellectual property rights of any Third Party from the use of the Sandoz Trademarks and Copyrights on Product Labeling or RareGen Activity Materials in accordance with this Agreement, (d) the failure of the Product to meet Specifications, (e) the failure of Sandoz to supply Third Parties with Products in accordance with its obligations to such Third Parties, except to the extent such failure is due to the acts or

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omissions of RareGen, (f) death or personal injury to any person related to use of the Product, or (g) any material breach of the Mainbridge Development Agreement by Sandoz; except in each case to the extent any such Claims, and all associated Losses, are caused by an item for which RareGen is obligated to indemnify Sandoz pursuant to Section 11.2.

g. Section 11.2 of the Agreement is amended and restated as follows:

11.2 **Indemnification by RareGen.** RareGen shall defend, indemnify and hold harmless Sandoz and its Affiliates and its and their respective officers, directors, employees, agents, representatives, successors and assigns from and against all Claims and all associated Losses, to the extent incurred or suffered by any of them to the extent resulting from or arising out of (a) any misrepresentation or breach of any representations, warranties, or covenants (or any of its Affiliates or its and their respective officers, directors, employees, agents or representatives) of RareGen under this Agreement, (b) the negligence, willful misconduct, or violation of Applicable Laws by RareGen (or any of its Affiliates or its and their respective officers, directors, employees, agents or representatives), (c) the infringement of the intellectual property rights of any Third Party from the use of RareGen Property, (d) death or personal injury to any person related to use of the Product, arising from any breach of RareGen under this Agreement, or (e) any material breach of the Mainbridge Development Agreement by RareGen; except in each case to the extent any such Claims, and all associated Losses, are caused by an item for which Sandoz is obligated to indemnify RareGen pursuant to Section 11.1.

3. **Effect of Amendment.** Except as otherwise provided herein, all of the provisions of the Agreement are hereby ratified and confirmed and all the terms, conditions and provisions thereof remain in full force and effect.

4. **Governing Law.** This Amendment and any and all matters arising directly or indirectly here from shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, U.S.A. applicable to agreements made and to be performed entirely in such state, without giving effect to the conflict of law principles thereof. The Parties expressly agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Amendment or any Party's performance hereunder.

5. **Counterparts.** This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment may be executed by the exchange of faxed executed copies, certified electronic signatures or executed copies delivered by electronic mail in Adobe Portable

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Document Format or similar format, and such signature shall be deemed an original signature for purposes of this Amendment. The Parties agree that the electronic signatures appearing on this Amendment are the same as handwritten signatures for the purposes of validity, enforceability and admissibility pursuant to the Electronic Signatures in Global and National Commerce (ESIGN) Act of 2000 and Uniform Electronic Transactions Act (UETA) model law or similar applicable laws.

[Signature page follows.]

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IN WITNESS WHEREOF, the Parties have executed this Third Amendment as of the Third Amendment Effective Date.

SANDOZ:

SANDOZ INC.

By: /s/ Timothy de Gavre
Name: Timothy de Gavre
Title: VP, Chief Commercial Officer US

RAREGEN:

LIQUIDIA PAH, LLC

By: /s/ Scott Moomaw
Name: Scott Moomaw
Title: Senior Vice President, Commercial

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EXHIBIT A

MAINBRIDGE DEVELOPMENT AGREEMENT

[*]**

DEVICE DEVELOPMENT AND SUPPLY AGREEMENT

This Device Development and Supply Agreement (“Agreement”) is made this 1st day of December, 2022 by and among Mainbridge Health Partners, LLC, with its principal place of business at 30399 North Chardon Lane; Grayslake IL 60030, (“Mainbridge”), Liquidia PAH, LLC, with its principal place of business at 419 Davis Drive, Suite 100, Morrisville, NC 27560 (“Liquidia”) and Sandoz Inc., with its principal place of business at 100 College Road West, Princeton, NJ, 08540 (“Sandoz” and, collectively with Mainbridge and Liquidia, the “Parties” and each a “Party”).

RECITALS

A. Mainbridge is exclusive North American distributor for certain infusion pump technology and products, and related supplies and peripherals. The Pumps deliver precise subcutaneous micro-dose infusion of medication. The Pumps are not currently approved by the FDA or configured for the administration of treprostinil.

B. Liquidia and Sandoz promote, sell and commercialize Sandoz’s generic treprostinil for parenteral administration (“Treprostinil”) in the United States, its territories and possessions (the “Territory”).

C. Liquidia, Sandoz and Mainbridge desire to work together to (i) develop a version of the Pump that is suitable for the administration of Treprostinil, (ii) obtain FDA approval for the Pump, including use of the Pump for administration of Treprostinil, and (iii) make the Pumps and related Consumables available for use in administering Treprostinil, when such Pumps are approved by the FDA, through Liquidia, Sandoz and/or one or more specialty pharmacy companies to be chosen by Liquidia and Sandoz from time to time (with any specialty pharmacies so designated at any given time being referred to herein as the “Designated Specialty Pharmacy”).

NOW THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

Definitions

As used herein, the following terms shall have the meanings set forth below:

“Agreement” has the meaning set forth in the preamble.

“Agreement Coordinator” has the meaning set forth in Section 9.5.

“Applicable Purchaser” has the meaning set forth in Section 3.1.

“Bankruptcy” has the meaning set forth in Section 10.3.

“cGMP” shall mean the current and any future good manufacturing practices and quality system regulations promulgated by the FDA under the authority of the Federal Food, Drug and Cosmetic Act, as amended, as set forth in 21 C.F.R. Parts 210, 211, and 820 or the counterpart laws and regulations set forth by a regulatory authority of a country in which the Pumps or Consumables shall be manufactured or sold, and if the Pumps or Consumables are manufactured outside of the Territory, the current and any future good manufacturing practices and quality system regulations in the country(ies) in which the Pumps or Consumables, as applicable, are manufactured.

“Confidential Information” has the meaning set forth in Section 13.1.

“Consumables” means (a) the items listed under the heading “Consumables” in Section 7.1 below and described in detail in Exhibit A, including any additions thereto from time to time, and (b) any supplies or consumables related to the Pump that are introduced after the date hereof.

“Designated Specialty Pharmacy” has the meaning set forth in the recitals.

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“Development Work” has the meaning set forth in Section 2.1.2.

“Discloser” has the meaning set forth in Section 13.1.

“FDA” has the meaning set forth in the recitals.

