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.

LIQUIDIA CORPORATION

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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 SM 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 Plastiape'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 Uptravi® (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

YUTREPIA™ (treprostinil) Inhalation Powder to Treat PAH

Our lead investigational drug, YUTREPIA™ (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 form both patient groups provide confidence that a physician may prescribe YUTRPEIA 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.

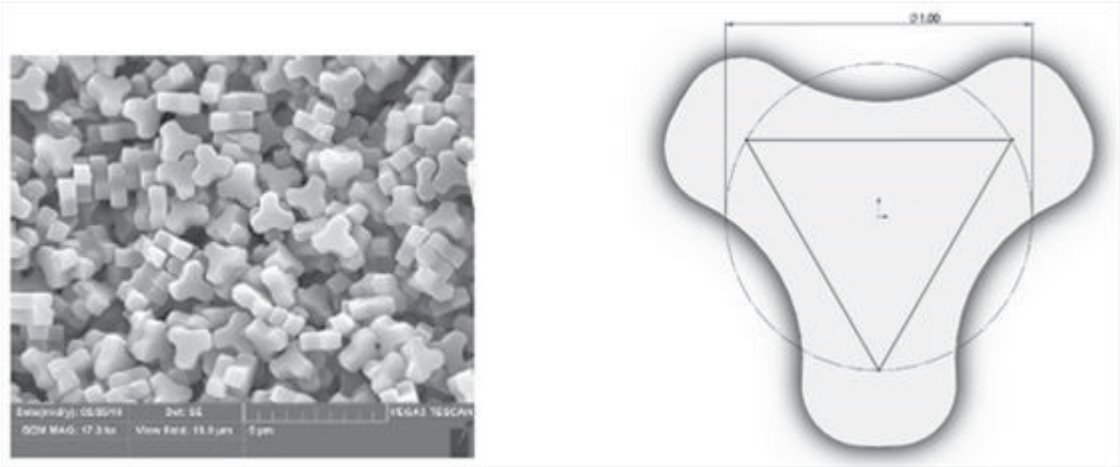
Separately, Smiths Medical has announced that it will discontinue support of the CADD Legacy pump, which is used to administer Treprostinil Injection intravenously, starting in 2028. We are working to identify alternative pumps that may be used for the intravenous administration of Treprostinil Injection.

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 treprostinil, the active pharmaceutical ingredient of YUTREPIA, and we currently rely on a sole supplier, Plastiape S.p.A ("Plastiape"), 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 Treprostinil 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 Treprostinil 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 Treprostinil 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 treprostinil, Treprostinil 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 Treprostinil 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 treprostinil; regulatory submission and interactions with the FDA pertaining to treprostinil, 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 treprostinil; 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 treprostinil.

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 treprostinil, 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 treprostinil, 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 treprostinil 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 helps 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 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 though 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 Uptravi®, 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 as 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 Treprostinil 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 Treprostinil, the Active Ingredient in Remodulin®", and U.S. Patent No. 9,593,066 (the "'066 Patent"), entitled "Process to Prepare Treprostinil, 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 "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 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 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, 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 treprostinil 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 treprostinil, 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 Treprostinil 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 Treprostinil Injection may be adversely affected.

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

Holders

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,		$	%
	2022	2021	Change	Change
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	$ 35,789	$ (7,822)

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
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(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).

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

	Exhibit 10.16 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018).
10.15++	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 Saggar (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).

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

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:

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

LIQUIDIA CORPORATION

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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)

	Year Ended December 31,	
	2022	2021
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	52,287,737	$ 52	$ 374,794	$ (309,581)	$ 65,265
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	64,517,912	$ 64	$ 440,954	$ (350,596)	$ 90,422

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	(28,588)	(34,035)
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	(587)	(107)
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	64,964	26,320
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	$ 93,283	$ 57,494
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,626	$ 423
Cash paid for operating lease liabilities	$ 1,244	$ 1,208
Reduction of lease liability and right-of-use asset from lease modification	$ —	$ 39
Non-cash increase in property, plant and equipment through accounts payable	$ 139	$ —
Non-cash increase in indemnification asset through accounts payable	$ 313	$ 4,895

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

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 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. 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 Treprostinil 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 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 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 treprostinil 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 Treprostinil 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	8,601,571	5,663,054

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:

December 31, 2022	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
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	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
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	$ 4,151	$ 5,017

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	$ 5,522	$ 5,171

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:

	Number of warrants	Exercise Price	Expiration Date
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 deGoa, 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. deGoa's employment on January 31, 2022. However, the CEO Option will remain exercisable so long as Mr. deGoa 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:

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

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	8,398,262	$ 4.49	8.5	$ 17,628
Exercisable as of December 31, 2022	3,327,055	$ 4.03	7.8	$ 9,442
Vested and expected to vest as of December 31, 2022	7,914,670	$ 4.47	8.5	$ 16,849

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 Saggar, 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	407,726	$ 5.57

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 Treprostinil 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	$ —	— %	$ —	— %

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	$ 390

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	Year Ended December 31, 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		$ 947	$ 1,090

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.

Exhibit 31.1

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)

Exhibit 31.2

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)

Exhibit 32.1

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)

Exhibit 32.2

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)

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