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, 2024

or

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

For the transition period from to

Commission File Number: 001-39724

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, 2024 which was the last business day of the registrant's most recently completed second fiscal quarter, was $685,662,096 based on a $12.00 closing price per share as reported on the Nasdaq Capital Market.

As of March 10, 2025, there were 85,298,537 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Liquidia Corporation Definitive Proxy Statement with respect to the 2025 Annual Meeting of Stockholders to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2024 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 includes our trademarks, trade names and service marks, such as Liquidia, the Liquidia logo, YUTREPIA and PRINT, which are protected under applicable intellectual property laws and are the property of Liquidia Technologies, Inc. This Annual Report on Form 10-K 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 on Form 10-K may be forward-looking statements. We intend such forward-looking statements to be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act").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 on Form 10-K. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," contemplates," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "projects," "should," "targets," "will," "would" 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:

- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including the potential for, and timing regarding, final approval by the FDA (as defined below) of and our ability to commercially launch YUTREPIA and L606, including the potential impact of regulatory review, approval, and exclusivity developments which may occur for competitors, and the scope of any such approvals and the indications for which we receive approval;
- the timeline or outcome related to our patent litigation with United Therapeutics that was filed in the U.S. District Court for the District of Delaware, our litigation with United Therapeutics that was filed in the Superior Court for Durham County, North Carolina, the lawsuit we filed against the FDA in the U.S. District Court for the District of Columbia, including the cross claims filed by United Therapeutics in that action, or any future litigation with United Therapeutics or any other third-party, including any related rehearings or appeals;
- the timing and our ability to enroll our planned clinical trials for our product candidates, including planned clinical trials for YUTREPIA and L606;
- the timing and availability of data from our clinical trials and our ability to meet endpoints in such clinical trials;
- our plans to develop and commercialize our product candidates;
- the timing and related contents of our planned regulatory filings and/or applications;
- 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 ability and sufficiency of our current manufacturing facilities to produce development and commercial quantities of our product candidates;
- our ability to establish and maintain collaborations, including any third-party license agreements;
- our expectations regarding the size of the patient populations, market opportunities, market acceptance, third-party payor coverage and opportunity for those products that we commercialize, including our own products and products we commercialize in collaboration with third parties, including Sandoz's 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 ICU Medical's CADD-MS® 3 ambulatory infusion pump ("CADD-MS 3 infusion pump"), the RG 3ml Medication Cartridge that we developed in collaboration with Chengdu Shifeng Medical Technologies LTD. used for the subcutaneous administration of Sandoz's generic treprostinil injection, ICU Medical's CADD Legacy and CADD-Solis infusion pumps used for the intravenous administration of Sandoz's generic treprostinil injection, an infusion pump that we are developing with Sandoz for the subcutaneous administration of Sandoz's generic treprostinil injection, Plastiape's RS00 Model 8 dry powder inhaler, which we plan to use for the administration of YUTREPIA, and any devices used for the administration of L606;
- our and our business partners' ability to develop and to obtain and maintain regulatory clearances and approvals, and the timing of any such clearances and approvals, for medical devices used to administer our products and products we commercialize, including a nebulizer for the administration of L606 and the infusion pump that we are developing with Sandoz;
- the effects on our company or our subsidiaries of future changes in law, including regulatory developments or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we are subject, tariffs that may apply to products that we purchase or sell, or judicial decisions overturning or establishing new legal precedents;
- adverse outcomes of pending or threatened litigation or governmental investigations, including our ongoing litigation involving United Therapeutics and the FDA and any future litigation with United Therapeutics, the FDA or any other third party;
- the failure to renew, or the revocation of, any license or other required permits;
- our ability to retain, attract and hire key personnel;
- our intellectual property position and the duration of our patent rights;
- prevailing economic, market and business conditions;
- changes in the industry in which we operate;
- the volatility and unpredictability of the stock market and credit market conditions;
- conditions beyond our control, such as natural and man-made disasters, global health emergencies, such as pandemics and epidemics, or geopolitical conflict, such as acts of war, terrorism and civil disorder;
- our ability to continue operations as a going concern without obtaining additional funding;
- our ability to satisfy the covenants contained in the HCR Agreement (as defined below);
- the cost and availability of capital and any restrictions imposed by lenders or creditors;
- 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 the Company or our subsidiaries may be different from market expectations, 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;
- conduct of and changing circumstances related to third-party relationships on which we rely, including the level of credit worthiness of counterparties;
- fluctuations in interest rates;
- fluctuations in the trading price of our common stock;
- variations between the stated assumptions on which forward-looking statements are based and our actual experience;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and
- our expectation that the use of proceeds from prior public and private equity 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. The forward-looking statements in this Annual Report on Form 10-K 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 ("Liquidia Technologies") and Liquidia PAH, LLC (formerly known as RareGen, LLC ("RareGen")), a Delaware limited liability company ("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 rare cardiopulmonary diseases such as pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). We operate through our wholly owned operating subsidiaries, Liquidia Technologies and Liquidia PAH, formerly known as RareGen.

We currently generate revenue 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. We employ a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of PAH and PH-ILD in the United States, as well as key stakeholders involved in the distribution and reimbursement of medicines to treat these patients. We established our commercial presence in the field to support Treprostinil Injection and have since expanded our presence to support the potential launch of YUTREPIA (treprostinil) inhalation powder ("YUTREPIA"), further validating our reputation as a company committed to supporting PAH and PH-ILD 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, to enable 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 and PH-ILD. 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 effort dry-powder inhaler ("DPI") and by achieving higher dose levels than the labeled doses of current inhaled therapies. On August 16, 2024, the United States Food and Drug Administration (the "FDA") (i) granted tentative approval for our New Drug Application ("NDA") for YUTREPIA for the treatment of PAH and PH-ILD and (ii) simultaneously determined that Tyvaso DPI, approved on May 23, 2022, qualifies for a three-year New Clinical Investigation exclusivity for the chronic use of dry powder formulations of treprostinil for the approved indications. As a result, final approval of YUTREPIA for PAH and PH-ILD is delayed until after expiry of the three-year regulatory exclusivity for Tyvaso DPI on May 23, 2025.

We are also developing L606, an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, which we licensed from Pharmosa Biopharm Inc. ("Pharmosa"). L606 is currently being evaluated in an open-label study in the United States for treatment of PAH and PH-ILD with a planned pivotal study for the treatment of PH-ILD.

About Pulmonary Arterial Hypertension and Pulmonary Hypertension Associated with Interstitial Lung Disease

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"), Chronic Obstructive Pulmonary Disease ("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 45,000 patients.

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. We currently estimate diagnosed and undiagnosed prevalence of PH-ILD in the United States to be approximately 60,000. The prevalence of PH in many of the underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until 2021.

Treatments

There is currently no cure for PAH or PH-ILD, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression and improve quality of life. The FDA has approved several classes of drugs to treat PAH over the last 25 years, including drugs acting through the prostacyclin pathway, the nitric oxide pathway, the endothelin pathway and, starting in 2023, the inhibition of activin signaling. There are currently only two FDA-approved treatments for PH-ILD, both of which are inhaled forms of treprostinil, a prostacyclin analog. Without a curative treatment, we expect continued development of new mechanisms of action that may be used in combination with approved 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. Increased drug exposure of prostacyclin analogs like treprostinil, if tolerated by the patient, has demonstrated increased clinical benefit, making it the only titratable mechanism of action to treat these diseases.

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. Observations from a large retrospective study of Tyvaso supported the finding that higher doses of inhaled treprostinil correlated to better clinical outcomes including delayed transition to more invasive administration, persistence on therapy, and improved three-year survival. 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 2024, the total reported net revenue of branded therapies that targeted the prostacyclin pathway to treat PAH and PH-ILD in the United States was $4.1 billion. United Therapeutics reported that its class of branded treprostinil-based products generated U.S. net revenue of $2.5 billion in 2024, of which the Tyvaso® franchise contributed $1.6 billion, Orenitram contributed $434 million and Remodulin® contributed $464 million. Since 2019, reported annual sales of products in the Tyvaso franchise have increased from $400 million to $1.6 billion, correlating with the expansion into the PH-ILD indication in 2021 and addition of Tyvaso DPI in 2022.

Our Products and Product Candidates

YUTREPIA™ (treprostinil) Inhalation Powder to Treat PAH and PH-ILD

Our lead investigational drug, YUTREPIA™ (treprostinil) inhalation powder, 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 the labeled doses of current inhaled therapies while using a convenient, easy-to-use dry-powder inhaler, the RS00 Model 8 DPI. YUTREPIA was initially tentatively approved by the FDA for the treatment of PAH in November 2021. In August 2024, the FDA (i) granted tentative approval for our NDA for YUTREPIA for the treatment of both PAH and PH-ILD and (ii) simultaneously determined that Tyvaso DPI, approved on May 23, 2022, qualifies for a three-year New Clinical Investigation exclusivity for the chronic use of dry powder formulations of treprostinil for the approved indications. As a result, final approval of YUTREPIA for PAH and PH-ILD is delayed until after expiry of the three-year regulatory exclusivity for Tyvaso DPI on May 23, 2025.

We believe YUTREPIA can become the prostacyclin of first choice across the disease continuum in PAH and PH-ILD because of its convenience, low-effort 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 a low-effort, 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. By contrast, Tyvaso DPI uses a high resistance device that has only been used previously in patients with diabetes.

YUTREPIA has been safely titrated to doses higher than the target labeled doses of Tyvaso and Tyvaso DPI. Historically, the labeled dose range for inhaled treprostinil has been 9-12 nebulized breaths per session (“bps”), for Tyvaso and the corresponding doses of Tyvaso DPI (up to 64 mcg, comparable to 12 bps). In contrast, YUTREPIA has been studied in PAH patients up to 291.5 mcg four times a day (comparable to at least 33 bps of Tyvaso), and in PH-ILD patients, as high as 318 mcg (comparable to at least 36 bps of Tyvaso) as part of an on-going open-label clinical study. The different combinations of YUTREPIA’s four proposed capsule-strengths allow customized dosing and titration based on a patient’s disease progression. This expanded dose range of YUTREPIA may allow patients to remain on inhaled treprostinil therapy longer before transitioning to more invasive 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 the first two months of treatment. Patients on a stable dose of Tyvaso successfully transitioned to YUTREPIA while maintaining or improving clinical outcomes as measured by exploratory endpoints. The combination of data from both patient groups provide confidence that a physician may prescribe 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 NDA for YUTREPIA in January 2020. The FDA conducted on-site pre-approval inspections of two U.S. manufacturing facilities: our 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. In July 2023, we filed an amendment to our NDA to add PH-ILD to the labeled indications for YUTREPIA. The FDA issued a tentative approval of the amended NDA for both PAH and PH-ILD in August 2024. Final FDA approval of the NDA for YUTREPIA is delayed until the expiration on May 23, 2025 of New Clinical Investigation exclusivity that was granted to Tyvaso DPI.

Final FDA approval and launch may be impacted by litigation commenced by United Therapeutics in which it may seek to enjoin approval and launch of YUTREPIA as 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"). Of the 121 patients enrolled in the study, 55 were Transition patients and 66 were 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.

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 observed to date being 291.5 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 9 bps of Tyvaso (54 mcg). For reference, the target dose of Tyvaso is 9 to 12 bps, 4 times daily. Clinical results from the PK, pivotal and extension 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) from 2019 through 2024.

We are actively conducting and considering other clinical trials to generate additional data to support the use of YUTREPIA. In December 2023, we enrolled the first PH-ILD patient in the Open-Label Prospective Multicenter Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in Pulmonary Hypertension, referred to as the ASCENT study.

Future studies may include pediatric patients as well as transitions to, or combinations with, YUTREPIA and other approved treatments.

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 infusion 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 $464 million and $415 million in 2024 and 2023, 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 for Treprostinil Injection, Sandoz maintains responsibility for compliance with FDA regulatory and healthcare laws including any regulatory communications with the FDA or any other regulatory authorities with respect to Treprostinil Injection. 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 infusion 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 infusion pump manufactured by Smiths Medical.

Smiths Medical no longer manufactures or supports the CADD-MS 3 infusion pump. We have also experienced shortages of critical components 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. Although we believe that the number of available CADD-MS 3 infusion pumps will be sufficient to serve existing patients using Treprostinil Injection through at least the end of 2025, it is possible that the availability of CADD-MS 3 infusion pumps could end earlier. 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 December 2022, we entered into a Device Development and Supply Agreement (the "Pump Development Agreement") 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 replace the existing CADD-MS 3 infusion pumps.

Mainbridge is performing development, validation and testing activities required for the pump and related consumables. We have not yet submitted a 510(k) clearance application for a pump under the Pump Development Agreement and are currently uncertain when, if ever, such a 510(k) clearance application will be submitted with respect to the pump under development with Mainbridge. We and Sandoz are also evaluating alternative pump options for the subcutaneous administration of Treprostinil Injection, but we do not yet have any agreements in place with respect to the development of any alternative pumps. We and Sandoz are splitting the costs to develop a new pump equally.

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. Smiths Medical's CADD-Solis infusion pump has been identified as a replacement for the CADD Legacy pump, and patients can use the CADD-Solis pump in anticipation of the discontinuation of the CADD Legacy pump.

L606

In June 2023, we entered into the Pharmosa License Agreement (as defined below) pursuant to which we were granted an exclusive license in North America to develop and commercialize L606, an inhaled, sustained-release liposomal formulation of treprostinil currently being evaluated in a clinical trial for the treatment of PAH and PH-ILD. In October 2024, we and Pharmosa entered into the First Amendment (as defined below) to expand our licensed territory to include key markets in Europe, Japan and elsewhere, in addition to licensing proprietary nebulizers controlled by Pharmosa and being evaluated for use in a planned global pivotal study for the treatment of PH-ILD. L606 is a complement to our pipeline and furthers our mission to provide innovative treatment options that improve the lives of patients with improved product profiles.

L606 offers potential substantial benefits to patients with less frequent dosing than current inhaled products, improved tolerability with lower peak exposures and rapid delivery with a next-generation nebulizer. We believe L606 may provide best-in-class treprostinil exposure over a 24-hour period, including during sleeping hours, which could translate to improved efficacy, tolerability, and patient outcomes. Liposomes as a pulmonary drug delivery system have been reported to enhance the therapeutic benefits of drugs and to reduce the potential for systemic adverse effects. The L606 suspension uses Pharmosa's proprietary liposomal formulation to encapsulate treprostinil, which can be released slowly under a controlled manner/rate into the lung. This control enables modulation of drug release to achieve optimized drug exposure over an extended period of time and reducing local irritation on the respiratory tract.