“FDA Approval Date” means the first date on which the FDA sends a 510(k) letter that that the Pumps can be marketed in the U.S.

“First Sale Date” means the shipment of the Pumps by Mainbridge to Liquidia, Sandoz or the Designated Specialty Pharmacy after the FDA Approval Date

“Initial Pricing Period” has the meaning set forth in Section 7.1.

“Initial Term” has the meaning set forth in Section 10.1.

“Liquidia” has the meaning set forth in the preamble.

“Liquidia/Sandoz Development Work” has the meaning set forth in Section 2.1.2.

“Liquidia/Sandoz Indemnatee” has the meaning set forth in Section 11.2.

“Liquidia/Sandoz Indemnatee Claim” has the meaning set forth in Section 11.2.

“Liquidia/Sandoz Proposed Change” has the meaning set forth in Section 4.2.

“Mainbridge” has the meaning set forth in the preamble.

“Mainbridge Development Work” has the meaning set forth in Section 2.1.1.

“Mainbridge Proposed Change” has the meaning set forth in Section 4.1.1.

“Material Breach” has the meaning set forth in Section 10.3.

“Milestone Payments” has the meaning set forth in Section 6.1 below.

“Other Treprostini” has the meaning set forth in Section 8.1.

“Party” or “Parties” has the meaning set forth in the preamble.

“Pump” means the infusion pump with the specifications in Exhibit B, and such modifications and upgrades of such pump as allowed or required under this Agreement.

“Pump Complaint” has the meaning set forth in Section 5.9.

“Pump Manufacturer” means the manufacturer (identified in Exhibit B) of the Pump.

“Recipient” has the meaning set forth in Section 13.1.

“Renewal Term” has the meaning set forth in Section 10.2.

“Sandoz” has the meaning set forth in the preamble.

“Supply Agreement” has the meaning set forth in Section 3.1 below.

“Technical Support Office” has the meaning set forth in Section 9.3.

“Term” has the meaning set forth in Section 10.2 below.

“Territory” has the meaning set forth in the recitals.

“Treprostini” has the meaning set forth in the recitals.

“Treprostini Infusion Pumps” means those Pumps designated for the dispensing of Treprostini.

Development of Pumps and Consumables for Administration of Treprostini

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Development of Pump.

1.1.1. Mainbridge shall perform all development, validation and testing activities required to obtain FDA clearance for the Pump and Consumables (the "Mainbridge Development Work"). Mainbridge shall carry out all of the Mainbridge Development Work under this Agreement in a timely, diligent, efficient and skillful manner, consistent with the high professional standards common in the medical device development market. Mainbridge will furnish competent employees to perform its activities under this Agreement. Mainbridge represents and warrants that it has any and all necessary licenses and permissions to perform the Mainbridge Development Work and to enter into this Agreement for Liquidia and Sandoz to perform the Liquidia/Sandoz Development Work, including with Pump Manufacturer.

1.1.2. Liquidia and Sandoz shall provide Mainbridge with product requirements for the Pump and Consumables, which Mainbridge agrees to factor into its completion of the Mainbridge Development Work as appropriate, and shall each have the right to review proposed protocols for verification testing and human factor testing and the results of all such testing (the "Liquidia/Sandoz Development Work" and, collectively with the Mainbridge Development Work, the "Development Work"). Liquidia and Sandoz, collectively, shall carry out all of the Liquidia/Sandoz Development Work under this Agreement in a timely, diligent, efficient and skillful manner, consistent with the high professional standards common in the medical device development market. Liquidia and Sandoz or their Affiliates will furnish competent employees to perform its activities under this Agreement.

1.1.3. Each Party is responsible to the other Parties to report promptly any and all events which may affect the timing of the development of the Pump and Consumables or such Party's ability to perform any tasks assigned to it in a timely manner. The target date to complete the development of the Pumps and Consumables and to have commercially available Pumps and Consumables is [***].

1.1.4. In the event the Parties desire a change in the scope of the Development Work, a request for changes must be made in writing and delivered to the other Parties' Agreement Coordinators. All Parties' Agreement Coordinators shall review the proposed change and either approve it for further investigation or reject it. The investigation shall determine the effect that the implementation of the change shall have on the Development Work including the time to completion. Upon completion of the review, any changes in the Development Work shall be documented in writing and signed by the Parties' respective Agreement Coordinators. If, despite diligent and good faith negotiations, the Parties fail to agree on the character or effect of a change to the Development Work, then the Parties will continue performing the services hereunder without changes.

1.1.5. Each Party will use reasonable efforts to provide to the other Parties with the full measure of cooperation reasonably required to fulfill the objectives of this Agreement with the understanding that obligations or responsibilities for which Sandoz and Liquidia are jointly responsible may be performed by either or both Parties as agreed to between Sandoz and Liquidia as needed. Each Party is further responsible to the other Parties to participate in regular reviews of validation, testing and development, and reviews of any other business issues as they may arise during the Term of this Agreement. The Parties agree to exchange technical and business information pertinent to the Pump and Consumables so that design, development, testing, and conformance to statutory requirements, manufacturing status, service readiness, timing, and costs may be monitored by Liquidia and Sandoz. The Parties will exchange information and assistance which are reasonably necessary for the other Parties to conduct the testing and/or other work hereunder, coordinating all work through their Agreement Coordinators.

1.1.6. Each Party is responsible for providing the necessary systems, personnel, and materials to perform the tasks assigned to it according to the terms of this Agreement. Except as otherwise expressly set forth herein, each Party shall bear all of the costs and expenses incurred by it for any deliverables associated with such Party's Development Work under this Agreement. Except as otherwise expressly set forth herein or otherwise set forth in a separate written agreement between two or more of the Parties, in no event would any Party be entitled to recoup its costs and expenses incurred in connection with the Development Work.

Regulatory Approval. Mainbridge shall be responsible for, and bear the cost of, obtaining and maintaining all regulatory approvals and renewals required for Mainbridge to manufacture, market and sell the Pumps and Consumables in the Territory. Mainbridge shall be responsible for, and bear the cost of, generating and preparing any information needed for regulatory approvals and license maintenance in the Territory.

Supply of Pumps and Consumables

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Purchase of Pumps and Consumables. Consumables and Pumps will be purchased by Liquidia, Sandoz and/or one or more Designated Specialty Pharmacies pursuant to separate purchase agreements (each, a “Supply Agreement”) between Mainbridge and Liquidia, Sandoz and/or a Designated Specialty Pharmacy, as the case may be (with respect to such Supply Agreement, the “Applicable Purchaser”), which will be negotiated between Mainbridge and the Applicable Purchaser in good faith and shall contain terms that are consistent with the terms and conditions of this Agreement and such other terms as are normal and customary in a supply agreement related to medical devices. The prices for the Pumps and Consumables sold to the Applicable Purchaser pursuant to a Supply Agreement shall not exceed those prices set forth in Article 7 of this Agreement. Each of Liquidia and Sandoz shall have the right to add or remove Designated Specialty Pharmacies from time to time, in its sole discretion upon written notice to the other Parties. In the event Liquidia or Sandoz removes a given specialty pharmacy from the list of Designated Specialty Pharmacies, then Mainbridge shall discontinue sales of Pumps and Consumables to such specialty pharmacy except as may be permitted in Article 8.

Obligations of Mainbridge. Mainbridge shall be responsible only for providing Pumps and Consumables to the Applicable Purchasers pursuant to executed Supply Agreements. Mainbridge shall have no responsibility for providing patients with Trepstinil, Pumps or Consumables.

Provision of Forecasts. Under the terms of each Supply Agreement, on or before the last business day of each calendar quarter during the term of such Supply Agreement, the Applicable Purchaser shall provide Mainbridge with non-binding forecasts of the number of Pumps and Consumables that it will require in the upcoming [***] calendar quarters.

Shipping. Each Supply Agreement shall provide for shipping terms governing sales pursuant to that Supply Agreement.

Title and Risk of Loss. Each Supply Agreement shall provide that title and risk of loss to the Pumps and Consumables shall transfer to the Applicable Purchaser upon delivery of the Pumps and Consumables to the FOB location.

Ordering Lead Times. The lead time for submitting purchase orders for the Pumps under each Supply Agreement shall be (i) [***] for the first order and (ii) [***] from and after the FDA Approval Date. The lead time for submitting purchase orders for the Consumables shall be [***]. Any ordering lead time increase shall be subject to the prior written approval of both Liquidia and Sandoz, which approval shall not be unreasonably withheld, and shall only apply to orders placed after such approval.

Warranty and First Level Support. Under each Supply Agreement, Mainbridge will represent and warrant to the Applicable Purchaser that each Pump and Consumable delivered to the Applicable Purchaser will (i) conform with the specifications approved by the FDA for the Pumps and Consumables, (ii) be manufactured in accordance with all applicable laws and regulations, including cGMP, (iii) not be at the time of delivery adulterated or misbranded within the meaning of any applicable federal, state or municipal law, as such laws are constituted and effective at the time of delivery. The Applicable Purchasers shall be responsible for providing or arranging for first level telephone support with respect to Pumps and Consumables. Pumps and Consumables which breach the applicable warranty or which fail out of the box may be returned to Mainbridge by the Applicable Purchaser, and Mainbridge will repair or replace such defective Pumps and Consumables and provide repaired Pumps and/or Consumables or replacement Pumps and/or Consumables to the Applicable Purchaser free of charge. Mainbridge shall also be responsible for the shipping charges incurred by the Applicable Purchaser in returning to Mainbridge Pumps and Consumables that breach the applicable warranty as well as for shipping charges for the shipment of replacement devices to the Applicable Purchaser.

THE WARRANTIES SET FORTH IN SECTION 3.7 ARE THE SOLE WARRANTIES THAT MAINBRIDGE WILL BE OBLIGATED TO PROVIDE IN THE SUPPLY AGREEMENTS WITH RESPECT TO PUMPS AND CONSUMABLES, AND MAINBRIDGE DOES NOT MAKE, AND HEREBY SPECIFICALLY DISCLAIMS, ANY OTHER WARRANTY OF ANY NATURE, WHETHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS SET FORTH IN SECTION 5.8 AND SECTION 11.2 BELOW, MAINBRIDGE’S SOLE LIABILITY WITH RESPECT TO, AND THE SOLE REMEDY OF THE APPLICABLE PURCHASERS

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FOR, PUMPS OR CONSUMABLES THAT BREACH THE WARRANTY SET FORTH IN SECTION 3.7, SHALL BE THE REPAIR OR REPLACEMENT BY MAINBRIDGE OF (OR IF NEITHER OF THE FOREGOING IS POSSIBLE, THE REFUND OF ALL AMOUNTS PAID FOR) SUCH PUMPS AND CONSUMABLES IN ACCORDANCE WITH THE TERMS OF SECTION 3.7 OR THE RECALL PROVISIONS OF SECTION 5.8, AND MAINBRIDGE SHALL HAVE NO OTHER LIABILITY OR OBLIGATION TO THE APPLICABLE PURCHASER WITH RESPECT TO DEFECTIVE PUMPS OR CONSUMABLES. EXCEPT FOR AMOUNTS PAYABLE TO THIRD PARTIES UNDER SECTION 11.2, UNDER NO CIRCUMSTANCES SHALL MAINBRIDGE BE LIABLE TO ANY APPLICABLE PURCHASER FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOSS OF PROFIT, EVEN IF MAINBRIDGE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Sample Pumps. The price for sample Pumps to be used by Liquidia, Sandoz or their agents for marketing and testing shall be as set forth in Section 7.1 of this Agreement.

CHANGES TO PUMPS OR CONSUMABLES

Mainbridge-Initiated Changes. Mainbridge and Pump Manufacturer are free to make changes or modifications to any of the Pumps or Consumables, provided that such initiated changes and modifications to Pumps and Consumables sold to Applicable Purchasers pursuant to Supply Agreements shall be made only as permitted pursuant to this Section 4.1.

1.1.7. Notice of Proposed Changes. If Mainbridge wishes to make any process, design or other change to a Pump or Consumable (a "Mainbridge Proposed Change"), Mainbridge shall give Liquidia and Sandoz prior written notice of such Mainbridge Proposed Change, which notice shall contain a detailed description of the Proposed Change and shall be accompanied by one or more evaluation samples. Mainbridge shall not sell to Liquidia, Sandoz or any Applicable Purchaser any Pumps or Consumables containing a Proposed Change until all of the following have occurred: (a) Section 4.1.2 has been satisfied with respect to the Proposed Change, and (b) all necessary FDA clearances for the Pump and Consumable, with such Mainbridge Proposed Change, have been obtained by Mainbridge. Unless and until all of the foregoing conditions have been satisfied, the then-existing version of Pumps and Consumables being sold to Applicable Purchasers under this Agreement shall continue to be supplied to the Applicable Purchasers pursuant to the terms of this Agreement and the Supply Agreements. For purposes of clarification, the refusal of Liquidia and Sandoz to consent to a Proposed Change shall not affect Mainbridge's right to sell Pumps and Consumables containing the Proposed Change to Mainbridge customers other than Liquidia, Sandoz and the Applicable Purchasers.