L606 is supplied in six different dose strengths in disposable ampules, packaged as fourteen ampules in a foil pouch representing one week's supply of drug. L606 is administered with the L606 inhalation system (mesh-vibrating nebulizer), which is currently undergoing testing. Before each treatment session, a L606 ampule would be opened and the suspension would be transferred into the medication chamber of L606 nebulizer for oral inhalation. The L606 formulation inhalation system consists of an electronic, lightweight, and virtually silent mesh-vibrating nebulizer which can deliver a dose in less than 2-minutes using breath-actuated smart technology and patients' normal breathing pattern. The vibrating mesh technology generates fine-particle aerosols of the L606 formulation. Pharmosa has demonstrated clinically that L606 can be used with devices supplied by different manufacturers, providing us the option to improve the patient device experience without changing the intended dose administered.

We intend to develop L606 through the 505(b)(2) registration pathway in the United States. The FDA confirmed in meetings with Pharmosa, and subsequently with Liquidia in December 2023, that the registration requirements for L606 to treat PAH and PH-ILD should include clinical data that provides (i) comparable bioavailability to nebulized Tyvaso® in a Phase 1 study of health volunteers, (ii) short-term and long-term safety data from an open-label study in PAH and PH-ILD patients, and (iii) demonstrated efficacy from a single Phase 3 placebo-controlled efficacy trial in PH-ILD patients. Liquidia has also met with representatives in the European Medicines Agency ("EMA") to solicit input in support of the global Phase 3 study which will include PH-ILD patients in the European Union.

Comparable bioavailability was established in a Phase 1, randomized, 2-part study that was conducted by Pharmosa at a clinical research unit in the USA. The systemic exposures of a single dose of L606, 51 mcg, and, Tyvaso, 54 mcg, were compared. L606 resulted in a similar systemic exposure ("AUCinf") compared with the equivalent dose of Tyvaso, with a significantly reduced peak plasma concentration ("Cmax"), approximately 7.3-fold lower for L606 than for Tyvaso.

L606 demonstrated extended plasma concentrations up to 12 hours after a single dose, supporting a reduction in dosing frequency to twice daily, or every 12 hours. Peak and total exposure of treprostinil increased with increasing dose.

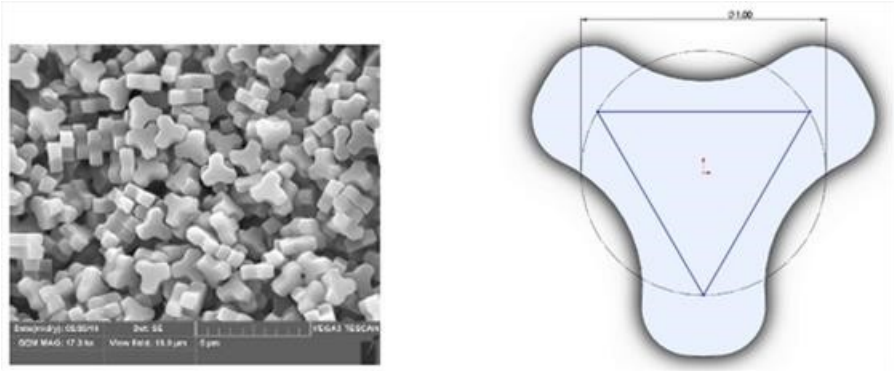
We are currently conducting in the United States an open-label study to assess the safety of L606 in patients with PAH and patients with PH-ILD transitioning from Tyvaso (nebulizer or dry-powder inhaler) or patients with PAH naïve to prostacyclins. The open-label study was fully enrolled during 2024 with 28 patients and includes some patients who have been successfully treated with L606 for longer than one year. L606 continues to be well tolerated up to our maximum dose of 318 mcg twice-daily, which is approximately 2 to 2.5-fold higher than comparable target dosing of Tyvaso (9 to 12 bps) four times daily.

We are preparing to conduct a global placebo-controlled efficacy study in PH-ILD. The clinical design will include approximately 340 patients across more than 100 sites in at least 20 countries. The primary outcome measure will be six-minute walk distance. To initiate the study, we must also support regulatory submissions related to the proprietary nebulizer which will be used in combination with L606.

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. 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. 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.

YUTREPIA leverages PRINT® technology to produce dry-powder drug particles that enhance deep-lung delivery. YUTREPIA drug particles are uniform in size (~1µm) and shape having been engineered for enhanced aerosolization and deep-lung deposition. 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 dry-powder formulation aerosolizes into free-flowing particles upon inhalation, allowing for the use of a low-effort inhaler. 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 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 United States. 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 United States either by ourselves or through partnership or licensing arrangements with other pharmaceutical companies. Outside of the United States, 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 a combination of in-house capabilities and external contract manufacturing organizations ("CMOs"), depending on the program requirements. For example, our current plans are for the dry powder formulation of YUTREPIA to be manufactured internally using PRINT Technology and for CMOs to produce, package and distribute YUTREPIA finished goods on a commercial scale. Conversely, L606 is planned to be manufactured exclusively by CMOs using the proprietary formulation methods provided by Pharmosa.

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 targeted sales force, calling on physicians involved in the treatment of PAH and PH-ILD in the United States, as well as key stakeholders involved in the distribution and reimbursement of therapies for PAH and PH-ILD. Strategically, we believe that our existing 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 and PH-ILD patients. Our commercial efforts focus on the highly concentrated target market of PAH and PH-ILD centers of excellence and high prescribers of approved 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 our specialty field team and other support functions, like medical science liaisons and reimbursement specialists to support the proper conveying of scientific, medical, and healthcare economic information regarding our products.

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, initial commercial demand for YUTREPIA.

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 and CMOs for commercial inventory and clinical supplies of YUTREPIA, including active pharmaceutical ingredients which are used in our product candidates. For example, we currently rely on a sole supplier, LGM Pharma, LLC ("LGM"), 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 ("Lonza"), for encapsulation and packaging services for YUTREPIA. If and when we receive final marketing approval for YUTREPIA, we expect to continue to rely on

third-party CMOs to manufacture, package and distribute some or all of our supply of YUTREPIA 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 infusion pumps and enable subcutaneous administration of Treprostinil Injection. The pumps used to administer Treprostinil Injection are currently all manufactured by ICU Medical, with whom we have no contractual relationship. We have entered into the Pump Development Agreement with Sandoz and Mainbridge for the development of a new pump for the subcutaneous administration of treprostinil.

L606 is manufactured exclusively by CMOs using the proprietary liposomal formulation methods provided by Pharmosa. Under the License Agreement, Pharmosa will manufacture clinical and commercial supplies of L606 and support Liquidia in establishing a redundant global supply chain. The proprietary nebulizer used to administer L606 will be manufactured by a third party. We are continuing to evaluate several options for the nebulizer that we will plan to use for L606.

Our Collaboration and Licensing Agreements

Pharmosa License Agreement

In June 2023, we entered into a license agreement with Pharmosa pursuant to which we were granted an exclusive license in North America to develop and commercialize L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of PAH and PH-ILD, and a non-exclusive license for the manufacture, development and use (but not commercialization) of such licensed product in most countries outside North America (the "Pharmosa License Agreement"). On October 2, 2024, we and Pharmosa entered into a First Amendment to the Pharmosa License Agreement (the "First Amendment") which, among other things, expands our licensed territory beyond North America to include key markets in Europe, Japan and elsewhere.

Concurrently with the execution of the First Amendment, we and Pharmosa also entered into a Device License Agreement (the "Device License Agreement"). Pursuant to the terms of the Device License Agreement, Pharmosa will provide (i) an exclusive license to Liquidia Technologies for the right to develop, manufacture, use and commercialize Pharmosa's next-generation smart-technology nebulizers (the "Device") for use with L606 in most countries (subject to certain exceptions) (the "Territory") and (ii) a non-exclusive license to Liquidia Technologies for the right to develop, manufacture and use (but not commercialize) the Device outside of the Territory.

Under the terms of the Pharmosa License Agreement, as amended, we will be responsible for development, regulatory and commercial activities of L606 in the Territory. Pharmosa will manufacture clinical and commercial supplies of the liposomal formulation through its global supply chain and support us in establishing a redundant global supply chain. In consideration for these exclusive rights, we paid Pharmosa an upfront license fee of $10 million and paid an additional $3.5 million upfront license fee in October 2024 in connection with the rights granted in the First Amendment and the Device License Agreement. In addition to the upfront fees, we will pay Pharmosa potential development milestone payments tied to clinical development and approvals in PAH and/or PH-ILD of up to $37.75 million, potential sales milestones of up to $185 million in North America and $150 million outside North American and two tiers of low, double-digit royalties on all net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication approved by the FDA after PAH and PH-ILD and each additional product approved by the FDA under the license, a $2 million milestone payment for each additional indication approved by the EMA after PAH and PH-ILD, and a $0.5 million milestone payment for each additional indication approved by Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") after PAH and PH-ILD.

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 Injection 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 on identifying, manufacturing and developing medical devices, including pumps and cartridges, that may be used to administer Treprostinil Injection. As the ANDA holder for Treprostinil Injection, Sandoz retains all rights to Treprostinil Injection and 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 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, and 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.

We and Sandoz also entered into a Pump Development Agreement with Mainbridge for the development of a new pump for the subcutaneous administration of treprostinil. Pursuant to 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. Sandoz and Liquidia PAH have agreed to split all of these 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 Treprostinil Injection 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 Treprostinil Injection 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 Treprostinil Injection 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 Treprostinil Injection 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 Treprostinil Injection 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 Treprostinil Injection 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 Treprostinil Injection 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. ("Aerie"), which in 2017 acquired most of the assets of Envisia Therapeutics, Inc., for broad usage in the design and commercialization of small molecule and biologic ophthalmic therapies. In November 2022, Alcon Inc. ("Alcon") completed its acquisition of Aerie to help bolster Alcon's presence in the ophthalmic pharmaceutical space and, as a result, retains Aerie's exclusive license to the use of our PRINT technology for ophthalmic therapies.

GlaxoSmithKline

In March 2023, we and GSK plc ("GSK") entered into a Research License Agreement (the "GSK License Agreement") which supersedes and replaces our prior agreements with GSK. Pursuant to the GSK License Agreement, the Company has granted to GSK a non-exclusive, non-sublicensable (except to affiliates), royalty free license to use our PRINT technology for the sole purpose of conducting pre-clinical research and pre-clinical development of inhaled formulations of GSK's Molecules in the Field and in the Territory (capitalized terms are as defined in the GSK License Agreement). The Company and GSK will each own and retain all rights, title, and interest in and to all inventions, discoveries and other subject matter (including Know-How (as defined in the GSK License Agreement)) together with all intellectual property rights therein which are owned or controlled by such party as of the date of the GSK License Agreement or which are invented or acquired by or on behalf of such party independent of the GSK License Agreement.

Liquidia is permitted to continuously use its PRINT technology for any inhaled formulation other than certain identified GSK proprietary molecules, pursuant to the GSK License Agreement. Under the terms of the new agreement, GSK will be required to seek an expanded license before it may use PRINT for clinical or commercial purposes.

Unless earlier terminated, the GSK License Agreement will continue in effect until the later of (i) the expiration of the last-to-expire Valid Claim (as defined in the GSK License Agreement) included within the Liquidia Technology (as defined in the GSK License Agreement) and (ii) all Arising PRINT Improvements (as defined in the GSK License Agreement) and Liquidia Know-How (as defined in the GSK License Agreement) are in the public domain. GSK may terminate the Agreement upon at least thirty days' prior written notice to the Company. The GSK License Agreement may also be terminated by either party for a material breach by the other party, subject to notice and cure provisions, or in the event of the other party's insolvency. In the GSK License Agreement, each party made customary representations and warranties and agreed to customary covenants, including, without limitation, with respect to indemnification, for transactions of this type.

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 127 patents and pending patent applications in our patent portfolio which protect our PRINT technology and drug products in development. As of December 31, 2024, we were the sole owner of 20 patents in the United States and 42 patents in foreign jurisdictions, as well as 11 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 42 patents and 12 patent applications licensed from third parties. As of December 31, 2024, we had an exclusive, worldwide license from UNC to 14 U.S. patents and 7 foreign patents, as well as one additional patent applications in the United States or selected foreign jurisdictions. Five of the patents and one patent application in the portfolio licensed from UNC are jointly owned by us. Also, as of December 31, 2024, we had an exclusive, worldwide license from Pharmosa Biopharm to four U.S. patents and 17 foreign patents, as well as 11 additional patent applications in the United States or selected foreign jurisdictions. YUTREPIA is specifically protected by 16 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.

Our product candidates, YUTREPIA and L606, will compete for market share to treat patients diagnosed with PAH or PH-ILD. Treprostinil Injection, which we commercialize with Sandoz, competes only in the PAH market. Each disease has different competitive forces as described below.

Competition in PAH

Our products and development programs directed toward the treatment of PAH compete with several approved classes of drugs in clinically validated signaling pathways. These drugs may be used alone or in combination and may include branded or generic formulations or molecules with the following mechanisms of action: antagonists of endothelin receptors ("ERAs") such as bosentan, macitentan and ambrisentan); PDE5 inhibitors in the nitric oxide pathway such as tadalafil and sildenafil; soluble guanylate cyclase ("sGC") stimulators such as riociguat; inhibitors of activin signaling such as sotatercept; and agonists of the prostacyclin pathway that either bind to the IP receptor, such as selexipag, or are analogs of endogenous prostacyclin, such as treprostinil, iloprost and epoprostenol. The branded forms of these molecules are commercialized by large pharmaceutical companies such as Johnson & Johnson under the name Janssen/Actelion, Gilead Sciences, Inc., Bayer Schering Pharma AG, Merck & Company, and United Therapeutics.

In PAH treatment, therapies targeting the prostacyclin pathway are usually added after oral formulations of ERAs, PDE5 inhibitors and/or oral sGCs. Injections of sotatercept, approved in March 2024, are usually added to patient therapy after prostacyclin products, but its clinical use is developing. It is possible that sotatercept may come to be used prior to prostacyclin therapies, which may have an adverse effect on the market potential for YUTREPIA and/or L606.

Competition with prostacyclin-targeted treatments in PAH

Inhaled prostacyclin products. We expect that our products will face competition from the following inhaled prostacyclin analogs, which may be more tolerable than systemically delivered oral and infused products.

- Tyvaso (treprostinil), is a nebulized formulation marketed by United Therapeutics for the treatment of PAH 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.

- Tyvaso DPI (treprostinil) is a dry-powder formulation commercialized by United Therapeutics in partnership with MannKind Corporation. Tyvaso DPI was approved for the treatment of PAH in May 2022.

- Ventavis® (iloprost) is the only other inhaled prostacyclin analog and marketed by Actelion, a division of Johnson & Johnson. Approved to treat PAH since 2004, Ventavis is administered six to nine times per day via a nebulizer. Ventavis is still available to patients though utilization has significantly dwindled due to the more frequent and burdensome treatment regimen.

Orally delivered prostacyclin products. Oral products are perceived to be more convenient than inhaled and infused products. Orenitram® (treprostinil), dosed three-times daily and sold by United Therapeutics, and Uptravi® (selexipag), dosed twice daily and sold by Janssen Pharmaceuticals/Actelion, are both approved to treat PAH.