1.1.8. Approval of Changes. Mainbridge shall not, without the prior written consent of Liquidia and Sandoz, make or incorporate in any Pump or Consumable provided under this Agreement, any Mainbridge Proposed Change which adversely affects the intended use, function or quality of such Pump or Consumable for the delivery of Trepstinil. Mainbridge shall have the right, without the consent of Liquidia, Sandoz or any Applicable Purchaser, to make process, design or other changes to any Pump or Consumable so long as (i) Mainbridge has complied with Section 4.1.1 and (ii) such changes do not adversely affect the intended use, function or quality of such Pump or Consumable in delivering Trepstinil. If either Liquidia or Sandoz does not consent to a Mainbridge Proposed Change, it must notify Mainbridge within 60 days of receipt of the Mainbridge Proposed Change and specify the intended use, function or quality of the Pump or Consumable that is adversely affected by the Mainbridge Proposed Change. If neither Liquidia nor Sandoz notifies Mainbridge within such 60 days, Liquidia and Sandoz will be deemed to have consented to the Mainbridge Proposed Change. If within 60 days receipt of Liquidia's or Sandoz's objection to a Mainbridge Proposed Change, the Parties have not come to agreement about how to proceed (if at all) with the Mainbridge Proposed Change, the Parties agree to submit the Mainbridge Proposed Change to an FDA pump expert to be agreed to by all Parties (the "Expert") for resolution as to whether such Mainbridge Proposed Change adversely affects the intended use, function or quality of such Pump or Consumable. Mainbridge and any Party(ies) objecting to the Mainbridge Proposed Change shall bear the cost of such Expert equally. If the Parties cannot agree to an Expert, each Party shall choose its own Expert and the two chosen Experts will choose a third Expert who will resolve the dispute.

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Liquidia/Sandoz-Initiated Changes. Liquidia and Sandoz shall each have the right to request that Mainbridge make changes or modifications to Pumps and Consumables, provided that such changes or modifications shall be made only in accordance with the terms of this Section 4.2. If Liquidia or Sandoz wishes Mainbridge to make a modification or change to a Pump or Consumable (a "Liquidia/Sandoz Proposed Change"), Liquidia or Sandoz, as the case may be, shall provide to Mainbridge a written request for such change. Such request shall contain a detailed description of the Liquidia/Sandoz Proposed Change and the reasons for such Liquidia/Sandoz Proposed Change. Mainbridge shall have the right to consent to, or to refuse to consent to, the implementation of such Liquidia/Sandoz Proposed Change. Without limiting Mainbridge's right to refuse consent for any reason, Mainbridge may condition its consent to a Liquidia/Sandoz Proposed Change on Liquidia, Sandoz and Mainbridge reaching mutual agreement as to (a) the responsibility for, and allocation of, the costs of implementing the Liquidia/Sandoz Proposed Change, including without limitation, the costs of undertaking the development and engineering work necessary to implement the Liquidia/Sandoz Proposed Change, the costs of any required clinical trials involving Pumps or Consumables incorporating the Liquidia/Sandoz Proposed Change and the costs of obtaining any required new FDA approvals or new FDA clearances for Pumps containing the Liquidia/Sandoz Proposed Change (which allocation shall take into account whether Pumps and consumables that contain the Liquidia/Sandoz Proposed Change will be exclusive to Liquidia and Sandoz), (b) any changes in price from Mainbridge to Liquidia, Sandoz and the Applicable Purchasers for Pumps and Consumables containing the Liquidia/Sandoz Proposed Change, and (c) any changes in the ordering lead time or delivery schedule for Pumps and Consumables containing such Liquidia/Sandoz Proposed Change. Mainbridge shall not be required to sell to Liquidia, Sandoz or any Applicable Purchaser any Pumps or Consumables containing a Liquidia/Sandoz Proposed Change until all of the following have occurred: (a) Mainbridge has consented in writing to the Liquidia/Sandoz Proposed Change, and (b) all necessary FDA clearances have been obtained by Mainbridge. Unless and until all of the foregoing conditions have been satisfied, the then-existing version of Pumps and Consumables being sold to Liquidia, Sandoz and the Applicable Purchasers under this Agreement and the Supply Agreements shall continue to be supplied to Liquidia, Sandoz and the Applicable Purchasers pursuant to the terms of this Agreement and the Supply Agreements.

REGULATORY AND QUALITY MATTERS

Mainbridge Regulatory Approvals. Mainbridge shall be solely responsible for identifying, obtaining and maintaining at its sole cost and expense all FDA and other clearances and/or approvals which are required for the marketing and sale in the Territory of the Pumps and related Consumables. Mainbridge shall submit a 510(k) clearance application to the FDA for the Pumps within [***] of the execution of this Agreement and will use reasonable commercial efforts to obtain 510(k) clearance for the Pumps.

Regulatory Approvals for Trepstinil. Mainbridge shall have no responsibility for identifying, obtaining, and maintaining all FDA and other approvals which are required for the marketing and sale of Trepstinil in the Territory.

Mainbridge Compliance with Applicable Laws. Mainbridge represents and warrants to Liquidia, Sandoz and the Applicable Purchasers that (i) neither it nor any of its affiliates or suppliers, have been debarred by the FDA, nor, to the best of its knowledge, are any such entities subject to an FDA debarment investigation or proceeding and (ii) Mainbridge will perform all relevant quality control and release procedures on Pumps that are supplied to Applicable Purchasers. Notwithstanding the foregoing, it shall not be a breach of this Agreement if during the Term, an affiliate of Mainbridge is debarred by the FDA or subject to an FDA debarment investigation or proceeding (or similar proceeding of the EMEA) so long as such affiliate is not involved in the manufacture or sale of Pumps or Consumables under this Agreement.