Infused prostacyclin analogs. Our Treprostinil Injection product to treat PAH 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 iloprost and epoprostenol, which are 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-MS 3 infusion pumps currently used to deliver treprostinil subcutaneously. United Therapeutics also maintains intellectual property that could lead to improved product profiles for a variety of PAH treatments, including using prodrugs of treprostinil to decrease site pain associated with subcutaneous delivery or extend the release profile of treprostinil. Similarly, Corsair Pharma, a former partner of United Therapeutics, is developing a prodrug and transdermal patch intended to provide continuous and consistent blood levels of treprostinil comparable to an infusion pump.

Competition in PH-ILD

Unlike PAH, there is less competition from competing products and mechanisms of action ("MOAs") to treat PH-ILD patients. Inhaled treprostinil is the only approved treatment and route of delivery. In April 2021, United Therapeutics announced that Tyvaso was approved by FDA as the first and only treatment for patients with PH-ILD. Tyvaso DPI is also indicated to treat PH-ILD. We expect other programs to initiate trials given the very clear unmet needs of this patient group.

Potential competition from products in development to treat PAH and/or PH-ILD

We also expect continued development by competitors of clinically validated or novel MOAs that may be approved during the period of time that our products, if approved, are being commercialized. The approval of some or any of these could change the treatment paradigm and impact the utilization of our products in the prostacyclin class. Specific products in later stage development include:

- Ralenipag, a once-daily oral IP agonist, is being developed by United Therapeutics to treat PAH as a better choice to twice-daily oral Uptravi (selexipag). Data from the pivotal studies may be reported in 2026.

- Treprostinil Palmitil Inhalation Powder ("TPIP"), a once-daily, dry-powder formulation of a treprostinil prodrug, is being developed by Insmed to treat PAH and PH-ILD. Insmed expects to complete a placebo-controlled Phase 2 trial in PAH in 2025, having already concluded a smaller open-label Phase 2 study in PH-ILD in 2024.

- Seralutinib, a tyrosine kinase inhibitor delivered as an inhaled dry-powder, is being developed by Gossamer to treat PAH and PH-ILD. Results from Phase 2 study met the primary endpoint with greater effects in patients with more severe disease. Gossamer expects data from a Phase 3 study in PAH in 2025 and has stated they intend to also initiate a Phase 3 study in PH-ILD in 2025. If successful, this would be the second MOA to treat both PAH and PH-ILD.

- Mosliciguat, a once-daily, inhaled sGC activator, is being developed by Pulmovant to treat PH-ILD, building on the body of knowledge from approved oral sGC stimulators in PAH. Pulmovant has initiated a Phase 2 study in 2024, having presented favorable data from a Phase 1 study demonstrating tolerability and a clinically meaningful reduction in pulmonary vascular resistance ("PVR"). If successful, this would be a potential third MOA to treat PH-ILD.

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 and/or PH-ILD in the United States, including programs from Cereno Scientific, Novartis AG, and Forsee Pharmaceuticals among others.

Human Capital

As of March 10, 2025, we employed 157 salaried and 13 hourly employees, 168 of whom are located in the United States and two of whom are located in Europe. 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 December 31, 2031 and includes an option for us to renew the lease for an additional five years through December 31, 2036. The primary use of this location is general office, laboratory, research and development and light manufacturing. 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 on Form 10-K and all of our filings under 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 authorities in the United States at the federal, state and local level, the European Union, the United Kingdom 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.

Government Regulation in the United States

United States Drug Development Process

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

Failure to comply with the applicable requirements in the United States 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 new 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 institutional review board ("IRB"), data safety monitoring boards ("DSMBs") or ethics committees ("ECs") at each clinical site before each trial may be initiated or continued;

- 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 FDA inspections 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 study commitments or requirements 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, IRBs, DSMBs, or ECs must review and approve the plan for any clinical study before it commences at any institution, and the IRBs must conduct continuing review and reapprove the study at least annually. IRBs, DSMBs, or ECs consider, among other things, whether the risks to individuals participating in the clinical study are minimized and are reasonable in relation to anticipated benefits. The IRBs, DSMBs, or ECs also approve 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, DSMBs, or ECs 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, IRBs, DSMBs, or ECs can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the requirements of IRBs, DSMBs, or ECs 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.

United States 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; chemistry, manufacturing, and control ("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

Drug products may obtain FDA marketing approval pursuant to an NDA (described above) for innovator products, or an ANDA for generic products. Relevant to ANDAs, the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") amended the FDCA to establish 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 reference listed drugs). Because the safety and efficacy of reference 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 reference 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 reference 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 for obtaining FDA marketing approval 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. An application with a section viii statement or carve out may be approved if the removal of language from the label necessitated by the carve out does not make the generic drug less safe or effective.

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 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, 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 drugs, biological products, or medical devices may be 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. L606 is also classified as a drug/device combination as it relies on the use of nebulizer. Both YUTREPIA and L606 will seek approval by way of the NDA process by CDER as their primary mode of action is their drug component.

Expedited Development and Review Programs

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These expedited review programs are referred to as fast track designation, breakthrough therapy designation and priority review designation. The FDA has published a final Guidance for Industry titled "Expedited Programs for Serious Conditions-Drugs and Biologics" which provides guidance on the FDA programs that are intended to facilitate and expedite development and review of new product candidates as well as threshold criteria generally applicable to concluding that a product candidate is a candidate for these expedited development and review programs.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The FDA may designate a product as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team, and taking other steps to design the clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity or mortality. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival

or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, the manufacturer of an investigational drug for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on responding to requests for expanded access. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

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. Under the Prescription Drug User Fee Act, there are also 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.

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, 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. 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 Extension

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension ("PTE") under the Hatch-Waxman Act. The Hatch-Waxman Act permits the extension of a patent term by up to five years as compensation for patent term

effectively lost during product development and the FDA regulatory review process. However, PTE 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 PTE. PTEs are not granted as a matter of right and 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. 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. The length of such PTEs will depend on the length of the regulatory review; however, there can be no assurance that any such extension will be granted to us.

Regulatory Exclusivity

Regulatory, non-patent 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 data 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 ("NCE") 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 NCE 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 new clinical investigation marketing 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 new clinical investigation marketing 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.

Under the FDCA, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan designation subsequently receives either the first FDA approval for the disease or condition for which it has such designation or, if not the first FDA approval for such drug for the treatment of such disease or condition, such drug is clinically superior to any already approved or licensed drug that is the same drug for such disease or condition, the product is entitled to orphan product marketing exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be

entitled to orphan exclusivity. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

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. 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, 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 –Risks Related to Government 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.

Government Regulation Outside of the United States

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.

European Union

In the European Union ("EU") and the European Economic Area ("EEA"), Regulation (EU) 536/2014 on clinical trials (the "CTR") requires sponsors to submit a single clinical trial application ("CTA") through the Clinical Trials Information System ("CTIS"), an online portal designed to streamline the authorization process. Under the previous Directive 2001/20/EC (the "CTD"), sponsors had to obtain separate approvals in each EU/EEA member state. In contrast, CTIS serves as a single-entry point, allowing sponsors to apply for trial authorization in up to 30 EU/EEA countries through a unified process. The CTIS authorization procedure consists of two parts: (i) during the Part I assessment, member states collaborate to assess the CTA jointly and (ii) during the Part II assessment, each member state conducts an individual assessment of the CTA. All ongoing clinical trials in the EU/EEA were required to transition to CTIS by January 30, 2025, marking the end of a three-year transition period that began when the CTR became applicable, repealing the CTD.

Medicinal products need a marketing authorization ("MA") to be placed on the EU market. The MA is issued following a scientific assessment of the quality, safety, and efficacy of the product. To obtain an MA, pharmaceutical companies

may submit MA applications ("MAA") under the centralized, decentralized, mutual recognition, or national authorization procedure.

Under the centralized procedure, the European Commission ("EC") grants a single MA, valid in all EU/EEA member states, following a favorable opinion from the European Medicines Agency (the "EMA"). The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicinal products ("ATMPs"), and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, autoimmune diseases and other immune dysfunctions, or viral diseases. The centralized procedure is optional for products containing new active substances for indications other than those stated above, products that represent a significant therapeutic, scientific, or technical innovation, or whose authorization would be in the interest of public health. Under this procedure, the maximum evaluation timeframe for an MAA by the EMA is 210 days, excluding "clock stops" when the applicant must provide additional written or oral information in response to questions from the Committee for Medicinal Products for Human Use ("CHMP"). Alternative pathways may apply in specific cases, including:

- *Accelerated Assessment Procedure* – Reduces the review period from 210 to 150 days for products of major public health interest that offer significant therapeutic innovation.
- *Conditional MA* – Granted when comprehensive clinical data is not yet available, but the product addresses an unmet medical need and demonstrates a favorable benefit-risk profile.
- *MA under Exceptional Circumstances* – Applies when full safety and efficacy data may never be obtainable, usually due to the rarity of the condition.
- *PRIME Scheme* – Streamlines development and provides early scientific advice, potentially leading to accelerated assessment during the MAA.

While the mutual recognition procedure ("MRP") and decentralized procedure ("DP") both result in national MAs, the assessment process is coordinated across the EU. The key difference between such procedures is that the MRP applies to products already authorized in at least one EU member state on a national basis and the DCP is used for products not yet authorized in any EU member state. The evaluation process can take up to 210 days under the DCP and 90 days under the MRP after the submission of a valid MAA. Once all involved member states reach an agreement on the assessment, the procedure concludes, and each member state must grant a national MA. While this authorization should be issued within 30 days, in practice, national phase timelines and fees vary, as they are subject to individual national regulations. The national procedure grants an MA that is valid only in the member state where it is issued.

An MA has an initial validity of five years, with some exceptions. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU member state in which the original MA was granted. The EC or the competent authorities of the EU member states may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period.

The EMA's Committee for Orphan Medicinal Products ("COMP") may recommend orphan medicinal product designation to promote the development of medicines for life-threatening or chronically debilitating conditions affecting no more than five in 10,000 people in the EU. The COMP can only recommend orphan designation to products that offer a significant clinical benefit over existing approved treatments for the relevant indication. Orphan medicinal product designation entitles the sponsor to financial incentives, such as fee reductions or waivers, and grants 10 years of market exclusivity following approval of the MA. During this period, regulatory authorities cannot approve a similar medicinal product for the same therapeutic indication unless the holder of the MA for the original orphan medicinal product has given his consent to the second applicant, the new product offers a significant clinical benefit, or the holder of the MA for the original orphan product is unable to supply sufficient quantities. This period of protection is extended by two years for medicines that also have complied with an agreed pediatric investigation plan granted at the time of review of the orphan medicine designation.

In the EU, MAAs for generic medicinal products do not require the inclusion of pre-clinical and clinical trial results. Instead, they can refer to the data included in the MA of a reference product, provided that the data exclusivity period for the reference product has expired.

Medicines containing a new active substance qualify for eight years of data exclusivity and are granted an additional two years of market exclusivity upon MA. The data exclusivity period prevents generic applicants from relying on the preclinical and clinical trial data in the dossier of the reference product when applying for a generic MA in the EU. This restriction lasts for eight years from the date the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic applicant from commercializing its product in the EU until 10 years have passed since the initial MA of the reference product in the EU. This 10-year market exclusivity period can be extended to a maximum of 11 years if, during the first eight years, the MA holder obtains approval for one or more new therapeutic indications that, upon scientific evaluation, are determined to bring a significant clinical benefit compared to existing therapies.

Controls on the pricing of medicines in the EU, as well as decisions on their reimbursement by national social security systems, are determined exclusively at the national level. As a result, access to reimbursement and pricing decisions can vary significantly across the member states.

Recently adopted and pending legislation in the EU will impact regulatory procedures for medicinal products, including the Regulation (EU) 2021/2282 on health technology assessment ("HTA Regulation") adopted in January 2025, which, among other things, is designed to increase cooperation between EU member states to provide for a common assessment of clinical effectiveness to be taken into account by national reimbursement authorities across the EU. In addition, in April 2023, the European Commission adopted a proposal to revise the EU pharmaceutical legislation consisting of a new directive that would replace Directive 2001/83/EC and Regulation (EC) 726/2004, among others. The EU legislative process remains ongoing, with several stages still required before the regulations may receive final approval. If approved, such regulations would mark a significant overhaul of the current EU pharmaceutical legal framework and is anticipated to have a wide range of impact, including, but not limited to, regulatory approval procedures, regulatory data and market exclusivity periods, incentives for orphan medicines, and the so-called "Bolar exemption," among others.

Regulation (EU) 2017/745 (the "MDR") governs medical devices in the EU. Unlike medicinal products, medical devices do not require prior authorization from regulatory authorities. However, they must undergo a conformity assessment procedure and obtain the "CE" marking before being placed on the EU market. The specific conformity assessment procedure varies depending on the device's risk classification. For Class I devices, manufacturers may carry out the conformity assessment autonomously. Conversely, for Class IIa, IIb, and III devices, the assessment requires the involvement of a notified body. Medical devices intended to administer medicinal products qualify as (i) medical devices, where the medicinal product is supplied separately, or (ii) medicinal products, where the device and the medicinal product are placed on the market as a "single integral product" which is intended exclusively for use in the given combination and is not reusable. Single integral products must be authorized as medicines in the EU, while also meeting the general requirements that apply to medical devices. Examples of single integral products include pre-filled syringes, pre-filled pens, nebulizers pre-charged with a specific medicinal product, patches for transdermal drug delivery and pre-filled inhalers.

United Kingdom

The Medicines and Healthcare products Regulatory Agency ("MHRA") is the standalone regulator for medicinal products and medical devices in the United Kingdom. Starting in January 2025, only the MHRA has authority to approve new medicines across the entire United Kingdom, whereas for medical devices, the EU rules continue to apply with respect to Northern Ireland only.

MAs for medicinal products in the United Kingdom are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 2021, MAs previously submitted using the EU centralized procedure are not valid to be considered in the United Kingdom. As a result, companies established in the United Kingdom cannot use the EU centralized procedure and instead must follow one of the United Kingdom's national authorization procedures or

remaining international cooperation procedures established after the United Kingdom's withdrawal from the European Union in 2020 ("Brexit") to obtain an MA to market products in the United Kingdom. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into MAs in the United Kingdom, effective in Great Britain only, free of charge starting in January 2021, unless the MA holder opted-out of this option.

The MHRA has introduced additional changes to MA procedures in the United Kingdom post-Brexit. This includes the introduction of procedures to prioritize access to new medicines that will benefit patients, which includes a 150-day assessment route and a rolling review procedure. In addition, since January 2024, the MHRA has been able to rely on the International Recognition Procedure ("IRP") when reviewing certain types of MAs. This procedure is available for MA applicants who have already received approval for the same product from a reference regulator, which includes the FDA, the EMA, and national competent authorities of individual EU countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the EU mutual recognition or decentralized procedures are also considered to have received marketing approval for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the United Kingdom. The MHRA reviews applications for orphan designation in parallel to the corresponding MA. The orphan designation criteria in the United Kingdom are similar to those in the EU, but have been tailored for the United Kingdom market. For example, to be eligible for orphan designation in the United Kingdom, the prevalence of the condition in Great Britain, rather than the EU, must not be more than five in 10,000 individuals. Upon the grant of an MA with orphan designation, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. This market exclusivity period will begin on the date of first approval of the product in Great Britain.

The current regulatory framework in the United Kingdom with respect to clinical trials is derived from the EU CTD. Amendments to the United Kingdom's regulatory framework governing clinical trials are currently going through the parliamentary process, and the new rules are expected to apply starting in 2026, following a one-year transition period.

The regulatory framework in the United Kingdom with respect to medical devices is also expected to undergo significant changes. The current applicable legislation in Great Britain is largely still based on the European Economic Community's Medical Devices Directives (93/42/EEC), which is no longer in effect in the EU after the adoption of the EU MDR, which came into effect after Brexit, and consequently was only implemented in Northern Ireland according to the provisions of the Windsor Framework. Notwithstanding the differing legal regimes in place in the United Kingdom, medical devices with a valid CE marking from the EU are authorized to be placed in the United Kingdom market until June 30, 2030 at the latest, depending on the device type and classification.

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 will depend on our ability to fund future operations and capital requirements with additional capital from external financing.
- We have a history of losses and our future profitability remains uncertain. Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.

- We are primarily dependent on the success of our product candidates, YUTREPIA and L606, and these product candidates may fail to receive final marketing approval (in a timely manner or at all) for some or all of the indications for which we are seeking approval or may not be commercialized successfully.
- United Therapeutics has initiated multiple lawsuits against us in which it has claimed that YUTREPIA is infringing its patents, two separate lawsuits 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 and that United Therapeutics is entitled to an ownership interest in a portion of our intellectual property, and a separate lawsuit against the FDA asserting that the FDA improperly accepted for review an amendment to our NDA for YUTREPIA. These lawsuits, and other lawsuits that United Therapeutics may file in the future, may result in our company being further delayed in its efforts to commercialize YUTREPIA, result in substantial damage claims against us if we launch YUTREPIA and we are later found to infringe or to have misappropriated trade secrets, or result in United Therapeutics owning an interest in a portion of our intellectual property.
- Our clinical trials, including our planned pivotal clinical trial of L606, may be delayed or may not be successful and delays to such clinical trials may cause our costs to increase and significantly impair our ability to commercialize our product candidates.
- Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection, the RG Cartridge or pumps used to administer Treprostinil Injection and is dependent on Sandoz, Chengdu and the pump manufacturers to manufacture and supply Treprostinil Injection, the RG Cartridge and pumps used to administer Treprostinil Injection, respectively, in compliance with FDA requirements, and is more broadly dependent on their FDA and healthcare compliance relative to Treprostinil Injection, the RG Cartridge and the pumps used to administer Treprostinil Injection, respectively.
- Treprostinil Injection is presently administered subcutaneously via ICU Medical's CADD-MS 3 infusion pump. ICU Medical no longer manufactures or supports the CADD-MS 3 infusion pump. It is expected that, over time, the CADD-MS 3 infusion pumps that are currently available and in service will require maintenance and therefore cease to be available. 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 ICU 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 and/or L606 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 and/or L606.
- Our financing facility with HealthCare Royalty Partners IV, L.P. ("HCR") 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 or third-party payor coverage.
- Our product candidates are based on proprietary, novel technology, which have 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. In addition, we may experience unexpected challenges as we ramp up our manufacturing capacity to meet demand or during commercial manufacturing, which may result in our inability to supply sufficient quantities of product to meet demand.

- Our business and operations may be adversely affected by the effects of global health emergencies, including pandemics and epidemics.
- We may not be able to build or maintain a commercial operation, including establishing and maintaining marketing and sales capabilities or entering 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 and single suppliers for the drug product and device for L606. In the event of any disruption in these supplies, our ability to develop and commercialize, and the timeline for commercialization of, YUTREPIA and/or L606 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 will depend on our ability to fund future operations and capital requirements with additional capital from external financing.

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, 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. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for and successfully commercialize one or more of our 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 will depend on our ability to fund future operations and capital requirements with additional capital from external financing. We may seek additional funding through public or private financings, debt financing or collaboration. Our inability to obtain funding, 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. Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.

We have incurred net losses of $130.4 million during the year ended December 31, 2024, and $78.5 million and $41.0 million during the years ended December 31, 2023 and 2022, respectively. We also had negative operating cash flows for each of these periods. As of December 31, 2024, we had an accumulated deficit of $559.5 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. We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow. These factors raise substantial doubt about our ability to continue as a going concern and to satisfy our estimated liquidity needs for one year from the issuance of the consolidated financial statements included in this Annual Report on Form 10-K. Accordingly, we will require additional funding over the next twelve months to continue our operations and maintain compliance with debt covenants, and could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or commercialization efforts, which could adversely affect our business prospects, or potentially force us to cease operations.

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 and/or L606 or for which there may be a greater likelihood of success.

We expect that we will need to raise additional funds to meet our future funding requirements for the continued research, development and commercialization of our product candidates and technology. 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. 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 fail to obtain financing 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 HealthCare Royalty Partners IV, L.P. ("HCR") 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.

Under the terms of the revenue interest financing agreement with HCR dated January 9, 2023, as amended (the "HCR Agreement"), 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 to maintain at all times a minimum cash balance of $15.0 million. Our obligations under the HCR Agreement are collateralized by all of our assets and property, subject to limited exceptions.

If we breach certain of our covenants in the HCR Agreement 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 HCR Agreement, 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 September 2024 public equity offering, the September 2024 Private Placement, the January 2024 Private Placement 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 and servicing of pumps for the administration of Treprostinil Injection, the development of L606, 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.

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, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, our business and prospects may be materially and adversely affected.

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 "IRC"), 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. Given our many financings and other equity issuances, including our September 2024 public equity offering, our September 2024 Private Placement, our January 2024 Private Placement, our December 2023 public equity offering, our December 2023 private placement, our April 2022 public equity offering, our 2021 private placement, the closing of the RareGen acquisition in November 2020, our July 2020 public 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 such "ownership changes" 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.

Changes to existing tax laws, or challenges to our tax positions could adversely affect our business and financial condition.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. Following the change in U.S. administration, there is uncertainty regarding future legislative and regulatory changes and policies related to matters such as taxation and importation, and any such proposed or enacted regulations by the current or a future U.S. administration, Congress, or taxing authorities in other jurisdictions could materially affect our tax obligations and operating results.

For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. In January 2024, the U.S. House of Representatives passed the Tax Relief for American Families and Workers Act, which would retroactively repeal for 2022 and 2023, and defer until 2026, the requirement to capitalize research and development expenditures for research activities conducted in the United States. Uncertainty exists as to whether the bill will be enacted into law. In addition, the IRA, among other things, included a new 15% alternative minimum tax on the adjusted financial statement income of certain large corporations for tax years beginning in 2023. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes could adversely impact our business, results of operations and financial position.

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 in connection with the development of our product candidates and commercialization of any approved products.

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 ANDA for Treprostinil Injection and is responsible among other things for the compliant manufacture, distribution, labeling, and advertising of Treprostinil Injection. As a result, we are dependent on Sandoz to manufacture and supply Treprostinil Injection, and are 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, or cGMPs; 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. 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;
- any requirements by third-party payors to use generic treprostinil for parenteral administration in place of Remodulin;
- our ability to maintain availability of medical devices used to administer Treprostinil Injection and preferences of the target patient population and health care providers regarding the medical devices used to administer Treprostinil Injection versus medical devices used to administer 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 YUTREPIA, L606 and Treprostinil Injection.

In order for YUTREPIA, L606 or Treprostinil Injection to be administered to patients, patients must use certain other medical equipment, including dry powder inhalers (in the case of YUTREPIA), nebulizers (in the case of L606), and pumps, cartridges and infusion sets (in the case of Treprostinil Injection). We do not manufacture or control such medical equipment, which is manufactured by third parties. In addition, while we will distribute the necessary medical devices used for YUTREPIA and L606 in kits with our product, the medical devices for Treprostinil Injection are owned and dispensed by specialty pharmacies, hospitals or other third parties. Our ability to serve patients is dependent upon our ability and 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 we or specialty pharmacies are unable to obtain or maintain sufficient inventories of such medical equipment, our sales may be adversely impacted. If any manufacturers of such medical devices experience any quality problems, recalls or other adverse events, our ability to provide our products to patients will be limited.

The nebulizers we plan to use with L606 are currently undergoing testing and review. If those tests or reviews are delayed or do not yield satisfactory results, the nebulizers may require design changes and/or additional testing or we may need to identify and develop a different nebulizer for use with L606, all of which may delay the commencement of our planned pivotal trial for L606.

In addition, to administer Treprostinil Injection through subcutaneous injection, patients currently must use the CADD-MS 3 infusion pump manufactured by ICU Medical. ICU Medical no longer manufactures or supports the CADD-MS 3 infusion pump. Although we believe that the number of available CADD-MS 3 infusion pumps will be sufficient to serve patients through at least the end of 2025, it is possible that the availability of CADD-MS 3 infusion pumps could end earlier. Due to this limitation in the availability of pumps, specialty pharmacies will limit the number of patients that they place on subcutaneous Treprostinil Injection therapy in order to ensure that patients placed on subcutaneous administration of Treprostinil Injection will not have to discontinue such treatment due to the unavailability of CADD-MS3 infusion pumps. Until we are able to obtain a pump to replace the CADD-MS 3 infusion pump, 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.

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 a Pump Development 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 or, even if they do receive FDA 510(k) clearance for any such pumps, that they will do so in a timely manner. For example, we have still not submitted a 510(k) clearance application for a pump under our agreement with Sandoz and Mainbridge and are currently uncertain when, if ever, such a 510(k) clearance application will be submitted. If we are unable to identify, develop and obtain any required FDA clearance for new pumps for the subcutaneous administration of Treprostinil Injection prior to the unavailability of the CADD-MS 3 infusion pump, we may no longer be able to serve patients with Treprostinil Injection through the subcutaneous 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 at multiple financial institutions that may exceed the Federal Deposit Insurance Corporation insurance limits. If such financial institutions were to fail, we could lose all or

a portion of those amounts held in excess of such insurance limitations. If financial institutions with whom we hold accounts enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets or otherwise, our ability to access our existing cash may be threatened and could have a material adverse effect on our business, financial condition and results of operations. 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 its patents and that we have misappropriated its trade secrets and confidential information and has initiated a lawsuit against the FDA challenging the FDA's acceptance of our amended NDA for YUTREPIA for review, which may result in our company being further delayed in its efforts to commercialize YUTREPIA and may limit the indications for which YUTREPIA is approved.

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.

In connection with an amendment to our NDA filed in July 2023 to add PH-ILD as an indication for YUTREPIA, we provided a new notice of the paragraph IV certification to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, in September 2023, United Therapeutics filed a complaint for patent infringement against us in the U.S. District Court for the District of Delaware (Case No. 1:23-cv-00975-RGA) (the "New Hatch-Waxman Litigation"). In the New Hatch-Waxman Litigation, United Therapeutics is asserting that the Company infringes U.S. Patent No. 11,826,327 (the "'327 Patent"), entitled "Treatment for Interstitial Lung Disease." In February 2024, United Therapeutics filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. The motion for a preliminary injunction was denied in May 2024, and trial is currently scheduled for June 2025.

Although we do not believe United Therapeutics is entitled to a new 30-month stay or a preliminary injunction in connection with the New Hatch-Waxman Litigation, it is possible that the Court could rule that a new mandatory 30-month delay has been triggered with respect to the approval of the 505(b)(2) NDA application or that a preliminary injunction is warranted.

In February 2024, United Therapeutics also filed a lawsuit against the FDA, challenging the FDA's acceptance of our amended NDA for review (the "Original FDA Litigation"). In March 2024, United Therapeutics filed a motion for a temporary restraining order in the Original FDA Litigation, seeking to enjoin the FDA from approving our NDA for YUTREPIA with respect to the indication to treat PH-ILD. United Therapeutics' motion was denied in March 2024. In May 2024, both we and the FDA filed motions to dismiss United Therapeutics' complaint. Prior to the Court's ruling on the motions to dismiss, United Therapeutics voluntarily dismissed its complaint in the Original FDA Litigation without prejudice. In September 2024, United Therapeutics re-asserted its challenge to FDA's acceptance of our amended NDA for review as a cross claim in the lawsuit we instituted against the FDA in August 2024 (the "New FDA Litigation"). Although we do not believe the arguments of United Therapeutics have merit, it is possible that the Court could rule that the FDA must reject the amendment to the YUTREPIA NDA to add PH-ILD to the label, in which case we may be required to later file a supplement to our NDA to add PH-ILD to the label. If we are required to file a supplement to add PH-ILD to the label for YUTREPIA, although we do not believe United Therapeutics would be entitled to a new 30-month stay, it is possible that the FDA or a Court could rule that a new mandatory 30-month delay has been triggered with respect to the supplement.

In addition, United Therapeutics may seek to assert newly issued patents against us, including U.S. Patent Number 11,723,887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA through one or more additional legal proceedings.

As a result of this litigation instituted to date and potential litigation that may be instituted in the future, final FDA approval of YUTREPIA for PAH and/or PH-ILD may be further delayed even after Tyvaso DPI's New Clinical Investigation exclusivity expires on May 23, 2025. Further, even if we receive FDA approval for YUTREPIA, we may be subject to significant delay and incur substantial additional costs in litigation before we are able to commercialize YUTREPIA, if at all. In addition, if United Therapeutics is successful in any of its claims that it has brought to date or any claims it may bring in the future, we may be unable to commercialize YUTREPIA for the treatment of one or more indications or at all until the expiration of the applicable United Therapeutics patents, which could materially harm our business. For example, in the event United Therapeutics prevails with respect to its claims regarding the '327 Patent, it is possible that an injunction could be issued, preventing the FDA from granting final approval for YUTREPIA for PH-ILD or forcing the FDA to revoke any prior approval for YUTREPIA for PH-ILD. Also, although United Therapeutics' initial requests for injunctive relief have been denied, if United Therapeutics is successful in obtaining a preliminary injunction or temporary restraining order in the New Hatch-Waxman Litigation or the New FDA Litigation, we could be limited to commercializing YUTREPIA only for the PAH indication for an extended time period.

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 (the "Former Employee") conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2024, the Former Employee filed a motion for summary judgment on all claims, but the motion was denied in July 2024. In addition, in July 2024, the Company filed a motion for summary judgment with respect to all claims. Briefing on the Company's motion is complete and a hearing was held in December 2024. The motion remains pending.