Notification of Defects. If any Party, after the FDA Approval Date, becomes aware of a defect or potential defect in a Pump or Consumable, that Party will promptly deliver written notice of the defect or potential defect to the other Parties, and each Party will provide to the other Parties all information and analysis related to the defect or potential defect reasonably requested by the other Parties. Further, Mainbridge will notify Liquidia and Sandoz promptly (but no later than 48 hours) after receipt of (a) any warning, citation, indictment, claim or proceeding issued or instituted by the FDA, any other governmental entity or agency or any third party against Mainbridge or any of its affiliates with respect to any Pump or Consumable (or the manufacture thereof) or (b) any revocation of

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any license or permit issued to Mainbridge, Pump Manufacturer, or any of their affiliates that is necessary for Mainbridge, Pump Manufacturer, or such affiliate to have Pumps or Consumables manufactured or to sell Pumps or Consumables.

Traceability System. Mainbridge shall maintain a traceability system that assures that each Pump delivered to each Applicable Purchaser can be separately identified. Each Supply Agreement shall require the Applicable Purchaser to maintain a traceability system that assures that each Pump can be traced to the patient to whom such Pump has been provided.

Maintenance of Records. Mainbridge shall maintain quality records with respect to Pumps and Consumables that meet all applicable regulatory requirements.

Quality Audits. Pumps are manufactured by Pump Manufacturer for Mainbridge. Mainbridge will conduct periodic quality audits of Pump Manufacturer manufacturing facilities. Mainbridge will provide Liquidia and Sandoz, within thirty (30) days after completion of each such audit, a certificate stating that such audit has been completed and the date on which it took place.

Recalls. Mainbridge shall promptly notify Liquidia, Sandoz and each Applicable Purchaser in the event of a Pump or Consumables recall. In the event of such a recall, Mainbridge shall notify each Applicable Purchaser of the affected lot or serial numbers of the Pumps and/or Consumables being recalled. Mainbridge will pay freight charges for all recalled Pumps and Consumables from the Applicable Purchasers' facilities to Mainbridge. Replacements for recalled Pumps and Consumables will be shipped free of charge to the Applicable Purchasers by Mainbridge as soon as reasonably feasible.

Complaint Handling and Notification. Liquidia, Sandoz and each Applicable Purchaser shall promptly notify Mainbridge of any Pump Complaints (as hereinafter defined) of which it becomes aware, and Mainbridge will investigate such Pump Complaint. Mainbridge shall maintain a database of all Pump Complaints and any confirmed defects relating to Pumps or Consumables. As used in this Section 5.9, the term "Pump Complaint" means any alleged deficiency relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a Pump or Consumable.

Duty to Report Incidents. Without limiting the obligations of Liquidia, Sandoz and the Applicable Purchasers under Section 5.9 above to notify Mainbridge of all Pump Complaints, Liquidia, Sandoz, the Applicable Purchasers and Mainbridge shall promptly inform each other of incidents, whether occurring in clinical trials or in patient use after the FDA Approval Date, involving death or serious injury, malfunctions that, if recurrent, may cause or contribute to death or serious injury, or other material quality problems or material quality concerns of which such Party becomes aware. Each Party shall fully cooperate with Mainbridge to enable Mainbridge to comply with any reporting obligations regarding such incidents or quality concerns.

MILESTONE PAYMENTS

The following milestone payments shall be payable by Liquidia and Sandoz, collectively, to Mainbridge, subject to the terms set forth below ("Milestone Payments"):

<u>Milestone</u>	<u>Milestone Payment</u>
Execution of this Agreement	[***]
Receipt of FDA notice of Acceptance Review of 510(k) for the Pumps and its associated 510(k) number	[***]
FDA Approval Date	[***]
First Sale Date	[***]

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All Milestone Payments will be invoiced by Mainbridge to Sandoz upon achievement of the applicable milestone and are due and payable within sixty (60) days of the date of the invoice, except the first Milestone Payment. Liquidia shall pay the first Milestone Payment within five (5) business days of the execution of this Agreement. Mainbridge shall notify Sandoz and Liquidia when each subsequent Milestone Payment becomes due. Sandoz shall issue a purchase order to Mainbridge for the total Milestone Payments amount after the first Milestone. Mainbridge shall then submit to Sandoz a written invoice for each Milestone Payment that references the Sandoz purchase order number.

PRICING AND PAYMENT

Pricing for Pumps and Consumables. The pricing to the Applicable Purchasers for the Pumps and Consumables from the date of this Agreement until the end of the [***] period following the FDA Approval Date (the "Initial Pricing Period") shall not exceed [***] per Pump. Following the end of the Initial Pricing Period, Mainbridge may, in its discretion (but no more than once per calendar year), increase the prices for Pumps and Consumables, but not by a percentage in excess of the increase in the medical consumer price index from the date of the last pricing change (or in the case of the first pricing change, the date of this Agreement) to the date of the pricing change then being implemented. Mainbridge will notify Liquidia, Sandoz and the Applicable Purchasers in writing thirty (30) days prior to any such price change taking effect. The Applicable Purchasers' obligation to pay the foregoing prices for the Pumps and Consumables is not contingent on either the availability, or amount, of reimbursement.

Favorable Pricing. Notwithstanding anything in Section 7.1 to the contrary, during the Term, the prices provided by Mainbridge to Liquidia, Sandoz or the Applicable Purchasers in the Territory shall be no higher than the prices at which the Pumps and Consumables (or comparable pumps and consumables) are sold to any third party.

Payment Terms. Milestone Payments and any other amounts due to Mainbridge under this Agreement are to be paid in U.S. Dollars. All payments other than Milestone Payments are due within sixty (60) days of the date of invoice. Any payment which is not made within sixty (60) days of the invoice date may, in the discretion of Mainbridge after a fourteen (14) day grace period, be subject to a late charge of 1.0% per month from the date such payment was due until the date such payment is made in full. If Mainbridge is required to engage third parties (such as attorneys) to collect on payments that are more than sixty (60) days past due, Mainbridge may also collect reasonable fees it incurs, including attorney fees, in the collection of such late payments.

Use Taxes, Sales Taxes and Duties. The prices for the Pumps and Consumables do not include sales taxes or duties that Mainbridge may be required to collect or pay upon shipment of the Pumps and Consumables to Applicable Purchasers, Sandoz or Liquidia. Any applicable sales taxes, duties or similar obligations will be the responsibility of the purchaser and will be invoiced to the purchaser by Mainbridge.

Rights to Protect Pumps for Liquidia/Sandoz Treprostinil

Exclusivity with Respect to Treprostinil. Liquidia and Sandoz shall each have certain exclusive rights, during the Term:

1.1.9. During the Term, Mainbridge will not enter into any agreements (including Supply Agreements) that would permit Pumps or Consumables to deliver generic treprostinil products other than Sandoz's Treprostinil ("Other Treprostinil") without Liquidia's and Sandoz's prior written consent.