In May 2024, United Therapeutics filed a second complaint in the Superior Court in Durham County, North Carolina, against the Former Employee, alleging that he breached prior employment agreements with United Therapeutics by failing to assign to United Therapeutics his interest in patents obtained by the Company that relied upon or benefitted from certain inventions, discoveries, materials, authorship, derivatives and results developed by the Former Employee while he was employed by United Therapeutics. The Company was also named as a defendant in this new lawsuit. As part of the lawsuit, United Therapeutics alleges that the Former Employee misappropriated certain intellectual property of United Therapeutics which led to the development of YUTREPIA. The complaint also seeks declaratory judgement such that all right, title and interest in and to any patentable or unpatentable inventions, discoveries, and ideas made or conceived by the Former Employee while employed by the Company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. In July 2024, the Company filed a motion to dismiss all claims. Briefing on the motion is complete and a hearing was held in December 2024. The motion remains pending.

Success in a lawsuit, including in any such lawsuit 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 in one proceeding, including with respect to a given patent, patent claim or trade secret, does not mean we will be similarly successful with respect to that same or a similar patent, patent claim or trade secret in another proceeding.

If we are found to infringe, misappropriate or otherwise violate any of 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 or other correspondence with the FDA, as United Therapeutics has done, 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 and PH-ILD, and L606, a nebulized, liposomal formulation of treprostinil for treatment of PAH and PH-ILD, will face competition from the following inhaled prostacyclin analog therapies that are either currently marketed or in clinical development:

- Tyvaso (treprostinil), marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009 and for PH-ILD since 2021. 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.

- Tyvaso DPI (treprostinil), 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.

- 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 has announced that it expects to complete a placebo-controlled Phase 2 trial in PAH in 2025, having already concluded a smaller open-label Phase 2 study in PH-ILD in 2024. Based on these Phase 2 results, Insmed has stated that it intends to pursue discussions with global regulatory authorities on the design of pivotal trials to support indications in PAH and PH-ILD. 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.

- Ventavis® (iloprost), marketed by Actelion, a division of Johnson & Johnson, has been approved for the treatment of PAH in the United States since 2004.

In addition to these other inhaled treprostinil therapies, we expect that YUTREPIA and L606 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 specialty pharmacies, Teva Pharmaceutical Industries Ltd. launched a generic treprostinil for parenteral administration in October 2019 that is sold primarily through specialty pharmacies 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. launched a generic treprostinil for parenteral administration in April 2023, 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 and/or PH-ILD include the following:

- ***IP-agonists to treat PAH***, such as selexipag, marketed by Actelion, and ralinepeg, licensed from Arena Pharmaceuticals, Inc. by United Therapeutics, which is currently in Phase 3 clinical development with initial results expected in 2025.
- ***Endothelin receptor antagonists to treat PAH***, such as bosentan and macitentan, both marketed by Actelion, and ambrisentan, marketed by Gilead. Generic versions of bosentan and ambrisentan are currently available.
- ***PDE-5 inhibitors to treat PAH***, such as tadalafil, marketed by United Therapeutics, and sildenafil, marketed by Pfizer Inc. Generic versions of both tadalafil and sildenafil are currently available.
- ***sGC stimulators***, such as oral riociguat marketed by Bayer for PAH, and inhaled mosliciguat being developed by Pulmovant for PH-ILD.
- ***Activin signaling inhibitor to treat PAH***, such as sotatercept marketed by Merck & Co.

Merck & Co's injectable sotatercept, with a brand name of Winrevair, was approved by the FDA in March 2024 and is a first-in-class molecule that targets the proliferation of cells in the pulmonary arterial wall. Its clinical use is developing, and it is possible that it may be used prior to prostacyclin therapies, which may have an adverse effect on the market potential for YUTREPIA and/or L606.

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 and/or PH-ILD in the United States, including programs from Gossamer Bio, Inc., Cereno Scientific, Novartis AG, and Forsee Pharmaceuticals among others.

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 Investigation 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). For example, United Therapeutics was recently awarded New Clinical Investigation exclusivity for Tyvaso DPI, which will expire in May 2025. As a result, the FDA will be unable to approve YUTREPIA until after the exclusivity expires in May 2025. In the event United Therapeutics sought and was able to obtain one or more other regulatory exclusivities with respect to Tyvaso DPI, it could further significantly delay our ability to obtain final approval for YUTREPIA. Even if the FDA does not recognize any new regulatory exclusivity for United Therapeutics, United Therapeutics could challenge the FDA's decision and seek an injunction to prevent approval of YUTREPIA in one or more indications until such challenge has been decided.

In addition, if one of our competitors is granted marketing approval before we are able to obtain FDA approval for our product candidates, as was the case with respect to the approval of United Therapeutics' Tyvaso DPI product, such competitors will be able to promote and market their products before we are able to do so, which may place us at a competitive disadvantage in the marketplace.

One or more products that are competitive with YUTREPIA could also obtain approval for additional indications or broader conditions of use. These additional indications and broader conditions of use could be protected by one or more patents or regulatory exclusivities, preventing YUTREPIA from obtaining approval for the same indications or conditions of use. For instance, if Liquidia is prevented from launching or selling YUTREPIA for the treatment of PH-ILD in connection with the patent litigation related to the '327 patent or the lawsuit that United Therapeutics filed against the FDA, Tyvaso and Tyvaso DPI would have broader labels than YUTREPIA. In addition, United Therapeutics is currently studying Tyvaso for the treatment of idiopathic pulmonary fibrosis, an indication for which it has received an orphan drug designation. Thus, even if YUTREPIA is approved, such competitive products could 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 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.

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 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 expiration 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.

Our products may not achieve market acceptance or adequate third-party payor coverage.

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 or third-party payor coverage, we may not be able to generate sufficient revenue to become profitable. The degree of market acceptance and third-party payor coverage 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 or sufficient third-party payor coverage, 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 entering 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. In addition, during 2023, we significantly increased the size of our sales force in anticipation of a potential launch of YUTREPIA. However, if we experience continued delays in the approval of YUTREPIA, we may be unable to retain our sales force. Moreover, we cannot assure you that we will be successful in further building or effectively managing 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 and develop additional drug candidates, including L606. 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. If the commercial launch of a drug candidate for which we recruit or have recruited 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;
- 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, commercialization 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 candidates, YUTREPIA and L606, 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. Our inability to obtain sufficient product liability insurance at an acceptable cost and/or scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with our collaborators. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs and commercialization efforts increase in size. 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.

Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources, adversely affect or eliminate the prospects for commercialization or sales of a product that is the subject of any such claim, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

Our business and operations may be adversely affected by the effects of public health emergencies, including pandemics and epidemics.

Our business and operations could be adversely affected by public health emergencies, including pandemics and epidemics, in regions where we have offices, manufacturing facilities, 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.

The extent to which such public health emergencies impact 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 severity and duration of outbreaks, the duration and effect of business disruptions and the administration, availability and efficacy of vaccination programs or other treatments and the effects of any travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat any such public health emergencies. These impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent any public health emergencies adversely affect 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 global economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability. Changes and instability in global economic conditions and geopolitical matters could have a material adverse effect on our business, financial condition and results of operations.

The United States and global markets are experiencing volatility and disruption, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation and interest rates, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of geopolitical conflicts, including in Russia and Ukraine, the Middle East and other areas, terrorism or other events. Sanctions and enhanced export controls imposed by the United States and other countries in response to such conflicts may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Changes in regulations and policies by the new U.S. administration and the resulting political and economic uncertainty in the United States may also impact us, the financial markets and the global economy. For example, we procure APIs, medical devices and other raw materials from suppliers in South Korea, Taiwan, China, Italy and elsewhere. In addition, Sandoz currently procures treprostinil from a production facility in Canada. Tariffs imposed on or by one or more of these jurisdictions may increase our costs. The new U.S. administration may also enact other new regulations or policies that affect trade with China or otherwise impact the pharmaceutical industry by enacting laws to restrict U.S. pharmaceutical companies from contracting with Chinese companies on the development, research or manufacturing of pharmaceutical products. Any executive orders, legislative action or potential sanctions on China could materially impact our current manufacturing partners. See Item 1A. Risk Factors – *We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA and single suppliers for the active ingredient, the device, bulk product manufacturing and packaging of L606.* In addition, natural and man-made disasters and global health emergencies, including pandemics and epidemics, may also adversely affect the financial markets and the global economy and result in significant business disruption. See Item 1A. Risk Factors – *Our operations are concentrated in Morrisville, North Carolina and interruptions affecting us or our suppliers due to natural or man-made disasters or other unforeseen events could materially and adversely affect our operations and result in losses that may not be covered by insurance*.

The volatile business environment or continued unpredictable and unstable market conditions may result in further deterioration of the equity and credit markets, significant volatility in commodity prices, as well as supply chain interruptions and result in an economic downturn, which would make any equity or debt financing more difficult, costly and dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce, or terminate our product development or future commercialization efforts.

Although our business has not been materially impacted by the adverse effects of geopolitical events, natural or man-made disasters or other business disruptions to date, such matters may affect our business in the future and it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which such matters may impact our business. The extent and duration of such adverse geopolitical events, natural or man-made disasters or other business disruptions and actual or perceived political or economic instability 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 political and economic environment in the United States could materially impact our business operations and financial performance, and uncertainty surrounding the potential legal, regulatory and policy changes by a new U.S. presidential administration may directly affect us and the global economy.

The political and economic environment in the United States and elsewhere has resulted in and will continue to result in some uncertainty. Changing regulatory policies because of the changing political environment could impact our regulatory and compliance costs and future revenues, all of which could materially and adversely affect our business, financial condition and operating results. Failure to adapt to or comply with evolving regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation, ability to do business with certain partners, access to capital and our stock price.

Further, the new U.S. administration and recent congressional seat turnover may result in increased regulatory and economic uncertainty. Changes in federal policy by the executive branch and regulatory agencies may occur over time through the new presidential administration's and/or Congress's policy and personnel changes, which could lead to changes involving the level of oversight and focus on the pharmaceutical industry; however, the nature, timing and economic and political effects of such potential changes remain highly uncertain. Any future changes in federal and state laws and regulations, as well as the interpretation and implementation of such laws and regulations, could affect us in substantial and unpredictable ways. At this time, it is unclear what laws, regulations and policies may change and whether future changes or uncertainty surrounding future changes will adversely affect our operating environment and therefore our business, 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, and this product candidate may fail to receive final marketing approval (in a timely manner or at all), may fail to receive approval for one or more indications for which we have sought approval 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 PAH and PH-ILD, and L606, a nebulized, liposomal formulation of treprostinil for treatment of PAH and PH-ILD.

We received tentative approval of our NDA for YUTREPIA for the treatment of PAH and PH-ILD in August 2024. The final approval of YUTREPIA for PAH and PH-ILD is delayed until after expiration of the three-year New Clinical Investigation exclusivity for Tyvaso DPI on May 23, 2025. Although the exclusivity period will expire on such date, the FDA may need more time after the expiration of the exclusivity period to review and approve our NDA. 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 or that we will receive final approval for both indications. United Therapeutics has invested considerable time and resources in an effort to block final approval of YUTREPIA, and expectations related to final FDA approval and projected product launch timelines are impacted by ongoing litigation following lawsuits filed by United Therapeutics. For instance, in connection with an amendment to our NDA filed on July 24, 2023 to add PH-ILD as an indication for YUTREPIA, we provided a new notice of the paragraph IV certification to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, in September 2023, United Therapeutics filed the New Hatch-Waxman Litigation, again asserting infringement by the Company of U.S. Patent No. 10,716,793, entitled "Treprostinil Administration by Inhalation" (the "'793 Patent"), which lawsuit was amended on November 30, 2023, to add claims asserting infringement of the '327 Patent. Although the claims related to the '793 Patent were subsequently withdrawn, in February 2024, United Therapeutics also filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. That motion for preliminary injunction was denied, but United Therapeutics may still seek injunctive relief in the future. In September 2024, United Therapeutics also filed a cross

claim in the New FDA Litigation, seeking to enjoin the FDA from approving our NDA for YUTREPIA with respect to the indication to treat PH-ILD. Although we do not believe United Therapeutics is entitled to any injunction or temporary restraining order in the New Hatch-Waxman Litigation or the New FDA Litigation, it is possible that the Court could rule that the FDA must reject the amendment to the YUTREPIA NDA to add PH-ILD to the label or that, even if YUTREPIA has launched for both PAH and PH-ILD, the Company must remove PH-ILD from the label for YUTREPIA.

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 for the treatment of PAH and PH-ILD 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 and/or L606 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 or L606 or, even if we do receive final marketing approval, the indications for which they will be approved. 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 there may be turnover and/or vacancies at the FDA, which may delay review of our NDA. In addition, uncertainties can be presented by the ability of FDA personnel, including any new FDA personnel who have not previously reviewed our NDA, 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, CMC or other data and information or conduct additional inspections. If any additional issues were identified in such information requests or inspections or if FDA determines that we failed to include required CMC information in the NDA for our products, including YUTREPIA, we may be delayed in obtaining final approval or may be unable to obtain final approval. Furthermore, responses to FDA's requests may be time-consuming and expensive. Status as a combination product, as is the case for YUTREPIA and L606, may complicate or delay the FDA review process. Product candidates that the FDA deems to be combination products, such as YUTREPIA and L606, 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 and/or L606 even if approvable after completing its review. For example, Tyvaso DPI was granted regulatory exclusivity that will delay final approval of YUTREPIA until after the exclusivity expires in May 2025. If a competing product comprised of an inhaled dry-powder formulation of treprostinil, such as Tyvaso DPI, is granted additional regulatory 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. It is also possible that recent decisions by the United States Supreme Court, eliminating court deference to decisions by administrative agencies, may delay any final decisions from the FDA as it considers how to implement this new ruling into its decision-making process.

If we successfully obtain marketing approvals for YUTREPIA and/or L606, we cannot assure you that they will be commercialized in a timely manner or successfully, or at all. For example, even if such products are approved by the FDA, they may not achieve a sufficient level of market acceptance or third-party payor coverage, 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 and L606 will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such products, even if approved. Any delay or setback we face in the commercialization of YUTREPIA and/or L606 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 and believe we have completed preclinical development of L606, 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 and L606 have, 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 prepare for and 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 obtaining suitable medical devices for the conduct of a clinical trial;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites;
- delays in obtaining approvals from IRBs, DSMBs, and ECs 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;
- delays in regulatory authorities’ review and approval of products caused by government funding shortages, government shutdowns, government personnel shortages, global health emergencies or other disruptions; 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 and L606. 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 IRBs, DSMBs, or ECs 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 and/or L606, we may be required to terminate development of these product candidates.

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, that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval or that additional CMC data or information for our product candidates must be submitted for review;

- 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 risk evaluation and mitigation strategies, or 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 a variety of factors, including, 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 natural and man-made disasters and global health emergencies, such as pandemics and epidemics.

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, including planned clinical trials for YUTREPIA and L606, 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 and L606, 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, and L606, which is delivered by a next generation nebulizer, to be drug-device combination products, with the primary mode of action determined to be a drug. Accordingly, the medical devices used to administer the products were, or in the case of L606 will be, 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 the nebulizer for L606, 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, and are pursuing this pathway for L606. 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 citizen petitions or other correspondence with the FDA or lawsuits against 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. For instance, United Therapeutics has a lawsuit against the FDA and previously filed a citizen petition in an attempt to prevent or delay the approval of YUTREPIA. 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 or for certain indications for our product candidates. Even if we are able to utilize the 505(b)(2) regulatory pathway, the approval of a drug developed under the 505(b)(2) regulatory pathway may be delayed by one or more regulatory exclusivities. For example, Tyvaso DPI was recently granted New Clinical Investigation exclusivity, which has delayed final approval of YUTREPIA until after the exclusivity expires in May 2025. Also, 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 or certain types of amendments to 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. Also, in connection with an amendment to our NDA filed in July 2023 to add PH-ILD as an indication for YUTREPIA, we provided a new notice

of the paragraph IV certification to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, in September 2023, United Therapeutics filed the New Hatch-Waxman Litigation, again asserting infringement by the Company of the '793 Patent, which lawsuit was amended on November 30, 2023, to add claims asserting infringement of the '327 Patent. In February 2024, United Therapeutics filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. Although the motion for preliminary injunction was denied, United Therapeutics may still seek injunctive relief and other remedies.

In addition, United Therapeutics may seek to assert newly issued patents against us, including U.S. Patent Number 11,723,887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA.

It is also not uncommon for a manufacturer of an approved product, such as United Therapeutics, to file a citizen petition or other correspondence with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products or to take other actions, such as engaging in litigation with the FDA to enjoin approval of a competing product. If successful, such petitions, correspondence or litigation can significantly delay, or even prevent, the approval of the new product. For example, United Therapeutics is currently pursuing litigation under the Administrative Procedures Act, seeking to require the FDA to reject our amendment to the YUTREPIA NDA to add PH-ILD to the label. Even if the FDA ultimately prevails in such litigation, the FDA may substantially delay approval while it is engaged in litigation or the FDA may be temporarily enjoined by a court from granting approval until the court has ruled on United Therapeutics' request.

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 products for the treatment of pulmonary hypertension and proprietary innovations to drug products using our PRINT technology. If we are unable to identify suitable product candidates for the treatment of pulmonary hypertension or off-patent drug products for which we can develop proprietary innovations using our PRINT technology or are otherwise unable to 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.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages, government shutdowns or global health emergencies or their inability to hire, retain or deploy key leadership and other personnel, could prevent new or modified products from being developed, approved or commercialized in a timely manner or at all or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our operations.

The ability of the FDA and other government agencies to review and approve new or modified products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and SEC, have had to

furlough critical employees and stop critical activities. In addition, government funding of agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Such disruptions at the FDA and other agencies may also increase the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If prolonged government shutdowns, inadequate funding, loss of employees (including those employees who were previously involved in the review of the NDA for YUTREPIA), changes in regulations or policies by the new U.S. administration or other disruptions were to occur at the FDA, a final FDA decision with respect to the NDA for YUTREPIA for PAH and PH-ILD may be further delayed even after Tyvaso DPI's New Clinical Investigation exclusivity expires on May 23, 2025.

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, we plan to conduct our Phase 3 pivotal clinical trial for L606 in multiple sites in China and we plan to use such data to support our NDA in the United States for the approval of L606. In order for the FDA to accept data from a foreign clinical trial, the study must have been conducted in accordance with 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.

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.

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.

Risks Related to Government 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. We also plan to conduct clinical trials and may in the future conduct business in jurisdictions outside of the United States, which may cause us to become subject to transparency law and privacy regulations in those jurisdictions as well.

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. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending or arranging for the prescription or purchase of any drug product may be subject to scrutiny if they do not qualify for an exception or safe harbor. This law applies to our marketing practices, educational programs, pricing policies and relationships with healthcare providers. We continue to evaluate what effect, if any, these rules will have on our business.

- 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 or the FDCA constitute a false or fraudulent claim for purposes of the FCA. Promotion that is deemed to be "off label" can also be the basis of FCA exposure.

- Federal law includes provisions established under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing regulations 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. Similar to the federal AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- Privacy and data security laws may apply to our business. Under Section 5(a) of the Federal Trade Commission Act, the Federal Trade Commission 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 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. In addition, if we engage in business activities outside of the United States, including clinical trials that we plan to conduct outside of the United States, we may become subject to privacy and data security laws in those additional jurisdictions in which we operate or conduct clinical trials. HIPAA, as amended by HITECH and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH created new tiers of civil monetary penalties, made civil and criminal penalties directly applicable to business associates, and gave state attorneys authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs. While we are not currently a covered entity or a business associate under HIPAA, our future operations could subject us to HIPAA as a business associate or covered entity, depending on the scope of such operations.

- 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, certain non-physician practitioners and teaching hospitals, as well as ownership and investment interests held by such healthcare professionals and their immediate family members.

- For both investigational and commercialized products, interactions with or communications directed to healthcare professionals, 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, 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.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. A government investigation, regardless of its outcome, could impact our business practices, harm our reputation, divert attention of management, increase our expenses and reduce availability of assistance to patients. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. The compliance and enforcement landscape, and related risk, is informed by government enforcement precedent and settlement history, Office of Inspector General advisory opinions, and special fraud alerts. Our approach to compliance may evolve over time in light of these types of developments. Additionally, the potential safe harbors available under the federal AKS are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. If our operations, including activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, qui tam actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations.

Recently enacted and future legislation and other legal developments may increase the difficulty and cost for us to obtain marketing approval of and commercialize our products and product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "ACA"), is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our product candidates are the following:

- establishment of a new pathway for approval of lower-cost biosimilars to compete with biologic products;
- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices, now reformed as a result of the IRA;
- expansion of manufacturers' Medicaid rebate liability; and
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. The ACA marketplace subsidies are set to expire in 2025, and without an extension, premiums will increase for the millions of enrollees. We cannot project the implications or if the subsidies will be renewed.

Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024, removing the 100% cap that was established in the ACA. In addition, on September 20, 2024, the Centers for Medicare & Medicaid Services issued a final rule titled "Medicaid Program; Misclassification of Drugs, Program Integrity Updates Under the Medicaid Drug Rebate Program" which may impact our reimbursement and rebate strategy. We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to price our products at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize our product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

Most significantly, the IRA, among other things, requires manufacturers of certain drugs to engage in the drug price negotiation program with Medicare (beginning in 2026) or face steep penalties if they don't agree to provide their drug at the government-set price subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (beginning in 2022); establishes an out-of-pocket maximum for beneficiaries in Part D; and replaces the Part D coverage gap discount program with a new discounting program (the last two both beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, and HHS announced another 15 drugs subject to negotiations in January 2025. The Medicare drug price negotiation program is currently subject to legal challenges.

Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our ability to price our products appropriately, which could negatively impact our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

There is also a great degree of uncertainty regarding how the recent U.S. Supreme Court decisions, including Loper Bright Enterprises v. Raimondo and Corner Post, Inc. v. Board of Governors of the Federal Reserve System, will impact FDA's enforcement and decision-making authority. Loper Bright explicitly overturned Chevron deference, which

previously gave judicial deference to administrative action by agencies in the executive branch. Further, the Supreme Court's decision in Corner Post may result in challenges to FDA decisions by new litigants long into the future, resulting in greater uncertainty about our continued operations.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Any actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation (including class claims), negative publicity or other adverse consequences that could negatively affect our operating results and business.

In the ordinary course of business, we and our partners process sensitive data, including personal data. As a result, we and our partners may be subject to numerous data privacy and security obligations, such as various federal, state and foreign laws and regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. In the United States, numerous federal, state and local governments have enacted laws and regulations, including state data breach notification laws, state health information privacy laws, federal and state consumer protection laws and other similar regulations that govern the processing of sensitive data, including health-related information. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information. There are additional federal and state privacy and security-related laws that may be more restrictive than HIPAA and could impose additional penalties. For example, even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of the Federal Tort Claims Act. 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.

In addition, numerous U.S. states—including California, Virginia, Colorado, Connecticut and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including, without limitation, providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. Failure to comply with these laws, where applicable, can result in significant statutory fines. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act of 2020, or CPRA, collectively the CCPA, applies to personal data of consumers, business representatives and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA and other comprehensive U.S. state privacy laws provide exceptions for some data processed in the context of clinical trials, but these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Outside the United States, an increasing number of laws and regulations, including the General Data Protection Regulation in the EU and UK (collectively, the "GDPR") may also apply to our processing of sensitive data, including health-related and other personal data. The GDPR imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern, when required, the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EU or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. In addition, the EU and other jurisdictions have enacted laws restricting the transfer of personal data from the EU and other jurisdictions to the United States due to data localization requirements or limitations on cross-border data flows. Although there are currently various mechanisms that may be used to transfer personal data from the EU and United Kingdom to the United States in compliance with law, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

Obligations related to data privacy and security (and consumers' data privacy expectations) are rapidly evolving, becoming increasingly stringent and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with U.S. and foreign data privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose sensitive data, or, in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Any actual or perceived failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation or adverse publicity and could negatively affect our operating results and business. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We, directly or through our third-party service providers, may adopt, use or incorporate artificial intelligence ("AI") technology and capabilities into the information technology systems or software that we use in our business and operations. Defects in such AI technology or related security breaches, loss of data and other disruptions as well as changes in implementation standards and enforcement practices under a rapidly evolving regulatory framework for AI technology may adversely affect our business and operations and potentially expose us to increasing liability.

We, directly or through our third-party service providers, may adopt, use or incorporate AI technology and capabilities into information technology systems or software to help us operate our business more efficiently than existing industry tools. The regulatory framework for AI technologies is rapidly evolving as many federal, state and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. In addition, existing laws and regulations may be interpreted in ways that would affect the use of AI in our business. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of such requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

Several governmental agencies in the U.S. and non-U.S. jurisdictions have proposed or enacted laws regulating AI technologies by setting out principles intended to guide AI design and deployment for the public and private sectors and signaling the increase in governmental involvement and regulation over AI technologies. In May 2024, the European Union legislators approved the EU Artificial Intelligence Act (the "EU AI Act"), which establishes a comprehensive, risk-based governance framework for AI in the EU market. The EU AI Act, and developing interpretation and application of the GDPR in respect of automated decision making, together with developing guidance and/or decisions in the impact of AI technology on data privacy, may affect our use of AI technologies and our ability to provide, improve or commercialize our business, require additional compliance measures and changes to our operations and processes, and result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, operations and financial condition.

Further, interpretation and implementation of intellectual property protection in the field of AI are rapidly evolving and there is uncertainty and ongoing litigation in different jurisdictions as to the degree and extent of protection warranted for AI and relevant system inputs and outputs. If we fail to obtain protection for intellectual property rights for any of our intellectual property that may incorporate or be developed using AI technologies, or later have our intellectual property rights invalidated or otherwise diminished, our competitors may be able to take advantage of our research and development efforts to develop competing products that could adversely affect our business, reputation and financial condition. Further, other parties may have, or in the future may obtain, patents or other proprietary rights that would prevent, limit or interfere with our ability to use any AI technologies that we may develop or use in our business.

It is possible that further new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI technologies for our business, or require us to change the way we use AI

technologies in a manner that negatively affects the performance of our system and business and the way in which we use AI technologies. We may need to expend resources to adjust our system in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses. Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects.

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

Compliance with environmental, social and governance (collectively, "ESG") regulations and policies, including diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste, which have recently been the focus of governmental authorities, non-governmental organizations, customers, employees and other external stakeholders, may 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. Changes in regulations and policies of the new U.S. administration may have the effect of scaling back or halting the progress of proposed or enacted ESG-related regulations, which may also have an effect on requirements and preferences of various government agencies and external stakeholders. While we strive to improve our ESG performance, to the extent such ESG-related regulations and policies remain in place, 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.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects.

We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

The adverse impacts of climate change include increased frequency and severity of natural and man-made disasters and extreme weather events such as hurricanes, flooding, typhoons, tornados, wildfires and fires, drought, extreme heat, earthquakes, water shortages, blizzards and other extreme weather conditions. Extreme weather and sea-level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, power outages, telecommunications, transportation or other infrastructure failure, cybersecurity incidents and other business interruption caused by such natural and man-made disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high-quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and its supply chain, which may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

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, or 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.

We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA and single suppliers for the active ingredient, the device, bulk product manufacturing and packaging of L606.

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 and L606, 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 located in Tampa, Florida 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. 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 have relied upon ICU Medical for servicing and support of CADD MS-3 infusion pumps that patients currently use to administer Treprostinil Injection through subcutaneous injection. ICU Medical no longer manufactures or supports the CADD MS-3 infusion pumps. Although we believe that the number of available CADD-MS 3 infusion pumps will be sufficient to continue serving patients through at least the end of 2025, we are working to develop new pumps for the subcutaneous administration of Treprostinil Injection to replace the CADD MS-3 infusion pumps. Prior to using any such new pumps, we or our development partners will be required to obtain FDA clearance. To date, we have not

submitted a 510(k) clearance application for any such new pumps, and we are currently uncertain when, if ever, such a 510(k) clearance application will be submitted. If the existing supply of CADD MS-3 infusion pumps become unavailable before the new pumps are cleared by the FDA, sales of Treprostinil Injection may be adversely affected.

We also rely upon manufacturers with operations or suppliers in China and Taiwan. Chengdu, which manufactures and supplies RG Cartridges for the subcutaneous administration of Treprostinil Injection, has facilities and suppliers located in China. For L606, we rely upon single sources of supply for the active pharmaceutical ingredient, the device, manufacture of bulk drug product and packaging, some of which are located in Taiwan. The operations of our current manufacturing partners and those of its suppliers may be materially disrupted by changes in regulations or policies by the new U.S. administration to increase tariffs or otherwise affect trade with China or restrict U.S. pharmaceutical companies from contracting with Chinese companies on the development, research or manufacturing of pharmaceutical products. Any such executive orders, legislative action or potential sanctions on China could result in trade wars, supply chain disruptions and heighten geopolitical tensions and instability in China and Taiwan and we may be unable to secure an adequate supply of RG Cartridges or L606 at a reasonable cost or in a timely manner, if at all. In addition, we are currently working to establish a secondary supply chain outside of Taiwan and evaluate devices to use for the administration of L606. If we are unable to identify a device to use for our L606 program, establish an agreement with the manufacturer of that device for the supply of such devices or obtain adequate quantities of that device in a timely manner or at all, we may be unable to successfully develop L606 or to do so in a timely manner.