1.1.10. With respect to all Pumps and Consumables sold by Mainbridge to parties other than Liquidia, Sandoz or an Applicable Purchaser, Mainbridge will enter into an agreement with such third party whereby the third party agrees that the Pumps and Consumables may not be used to administer treprostinil. Liquidia and Sandoz will be a named third-party beneficiaries of such agreements with respect to the enforcement of the limitations described above.

1.1.11. With respect to all Pumps and Consumables sold by Mainbridge, Mainbridge will provide a copy of all sales contracts to Liquidia and Sandoz (redacted for confidentiality purposes) to demonstrate consistency with Section 8.1.1 and Section 8.1.2.

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1.1.12. Mainbridge, Liquidia and Sandoz will also explore in good faith other methods (including software modifications), as mutually agreed upon among Liquidia, Sandoz and Mainbridge, to prevent the Pumps, other than those purchased by Liquidia, Sandoz and/or Applicable Purchasers, from being used for trestprostnil while not impeding Mainbridge's ability to use Pumps for drugs other than trestprostnil.

Survivability of Liquidia and Sandoz Rights and Mainbridge Rights. Except as set forth in this Article 8, Mainbridge shall retain the right to distribute Pumps and Consumables both inside and outside the Territory. In the event of an early termination of this Agreement due to an uncured Material Breach by Mainbridge or a Bankruptcy of Mainbridge, the exclusive rights granted to Liquidia and Sandoz (and corresponding restrictions on Mainbridge) in this Article 8 shall survive such termination for a period of time equal to the remainder of the Initial Term had this Agreement not been terminated.

Non-Circumvention. Liquidia and Sandoz understand and acknowledge that Mainbridge's relationship with Pump Manufacturer has taken much time and effort to develop and is valuable in nature. Liquidia and Sandoz agree that if Mainbridge has an exclusive contract to sell or market the Pump in the Territory, Liquidia and Sandoz will not (i) enter into an agreement with Pump Manufacturer for the distribution of the Pump and (ii) will not work with Pump Manufacturer to distribute the Pumps in the Territory through parties other than Mainbridge.

Mainbridge Support and Training and Cooperation

Training. At such times and places as the Parties may mutually agree, Mainbridge shall provide to selected employees, sales representatives and customer service representatives of Liquidia, Sandoz and the Applicable Purchasers appropriate training and instruction in the use of the Pumps and Consumables, the procedures necessary to perform quality assurance inspections and troubleshooting of the Pumps and Consumables, and the information necessary to provide first level telephone support to customers and patients with respect to Pumps and Consumables. Ten (10) training days will be provided by Mainbridge without charge to Liquidia, Sandoz and to each Applicable Purchaser, provided that Liquidia, Sandoz and the Applicable Purchasers are responsible for any reasonable travel costs incurred by their respective employees and representatives in attending such training, which shall be held in the United States. Any additional training days requested by Liquidia, Sandoz or any Applicable Purchaser will be provided at a fee of [***] per day, plus any reasonable travel costs incurred by Mainbridge personnel in providing such training, and any travel costs incurred by employees and representatives of Liquidia, Sandoz and/or such Applicable Purchaser in attending such training.

Pump and Consumables Information. Mainbridge shall furnish to Liquidia, Sandoz and each Applicable Purchaser, at no cost to Liquidia, Sandoz or the Applicable Purchaser, information and technical data with respect to Pumps and Consumables to enable Liquidia, Sandoz and/or the Applicable Purchaser to prepare appropriate product descriptions for use in connection with the Pump and Consumables.

Advanced Technical Support. Mainbridge will, on or before the First Sale Date, have established a technical support office, providing 24/7 support for second line questions about Pumps and Consumables ("Technical Support Office"). Prior to Mainbridge implementing such Technical Support Office, Liquidia and Sandoz shall have the right to review and provide input into the plan for the Technical Support Office, including identifying what support patients are likely to require. Mainbridge agrees to work in good faith with Liquidia and Sandoz to incorporate such input into the implementation of the Technical Support Office. Such Technical Support Office will provide trouble-shooting, testing, and technical advice to Liquidia, Sandoz or Applicable Purchasers when they cannot provide first line support.

Servicing of Pumps. Under the terms of the Supply Agreements, Mainbridge will agree to service the Pumps. Mainbridge shall provide a level of service with respect to the Pumps purchased by Liquidia, Sandoz and the Applicable Purchasers that is no less than the service level it provides with respect to other Pumps and at a cost that is no more than the amount charged to service other Pumps.

Agreement Coordinators. Each Party acknowledges that the Parties will need to work closely with each other in order to perform the transactions contemplated by this Agreement. Accordingly, each Party hereby designates a representative who will be such Party's primary contact under this Agreement (such Party's "Agreement Coordinator"). The initial Agreement Coordinator for Mainbridge shall be Douglas Schmidt, the initial Agreement Coordinator for Sandoz shall be identified by Sandoz within 30 days from the execution of this Agreement and the

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initial Agreement Coordinator for Liquidia shall be identified by Liquidia within 30 days from the execution of this Agreement. Any change in the identity of any of the Agreement Coordinators must be communicated to the other Parties in a writing signed by an officer of the Party changing its Agreement Coordinator.

Quarterly Business Reviews. It is expected that the Agreement Coordinators will be in frequent contact with each other. In addition, the Parties shall hold business reviews at least quarterly with respect to the performance of this Agreement. Such quarterly business reviews will be attended by the Agreement Coordinators, at least one other member of management of each Party and such other individuals as the Parties may agree.

Term and Termination

Initial Term. The initial term of this Agreement shall commence as of the date hereof and shall continue until the tenth (10th) anniversary of the FDA Approval Date unless sooner terminated in accordance with this Article 10 (the "Initial Term").

Automatic Extension. Subject to earlier termination pursuant to this Article 10, the term of this Agreement shall automatically be extended for successive one (1) year periods (each a "Renewal Term") unless a Party gives to the other Parties, at least twelve (12) months prior to the expiration of the Initial Term or the expiration of the then-current Renewal Term, written notice of its intention that this Agreement terminate at the end of the then-current term. The Initial Term together with any Renewal Terms shall be referred to herein as the "Term."