If any of our limited source suppliers are adversely affected by geopolitical events, natural or man-made disasters, public health emergencies or other events that disrupt or adversely affect their operations or their ability to supply us, our business may be adversely affected.

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 which restricts our ability to use PRINT for inhaled applications with respect to certain identified compounds.

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 to use PRINT for the development of inhaled therapeutics using certain identified compounds 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;
- 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 connection with an amendment to our NDA filed in July 2023 to add PH-ILD as an indication for YUTREPIA, a new notice of the paragraph IV certification was provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, United Therapeutics filed the New Hatch-Waxman Litigation, in which it sought a preliminary injunction. While the motion for a preliminary injunction was denied, United Therapeutics may still seek injunctive relief in the New Hatch-Waxman Litigation. Although we do not believe United Therapeutics is entitled to a preliminary injunction in connection with the New Hatch-Waxman Litigation, it is possible that the Court could enjoin us from commercializing YUTREPIA for the treatment of PH-ILD.

In addition, United Therapeutics may seek to assert newly issued patents against us, including U.S. Patent Number 11,723,887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA, including through temporary restraining orders or injunctions that they may seek in the New FDA Litigation.

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, limit the label of our products to fewer indications than intended, 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 matter 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 expiration 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.

Questions may also arise as to the ownership of our patents. For instance, in May 2024, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, in which it is seeking declaratory judgement such that all right, title and interest in and to any patentable or unpatentable inventions, discoveries, and ideas made or conceived by the Former Employee while employed by the Company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. If successful, United Therapeutics could obtain an ownership interest in our patents, which may either limit our ability to prevent United Therapeutics from using out patented inventions or even allow United Therapeutics to prevent us from using our own patented inventions.

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.

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.

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. We also license trade secrets from Pharmosa with respect to L606. 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 payment, 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, including YUTREPIA, 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.

Similarly, under our license agreement with Pharmosa, Pharmosa 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 Pharmosa terminates our license and we have a product that relies on that license, including L606, it may bring a claim against us, and if they are successful, we may be required to compensate Pharmosa 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 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.

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, 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, and the development of L606 using Pharmosa's proprietary liposomal technology. To our knowledge, no regulatory authority has granted final approval to market or commercialize drugs made using our PRINT technology or Pharmosa's liposomal technology. We may never receive final approval to market and commercialize any product candidate that uses our PRINT technology or Pharmosa's liposomal technology.

Even if we receive final approval to market YUTREPIA and/or L606, we will need to scale up our manufacturing capabilities to effectively commercialize the products. We have never completed a scale up of our PRINT manufacturing process or the manufacturing process for L606, and, if we are unable to do so in an effective and timely manner, our ability to commercialize these products, even if they receive final FDA approval, will be adversely affected.

We may experience unexpected challenges as we ramp up our manufacturing capacity to meet demand or during commercial manufacturing, which may result in our inability to supply sufficient quantities of product to meet demand.

The manufacturing process for our products is complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities or those of our CMOs could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single batch or a series of batches, requiring the destruction of products, or could halt manufacturing operations altogether. For instance, as we scale up the manufacture of YUTREPIA, we are adjusting the speed and scale at which our bulk powder is manufactured and at which blister packs are sealed. Our failure to meet required quality standards may result in our failure to timely deliver products to our customers in sufficient quantities to meet demand, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, damage to our reputation and relationships with patients, health care providers and third-party payors, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions,

including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

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.

Our operations are concentrated in Morrisville, North Carolina and interruptions affecting us or our suppliers due to natural or man-made disasters or other unforeseen events could materially and adversely affect our operations and result in losses that may not be covered by insurance.

Most of our current operations are concentrated in Morrisville, North Carolina. In addition, our inventory and certain equipment necessary for the manufacturing of our raw materials and for encapsulating and packaging our products is held in a limited number of locations. Our, and our suppliers' operations could be subject to the impact of natural or man-made disasters and other business disruptions, which include, but are not limited to, hurricanes, flooding, typhoons, tornados, wildfires and fires, drought, extreme heat, earthquakes, water shortages, blizzards and other extreme weather conditions, as well as power outages, telecommunications, transportation or other infrastructure failure, cybersecurity incidents or physical security breaches, public health emergencies, such as pandemics and epidemics, and geopolitical conflicts, including acts of terrorism, war and civil disorder or unforeseen events, resulting in significant damage to our facilities, to our inventory or to equipment which is necessary for our operations, which 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 or equipment 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. The cost of insurance has increased significantly, including as a result of the impact of climate change and inflation, and we may not be able to obtain sufficient coverage at a reasonable cost to protect us against losses from such disasters or unforeseen events. 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.

We are subject to information technology systems failures, security breaches, loss or leakage of data, technological malfunctions or other disruptions, which could result in, among other things, material disruption of our product development programs, financial losses, the inability to process transactions, the unauthorized release of confidential information and reputational risk, restrictions on accessing critical information and potential exposure to liability, all of which would negatively impact our business, financial condition or results of operations.

Our use of technology, infrastructure and data is critical to our continued operations. We are susceptible to operational, financial and information security risks resulting from security breaches, loss or leakage of data, technological malfunctions or other disruptions. Successful security breaches or technological malfunctions affecting us, our CROs, CMOs, suppliers or other third-party service providers can result in, among other things, material disruption of our product development programs, financial losses, the inability to process transactions, the unauthorized release of confidential information, proprietary or other business information (including personal data), reputational risk, restrictions on accessing critical information and potential exposure to liability.

Cyber-attacks include, but are not limited to, deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our and our service providers' systems and the information on such systems. Cyber-attacks can also include phishing attempts or e-mail fraud to cause unauthorized payments or information to be transmitted to an unintended recipient, or to permit unauthorized access to systems. As cybersecurity threats continue to evolve, we may be required to use additional resources to continue to modify or enhance protective measures or to investigate security vulnerabilities, which could have a material adverse effect on our business, financial condition or results of operations.

Any security breach or other incident, whether actual or perceived, could impact our reputation and/or operations, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach affects our systems (or those of our third-party service providers) or were to result in a loss of or accidental, unlawful or unauthorized access, use, release or other processing of personally identifiable information, confidential or proprietary information or damage to our data or applications, our product development programs could be materially disrupted and we could incur liability and become subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

We have also outsourced elements of our information technology infrastructure, and as a result, a number of third-party vendors have access to our confidential information. If the information technology systems of our third-party vendors become subject to disruptions or security breaches that compromise our confidential, proprietary or other business information (including personal data), we may incur liability and reputational damage but have insufficient recourse against such third parties. We will also have to expend significant resources to mitigate the impact of such an event and develop and implement protections to prevent future events of this nature from occurring.

Further, despite the implementation of security measures, our information technology systems and those of our third-party service providers are vulnerable to cybersecurity attacks, breakdowns or other damages or disruptions from service interruptions, system malfunction, unauthorized access or use, natural and man-made disasters, geopolitical conflicts and telecommunications, power outages or other infrastructure failures. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.

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 10, 2025, 85,298,537 shares of our common stock were outstanding, of which 77,091,301 shares of common stock, or 90.4% of our outstanding shares as of March 10, 2025, are freely tradable without restriction or further registration under the Securities Act, provided however, some of these shares are held by persons deemed to be "affiliates" under the Securities Act, including our officers and directors, as well as our principal stockholders, and may not be sold except: (i) in compliance with Rule 144 under the Securities Act or (ii) pursuant to any other applicable exemption under the Securities Act. The remaining 8,207,236 shares held by our stockholders as of March 10, 2025 have not been registered under the Securities Act and may be only be sold (i) pursuant to an effective registration statement under the Securities Act covering the sale of those shares, (ii) in compliance with Rule 144 under the Securities Act or (iii) pursuant to any other applicable exemption under the Securities Act.

Shares issued upon purchase under the employee stock purchase plan or upon the exercise of stock options or vesting of restricted stock units 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. We have 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.

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 and timing of commencement or completion of any clinical trials of any product candidate we may develop, including L606, or those of our competitors;
- the success of Sandoz's Treprostinil Injection to which we have commercial rights pursuant to the Promotion Agreement;
- the market acceptance of the RG Cartridge for the subcutaneous administration of Treprostinil Injection;
- whether we and Sandoz are 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 and L606, for marketing by the FDA or equivalent foreign regulatory authorities (and, if approved, the scope of the indications for which such product candidates are approved) or any failure to obtain such approvals;
- our involvement in significant lawsuits, such as stockholder litigation, litigation involving the FDA, including the New FDA Litigation, or litigation related to intellectual property, including inter partes review proceedings and Hatch-Waxman litigation with originator companies or others which may hold patents, including the ongoing litigation in connection with the patents, trade secrets and confidential information 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 and L606, 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 26.2% of our common stock as of March 10, 2025. 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 internal controls over financial reporting. See Item 4. Controls and Procedures for additional information.

Because we are a "smaller reporting company," we may take advantage of certain scaled disclosures available to us, resulting in holders of our securities receiving less Company information than they would receive from a public company that is not a smaller reporting company.

We are a "smaller reporting company" as defined under Rule 12b-2 of the Exchange Act. As a smaller reporting company, we may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. Based on the closing price of our common stock on June 30, 2024 we will remain a smaller reporting company through at least the end of 2025. To the extent we take advantage of any reduced disclosure obligations, it may make it harder for investors to analyze the Company's results of operations and financial prospectus in comparison with other public companies.

As a smaller reporting company, we are permitted to comply with scaled-back disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our SEC filings will result in less information about our company being available than for other public companies.

If investors consider our common stock less attractive as a result of our election to use the scaled-back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common stock and our share price may be more volatile.

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 (iv) 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 HCR Agreement 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 our 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 our 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 our results of operations in the period of such charge.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

Integrated Risk Management

Our cybersecurity risk management program is an important component of, and is integrated into, our overall risk management process. Our Board, acting primarily through the Audit Committee, actively oversees the strategic direction, objectives and effectiveness of our risk management practices, including cybersecurity risk management, while management is responsible for the day-to-day management of the Company's risk exposure, subject to the direction and objectives established by our Board. As an important component of our risk management process, management reviews risks from cybersecurity threats and our programs for evaluating, mitigating and educating its employees regarding cybersecurity risks. The program includes a comprehensive set of security policies and procedures, including regular network and endpoint monitoring, managed detection and response, system patching, managed security services, server and endpoint scheduled backups, awareness training and testing, periodic vulnerability assessments and penetration testing, to update our ongoing cybersecurity risk identification and mitigation efforts.

We have also implemented a well-established incident response plan to address cybersecurity threats and incidents related to operational risk, intellectual property theft, reputational risks, fraud and extortion, harm to the personal identifying data of employees or customers, violations of laws, and other risks, including procedures for (i) detection and analysis, (ii) containment and eradication, (iii) remediation and (iv) preparation for future incidents. These processes are aligned with standard industry frameworks, such as the National Institute of Standards and Technology, Committee of Sponsoring Organizations and International Organization for Standardization 27001, and other industry standards.

Engagement of Third-party Support

To further improve the effectiveness of our cybersecurity risk management program, we engage third-party service providers to conduct evaluations of our security controls, whether through penetration testing, independent audits or consulting on best practices to address new challenges. These evaluations include testing both the design and operational effectiveness of cybersecurity controls.

Third-party Risk Management

We also implement third-party risk assessments to identify, assess and monitor material risks from cybersecurity threats associated with the use of any third-party vendor who interacts with our technology infrastructure or our confidential, proprietary, or personal information, or is otherwise part of our supply chain. These assessments include identifying and evaluating cybersecurity risks as part of the due diligence conducted prior to the selection of third-party service providers, recurring risk assessments to ensure such third-party vendors have acceptable levels of cybersecurity controls in place and ongoing monitoring to address material cybersecurity risks that may arise from such third-party relationships.

Impact of Risks from Cybersecurity Threats

We do not believe that any of the risks from cybersecurity threats we have faced to date have materially affected, or currently viewed as reasonably likely to materially affect, the Company, our business strategy, results of operations or financial condition. However, the scope and impact of any future cybersecurity threats cannot be predicted and there can be no assurance that our cybersecurity risk management program will be effective in preventing material cybersecurity threats in the future. For a description of the risks from cybersecurity threats that may materially affect us, including our results of operations and financial condition, see *Item 1A. Risk Factors – We are subject to information technology systems failures, security breaches, loss or leakage of data, technological malfunctions or other disruptions, which could*

result in, among other things, material disruption of our product development programs, financial losses, the inability to process transactions, the unauthorized release of confidential information and reputational risk, restrictions on accessing critical information and potential exposure to liability, all of which would negatively impact our business, financial condition or results of operations.

Governance

Board Oversight of Cybersecurity Threats

The Board has oversight responsibility for the Company's overall risk management framework. The Board, acting primarily through the Audit Committee, is also responsible for oversight of our risk management practices, including as to cybersecurity, while management is responsible for the day-to-day risk management processes. Through our CEO and other members of management, the Board receives periodic reports regarding the risks facing the Company, including as to cybersecurity risks. In addition, the Audit Committee assists the Board in its oversight role by receiving regular reports from management regarding risks associated with technology, information systems and controls and security, including risks related to data security, cybersecurity and data privacy and the effectiveness of the Company's security controls, systems and policies.

Role of Management

Our management and information technology teams, collectively, have decades of experience in the areas of information technology, finance, legal, human resources, data privacy and risk management. Our internal information technology organization, overseen by our Controller, is responsible for our overall information security strategy, policy, security engineering, operations and cyber threat detection and response. The day-to-day activities of our information technology organization are managed by our current head of information technology, who has more than 30 years of experience in information technology systems and cybersecurity, including experience in safeguarding and monitoring networks and systems, responding to incidents, and reducing the risk of business exposure, and holds multiple industry-recognized certifications. The information technology organization also engages legal and cybersecurity professionals with appropriate subject matter expertise in support of its cybersecurity efforts. The information technology organization manages and continually enhances our enterprise security structure with the goal of preventing cybersecurity incidents to the extent feasible, while simultaneously increasing our system resilience to minimize the business impact should an incident occur.

Incident responses under our cybersecurity incident response plan are led by our incident response team, consisting of our Chief Executive Officer (the "CEO"), Chief Financial Officer (the "CFO"), General Counsel, head of information technology and head of human resources, and supported by Legal, Compliance and other functions as appropriate. The incident response team, in connection with outside legal and cybersecurity advisors, is responsible for investigating suspected cybersecurity incidents, taking appropriate steps to contain, mitigate or resolve a cybersecurity incident and reporting findings to management. In the event of a cybersecurity incident, our General Counsel is responsible for convening a materiality incident response team to assess the materiality of cybersecurity incidents meeting certain escalation criteria. Through ongoing communications with the incident response team, management is informed about and monitors the prevention, detection, mitigation and remediation of cybersecurity incidents and progress on cybersecurity initiatives. Management provides regular updates to the Audit Committee and the Board concerning the Company's technology and cybersecurity programs, associated risks and our efforts to help mitigate those risks.