Termination. This Agreement may be terminated by a Party (i) in the case of a material breach of this Agreement by another Party (in each case a "Material Breach"), which Material Breach is not cured within thirty (30) days following the giving of written notice of such Material Breach by the non-breaching Party to the breaching Party, or (ii) immediately, if another Party shall file a petition in bankruptcy, shall be adjudicated a bankrupt, shall take advantage of the insolvency laws of any state or nation, be voluntarily or involuntarily dissolved or shall have a receiver, trustee or other court officer appointed for substantially all of its property (collectively, "Bankruptcy").

Termination Upon Discontinuation of Sales of Trepstinil. This Agreement may be terminated by Mainbridge, upon thirty (30) days prior written notice to Liquidia and Sandoz, if Sandoz ceases to sell and distribute Trepstinil.

Survival. The obligations and restrictions described in this Agreement as surviving the termination or expiration of this Agreement, Sections 3.7 and 3.8 and Articles 10, 11, 12, 13 and 14 shall survive any termination or expiration of this Agreement.

Insurance, Indemnification, and Disclaimer of Liability

Maintenance of Insurance by Mainbridge. Mainbridge shall maintain at all times during the Term, product liability insurance with limits of not less than [***] per occurrence and [***] annual aggregate. Liquidia, Sandoz and each Applicable Purchaser shall each be entitled to the benefits of the vendor endorsement to Mainbridge's product liability insurance policy with respect to Pumps and Consumables resold by the Applicable Purchaser, Sandoz and Liquidia, as applicable. Mainbridge shall, from time to time, at the request of Liquidia, Sandoz or the Applicable Purchaser, provide the requester with a certificate of insurance evidencing the foregoing. Failure to maintain such insurance in full force and effect during the Term in accordance with all of the requirements of this Section 11.1, shall be a material breach of this Agreement.

Indemnification by Mainbridge. Mainbridge hereby agrees to indemnify and hold harmless Liquidia, Sandoz, each Applicable Purchaser, their respective successors and assigns, and each present, future and former director, officer, employee, agent and representative thereof (each a "Liquidia/Sandoz Indemnitee"), from and against any and all liabilities, obligations, losses, damages, penalties, claims, actions, suits, costs, expenses and disbursements, including reasonable legal fees and expenses, of whatsoever kind and nature, imposed on, incurred by or asserted against any Liquidia/Sandoz Indemnitee by an unrelated third party, arising out of, or resulting from any claim by such third party that (i) the Pumps or Consumables infringe or violate the intellectual property rights of such third party, or (ii) a manufacturing or design defect in a Pump or Consumable caused personal injury to such third party. The applicable Liquidia/Sandoz Indemnitee shall give Mainbridge prompt written notice of any such

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claim described in this Section 11.2 (a “Liquidia/Sandoz Indemnatee Claim”); provided, however, that failure to provide such notice promptly shall not limit Mainbridge’s obligations under this Article 11 except to the extent Mainbridge was prejudiced thereby. The applicable Liquidia/Sandoz Indemnatee will reasonably cooperate with Mainbridge, at Mainbridge’s sole cost and expense, to defend and/or settle such Liquidia/Sandoz Indemnatee Claim.

Mainbridge shall have sole control over the defense and settlement of the Liquidia/Sandoz Indemnatee Claim. Mainbridge shall not, without the prior written consent of any affected Liquidia/Sandoz Indemnatee, such consent not to be unreasonably withheld, enter into any settlement which imposes on such Liquidia/Sandoz Indemnatee any obligation other than the payment of money, which payment is fully covered by Mainbridge’s indemnification obligations under this Section 11.2.

Limitation of Damages. Except for consequential damages awarded against a Liquidia/Sandoz Indemnatee as a result of a Liquidia/Sandoz Indemnatee Claim, which damages are the responsibility of Mainbridge under Section 11.2, NO PARTY HERETO SHALL BE LIABLE TO THE OTHERS FOR ANY AMOUNTS REPRESENTING LOST REVENUES OR PROFITS, PUNITIVE DAMAGES, OR FOR ANY OTHER INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, EVEN IF THEY WERE FORESEEABLE OR A PARTY HAS INFORMED THE OTHER PARTIES OF THEIR POTENTIAL.

Survival. The indemnification and limitation of liability provisions of this Article 11 shall survive the termination or expiration of this Agreement.

Intellectual Property

Ownership of Intellectual Property Related to Pumps and Consumables. All intellectual property rights of Mainbridge and Pump Manufacturer relating to the Pumps and Consumables, including without limitation, the design thereof, and the technology contained therein, together with all trademark, copyright and patent protection thereon, as well as any trade secrets relating thereto, are, as between the Parties hereto, the sole and exclusive property of Mainbridge or Pump Manufacturer, and this Agreement does not confer on Liquidia or Sandoz any ownership rights in any intellectual property associated with the Pumps or Consumables.

Confidentiality

Confidential Information. During the Term, a Party (the “Recipient”) may receive, orally, or in writing, or have access to, confidential information of another Party (the “Discloser”) including but not limited to, information or data concerning the Discloser’s products or product plans, business operations, strategies, customers and related business information (“Confidential Information”). The Recipient shall not disclose Confidential Information of the Discloser to any third party and shall not use the Confidential Information of the Discloser for any purpose other than the performance of, or exercise of rights or licenses granted in, this Agreement. The Recipient will protect the confidentiality of the Discloser’s Confidential Information with the same degree of care as the Recipient uses for its own similar information, but no less than a reasonable degree of care. Except as permitted above, Confidential Information may be disclosed to, and used by, only those employees of the Recipient who have a need to know such information for the purposes related to this Agreement. The Parties acknowledge that all technical information related to the Pumps and the Consumables is Confidential Information of Mainbridge.

Required Disclosure. Notwithstanding Section 13.1, the Parties acknowledge that a Recipient may disclose Confidential Information of the Discloser if required to do so by law. In the event Recipient is required by law to disclose Discloser’s Confidential Information, the Recipient shall give the Discloser prompt written notice thereof in order to afford the Discloser a reasonable opportunity to seek a protective order or confidential treatment.

Exclusions. The foregoing confidentiality obligations shall not apply to any information that is (a) already known by the Recipient prior to disclosure, (b) independently developed by the Recipient without use of or reference to Discloser’s Confidential Information, (c) publicly available through no fault of the Recipient, or (d) rightfully received by the Recipient from a third party with no duty of confidentiality.

Survival. This Article 13 shall survive termination or expiration of this Agreement.

General Provisions

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Waiver. No departure from or waiver of any of the terms of this Agreement shall be deemed to authorize any prior or subsequent departure or waiver and a Party hereto shall not be obligated to continue any departure or waiver or to permit any subsequent departure or waiver.

Relationship of the Parties. The relationship between the Parties hereto is strictly that of independent contractors. It is not the intent of the Parties to form any partnership or joint venture or similar relationship of any kind.

Assignability. Neither this Agreement, nor any portion hereof, may be assigned by a Party without the prior written consent of the other Parties, which consent shall not be unreasonably withheld. If an entity that purchases all or substantially all of the capital stock or assets of a Party, which merges with a Party, or into which a Party merges, or which purchases the portion of the business of a Party to which this Agreement relates, shall not be considered an assignee for purposes of this provision, so that no consent to assignment shall be necessary in such situation. This Agreement shall be binding upon the successors (including by way of merger, acquisition, etc.) and assigns of both parties.

Notices. All notices, requests or demands required or given hereunder shall be in writing and shall be given by hand delivery or by reputable overnight courier service to the following addresses:

If to Mainbridge: Mainbridge Health Partners
 c/o Mike Ward
 30399 North Chardon Lane
 Grayslake IL 60030

If to Liquidia: Liquidia PAH, LLC
 419 Davis Drive, Suite 100
 Morrisville, NC 27560
 Attn: Scott Moomaw
 E-mail: scott.moomaw@liquidia.com

With copy to:

Liquidia PAH, LLC
419 Davis Drive, Suite 100
Morrisville, NC 27560
Attn: General Counsel
E-mail: legal@liquidia.com

If to Sandoz: Sandoz Inc.
 100 College Road West
 Princeton, NJ 08540
 Attn: President

With a copy to:
Sandoz Inc.
100 College Road West
Princeton, NJ 08540
Attn: General Counsel

Notices shall be deemed given on the date delivered if given by hand delivery or on the second business day following timely delivery to the overnight courier service if given by overnight courier service. This Section shall survive the termination or expiration of this Agreement.

Force Majeure. No Party shall be liable for failure to perform or for delay in performance due to fire, flood, strike or other labor difficulty, act of God, act of any governmental authority which is not specific to such Party, riot, embargo, delay in transportation, or due to any cause beyond such Party's reasonable control, including an inability

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THE REGISTRANT IF PUBLICLY DISCLOSED. [***] INDICATES THAT INFORMATION HAS
BEEN REDACTED.**

to obtain necessary labor or materials that is beyond such Party's reasonable control. In the event of delay in performance due to any cause described in this Section, the time for completion will be extended by a period of time reasonably necessary to overcome the effect of such delay.

Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

Integration; Amendment. This Agreement, together with any Supply Agreement(s) executed between the parties, supersedes any prior agreements between the Parties with respect to the subject matter hereof and contains the entire understanding of the parties with respect to the subject matter hereof. There are no other agreements existing among Mainbridge, Sandoz and Liquidia with respect to the subject matter hereof. This Agreement may not be amended or modified in any manner except by a written instrument properly executed by authorized officers of each Party hereto. The foregoing notwithstanding, this Agreement shall not affect any bilateral agreements between just two of the Parties hereto.

Severability. The invalidity or unenforceability of any term or provision of this Agreement or of the application of any such term or provision to any person or circumstance shall not impair or affect the remainder of this Agreement and its application to other persons or circumstances. Each invalid or unenforceable term or provision shall be enforced to the greatest extent permitted by law and the remaining terms and provisions hereof shall not be invalidated but shall remain in full force and effect.

Publicity/Press Releases. Without the prior written consent of the other Parties, no Party may publicize or disclose to any third party the terms of this Agreement; provided, however, that any Party may disclose the existence of this Agreement to any third party and any Party may disclose the terms of this Agreement as required by law, including the securities laws of the United States, or in confidence in connection with a financing, merger or other acquisition transaction. No Party shall issue a press release with respect to this Agreement or the relationship contemplated hereby without the prior written consent of the other Parties; provided that any Party, may issue a press release without the prior written consent of the other Parties if such press release is necessary to comply with that Party's obligations under the securities laws of the United States.

[signature page follows]

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IN WITNESS WHEREOF, the parties hereby affix their signatures as acceptance of the terms and conditions contained herein as of the date first above written.

Mainbridge Health Partners, LLC

By: /s/ Douglas Schmidt
Name: Douglas Schmidt
Title: President

DATE: 01-Dec-22

Liquidia PAH, LLC

By: /s/ Michael Kaseta
Name: Michael Kaseta
Title: Chief Financial Officer

DATE: 01-Dec-22

Sandoz Inc.

By: /s/ Timothy de Gavre
Name: Timothy de Gavre
Title: VP, Chief Commercial Officer US

DATE: 01-Dec-22

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EXHIBIT A
Description of Consumables

To be mutually agreed to by the parties subsequent to the date this Agreement is executed

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EXHIBIT B
Specifications for Pump

Pump Manufacturer: [***] and its successors and assigns who have rights to distribute or license the right to distribute the Pumps and Consumables in the Territory

Specifications to be mutually agreed to by the parties within thirty (30) days of the date upon which this Agreement is executed. Specifications will be based on the existing [***]

Liquidia Technologies, Inc.

Jurisdiction of incorporation: Delaware
Name under which business conducted: Liquidia Technologies, Inc.

Liquidia PAH, LLC

Jurisdiction of organization: Delaware
Name under which business conducted: Liquidia PAH, LLC

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-259265 and 333-251394) and Form S-8 (Nos. 333-263665, 333-263664, 333-263662, 333-252647, 333-251904 and 333-250179) of Liquidia Corporation of our report dated March 20, 2023 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Raleigh, North Carolina
March 20, 2023

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Roger A. Jeffs, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Liquidia Corporation;
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: March 20, 2023

By: /s/ Roger A. Jeffs, Ph.D.

Name: Roger A. Jeffs, Ph.D.

Title: Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael Kaseta, certify that:

1. I have reviewed this Annual Report on Form 10-K of Liquidia Corporation;
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: March 20, 2023

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer

(Principal Financial Officer)

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Liquidia Corporation, a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Roger A. Jeffs, Ph.D., Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to 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: March 20, 2023

By: /s/ Roger A. Jeffs, Ph.D.

Name: Roger A. Jeffs, Ph.D.

Title: Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Liquidia Corporation, a Delaware corporation (the "Company"), on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Kaseta, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to 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: March 20, 2023

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer
(Principal Financial Officer)