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 December 31, 2031 and includes an option for us to renew the lease for an additional five years through December 31, 2036. 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.

For information on our legal proceedings, see Note 14 "Legal Proceedings" included in our consolidated financial statements beginning on page F-31 of this Annual Report on Form 10-K.

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 10, 2025, there were 54 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 HCR Agreement 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, 2024.

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, 2024 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, 2024, as compared to the year ended December 31, 2023. This discussion should be read in conjunction with our consolidated financial statements for the two-year period ended the year ended December 31, 2024 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 rare cardiopulmonary diseases such as PAH and PH-ILD. We operate through our wholly owned operating subsidiaries, Liquidia Technologies and Liquidia PAH, formerly known as RareGen.

We currently generate revenue pursuant to the Promotion Agreement between Liquidia PAH and Sandoz, dated as of August 1, 2018, as amended, sharing profit derived from the sale of Sandoz's 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 involved in the treatment of PAH and PH-ILD in the United States, as well as key stakeholders involved in the distribution and reimbursement of medicines to treat these patients. We established our commercial presence in the field to support Treprostinil Injection and have since expanded our presence to support the potential launch of YUTREPIA, further validating our reputation as a company committed to supporting PAH and PH-ILD 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, to enable 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 and PH-ILD. 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 effort DPI and by achieving higher dose levels than the labeled doses of current inhaled therapies. On August 16, 2024, the FDA (i) granted tentative approval for our NDA for YUTREPIA for the treatment of PAH and PH-ILD and (ii) simultaneously determined that Tyvaso DPI, approved on May 23, 2022, qualifies for a three-year New Clinical Investigation exclusivity for the chronic use of dry powder formulations of

treprostinil for the approved indications. As a result, final approval of YUTREPIA for PAH and PH-ILD is delayed until after expiry of the three-year regulatory exclusivity for Tyvaso DPI on May 23, 2025.

We are also developing L606, an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, which we licensed from Pharmosa. L606 is currently being evaluated in an open-label study in the United States for treatment of PAH and PH-ILD with a planned pivotal study for the treatment of PH-ILD.

Since inception, we have incurred significant operating losses. Our net loss was $130.4 million and $78.5 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $559.5 million. 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 of such product candidates and pursue commercialization of any approved product candidates. 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. Additionally, our HCR Agreement contains fixed quarterly payments and minimum cash covenants that require us to maintain cash and cash equivalents in an amount at least equal to $15.0 million for the remainder of the payment term, which is expected to conclude in 2031.

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. Based on current operating plans and excluding any external financing, we will not have sufficient cash and cash equivalents to fund operating expenses and capital requirements and meet our minimum cash covenants beyond one year from the issuance of these consolidated financial statements, and therefore, we have concluded that there is substantial doubt about its ability to continue as a going concern. Accordingly, we will require additional funding over the next twelve months to continue our operations and maintain compliance with debt covenants, and could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or commercialization efforts, which could adversely affect our business prospects, or potentially force us to cease operations.

Recent Event

On March 17, 2025, we entered into the Sixth Amendment to the HCR Agreement pursuant to which HCR made an additional $100.0 million available for funding under the second tranche. An additional $25.0 million from the second tranche was funded on March 17, 2025. An additional $50.0 million may be funded upon the first commercial sale of YUTREPIA following receipt of final FDA approval for the treatment of PAH and PH-ILD, so long as no injunction has been issued prohibiting Liquidia from commercializing YUTREPIA for either or both of PAH and PH-ILD, and an addition $25.0 million upon the mutual agreement of the parties after achieving aggregate net sales of YUTREPIA in excess of $100 million at any time on or prior to June 30, 2026. As consideration for the additional $25.0 million funded at closing, Liquidia has agreed to a fixed payment schedule that terminates in 2032. Payments on the last two tranches, when funded, would also follow a fixed payment schedule. As further discussed in Note 13 “Long-term debt” to the accompanying financial statements, aggregate payments to HCR are capped at 175% of the total amounts advanced by under the HCR Agreement plus a potential true-up payment to be made by us if HCR’s internal rate of return is less than a minimum rate of return on the date the cap is reached. The minimum rates of return for the three new tranches are 16%, 13% and 12%, respectively.

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. To administer Treprostinil Injection through subcutaneous injection, patients currently must use the CADD-MS 3 infusion pump manufactured by ICU Medical. ICU Medical no longer manufactures or supports the CADD-MS 3 infusion pump. Although we believe that

the number of available CADD-MS 3 infusion pumps will be sufficient to serve patients through at least the end of 2025, it is possible that the availability of CADD-MS 3 infusion pumps could end earlier. Due to this limitation in the availability of pumps, specialty pharmacies will limit the number of patients that they place on subcutaneous Treprostinil Injection therapy in order to ensure that patients placed on subcutaneous administration of Treprostinil Injection will not have to discontinue such treatment due to the unavailability of CADD-MS infusion pumps. Until we are able to obtain a pump to replace the CADD-MS 3 infusion pump, the number of patients that can receive subcutaneous administration of Treprostinil Injection will continue to be constrained. Revenue will continue to be impacted or at risk until alternative pumps are available.

Cost of Revenue

Cost of revenue consists of (i) an allocation of the cost of our sales force associated with calling on physicians and hospital pharmacies involved in the treatment of PAH with Treprostinil Injection, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection and (ii) 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 unless objective and persuasive evidence exists that regulatory approval and subsequent commercialization of a product candidate is probable and where we also expect the future economic benefit from the sales of the product candidate to be realized;
- 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;
- costs of acquired product licenses and related technology rights where there is no alternative future use; and
- allocated 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, conduct existing clinical trials, and initiate 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. 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 can 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 equivalents. Interest expense consists of interest charges on finance leases and long-term debt. These charges include monthly recurring interest on such obligations in addition to interest accretion and amortization of debt discounts and issuance costs to interest expense.

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations:

	Year Ended December 31,		$	%
	2024	2023	Change	Change
Revenue	$ 13,996	$ 17,488	$ (3,492)	(20)%
Costs and expenses:				
Cost of revenue	5,879	2,888	2,991	104 %
Research and development	47,842	43,242	4,600	11 %
General and administrative	81,569	44,742	36,827	82 %
Total costs and expenses	135,290	90,872	44,418	49 %
Loss from operations	(121,294)	(73,384)	(47,910)	65 %
Other income (expense):				
Interest income	7,654	3,466	4,188	121 %
Interest expense	(12,486)	(6,273)	(6,213)	99 %
Gain (loss) on extinguishment of debt	(4,268)	(2,311)	(1,957)	85 %
Total other income (expense), net	(9,100)	(5,118)	(3,982)	78 %
Net loss and comprehensive loss	$ (130,394)	$ (78,502)	$ (51,892)	66 %

Revenue

Revenue was $14.0 million for the year ended December 31, 2024, compared to $17.5 million for the year ended December 31, 2023. Revenue related primarily to the Promotion Agreement. The decrease of $3.5 million was primarily due to lower sales quantities, driven by limitations on the availability of pumps used to administer Treprostinil Injection subcutaneously. Sales quantities will continue to be impacted or at risk until alternative pumps are available.

Cost of Revenue

Cost of revenue was $5.9 million for the year ended December 31, 2024, compared to $2.9 million for the year ended December 31, 2023. Cost of revenue related to the Promotion Agreement as noted above. The increase from the prior year was primarily due to our sales force expansion during the fourth quarter of 2023.

Research and Development Expenses

Research and development expenses were $47.8 million for the year ended December 31, 2024 compared to $43.2 million for the year ended December 31, 2023. The increase of $4.6 million or 11% was primarily due to (i) a $6.1 million increase in expenses related to our L606 program, (ii) a $5.3 million increase in expenses related to YUTREPIA research and development activities, including the ASCENT trial, (iii) a $5.1 million increase in personnel expenses (including stock-based compensation) related to increased headcount, and (iv) a $3.5 million upfront license fee due to Pharmosa for the exclusive license in Europe to develop and commercialize L606 recorded during the year ended December 31, 2024, offset by (i) $5.1 million lower commercial manufacturing expenses reflecting the impact of expensing YUTREPIA inventory costs in the prior year and (ii) a $10.0 million upfront license fee due to Pharmosa for the exclusive license in North America to develop and commercialize L606 recorded during the year ended December 31, 2023.

General and Administrative Expenses

General and administrative expenses were $81.6 million for the year ended December 31, 2024, compared to $44.7 million for the year ended December 31, 2023. The increase of $36.9 million or 82% was primarily due to (i) a $19.7 million increase in personnel expenses (including stock-based compensation) driven by higher headcount and expansion of our sales force in the fourth quarter of 2023, (ii) a $7.9 million increase in legal fees related to our ongoing

YUTREPIA-related litigation, and (iii) a $6.8 million increase in commercial expenses in preparation for the potential commercialization of YUTREPIA.

Other Income (Expense)

Total other expense, net was $9.1 million for the year ended December 31, 2024, compared to $5.1 million for the year ended December 31, 2023. The increase of $4.0 million was primarily driven by a $2.0 million increase in the net loss on extinguishment of debt resulting from the Fourth and Fifth Amendments to the HCR Agreement, which were executed in January 2024 and September 2024, respectively. Additionally, there was a $6.2 million increase in interest expense attributable to the higher borrowings under the HCR Agreement compared to the prior year and a $4.2 million increase in interest income attributable to higher money market 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 other long-term debt. Our principal uses of cash have been for working capital requirements and capital expenditures. As of December 31, 2024, we had cash and cash equivalents of $176.5 million, stockholders' equity of $77.3 million, and an accumulated deficit of $559.5 million.

In September 2024, we sold 6,460,674 shares of our common stock in an underwritten registered public offering at an offering price of $8.90 per share (the "2024 Offering") for gross proceeds of approximately $57.5 million, before deducting offering costs of approximately $3.8 million.

A fund affiliated with Paul B. Manning, a member of our Board of Directors, participated in the 2024 Offering and purchased shares of common stock in an aggregate amount of approximately $3.0 million at the public offering price per share and on the same terms as the other purchasers in the 2024 Offering.

Concurrently with the 2024 Offering referenced above, we entered into a common stock purchase agreement with funds managed by Caligan Partners LP ("Caligan"), our largest stockholder, for the sale by us in a private placement of an aggregate of 1,123,595 shares of our common stock at a purchase price of $8.90 per share for gross and net proceeds of approximately $10.0 million (the "Caligan 2024 Private Placement").

In January 2024, we sold 7,182,532 shares of our common stock in a private placement (the "2024 Private Placement") at a purchase price of $10.442 per share for gross proceeds of approximately $75.0 million, before deducting offering expenses of less than $0.1 million.

In December 2023, we sold 3,491,620 shares of our common stock in an underwritten registered public offering at an offering price of $7.16 per share for gross proceeds of approximately $25.0 million, before deducting offering costs of approximately $1.9 million.

In December 2023, we also entered into a common stock purchase agreement with Roger Jeffs, our Chief Executive Officer, for the sale by us in a private placement of an aggregate of 139,665 shares of our common stock at a purchase price of $7.16 per share for gross proceeds of approximately $1.0 million.

In January 2023, we entered into the HCR Agreement, pursuant to which HCR has paid us an aggregate investment amount of $100.0 million (the "Investment Amount"). $32.5 million of the Investment Amount was funded on January 27, 2023, $22.2 million of which was used to satisfy in full and retire our previously outstanding debt with Silicon Valley Bank. An additional $10.0 million of the Investment Amount was funded on July 27, 2023, which was used to fund payment of the $10.0 million upfront license fee due under the Pharmosa License Agreement. On January 5, 2024 and September 12, 2024 an additional $25.0 million and $32.5 million of the Investment Amount was funded, respectively. On March 17, 2025, we entered into the Sixth Amendment to the HCR Agreement pursuant to which HCR

made an additional $100.0 million available for funding under the second tranche, $25.0 million of which was funded on March 17, 2025. See Note 13 "Long-term debt" to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for further information.

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 operating losses and negative cash flows from operations. We plan to focus in the near-term on preparations for the potential commercial launch of YUTREPIA, continuing promotion of Treprostinil Injection, investing in research and development efforts for our YUTREPIA and L606 programs, and expanding our corporate infrastructure. 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 HCR Agreement. 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. Based on current operating plans and excluding any external financing, we will not have sufficient cash and cash equivalents to fund operating expenses and capital requirements and meet our minimum cash covenants beyond one year from the issuance of these consolidated financial statements, and therefore, we have concluded that there is substantial doubt about its ability to continue as a going concern. Accordingly, we will require additional funding over the next twelve months to continue our operations and maintain compliance with debt covenants, and could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or commercialization efforts, which could adversely affect our business prospects, or potentially force us to cease operations. See Note 1 to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for information regarding our ability to continue as a going concern.

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 and cash equivalents:

	Year Ended December 31,	
	2024	2023
Net cash provided by (used in):		
Operating activities	$ (93,422)	$ (41,564)
Investing activities	(8,441)	(11,288)
Financing activities	194,663	43,248
Net increase (decrease) in cash and cash equivalents	$ 92,800	$ (9,604)

Operating Activities

Net cash used in operating activities increased $51.8 million to $93.4 million for the year ended December 31, 2024, from $41.6 million for the year ended December 31, 2023. The increase was primarily due to $41.2 million higher net loss adjusted for non-cash items and unfavorable working capital changes of $10.7 million.

Investing Activities

Net cash used in investing activities was $8.4 million for the year ended December 31, 2024 compared to $11.3 million for the year ended December 31, 2023. During the year ended December 31, 2024, we made $4.9 million in property, plant and equipment purchases and a $3.5 million upfront license fee payment to Pharmosa for the exclusive license in Europe to develop and commercialize L606. During the year ended December 31, 2023, we made a $10.0 million upfront license fee payment to Pharmosa for the exclusive license in North America to develop and commercialize L606 and paid $1.3 million for property, plant and equipment purchases.

Financing activities

Net cash provided by financing activities was $194.7 million during the year ended December 31, 2024 compared to $43.2 million provided by financing activities the year ended December 31, 2023. During the year ended December 31, 2024, we received $138.6 million net proceeds from the sale of common stock primarily relating to the 2024 Offering and 2024 Private Placement, $57.5 million net proceeds from the HCR Agreement, and $3.0 million from the issuance of common stock under stock incentive plans. These inflows were offset by $4.9 million in payments under the HCR Agreement. During the year ended December 31, 2023, we received $41.7 million net proceeds from the HCR Agreement of which $22.2 million was used to repay existing indebtedness with Silicon Valley Bank, $24.2 million aggregate net proceeds from the sale of common stock in a public offering and a public private placement, and $1.2 million from the issuance of common stock under stock incentive plans. These inflows were offset by $1.7 million in payments under the HCR Agreement.

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, we entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to our manufacturing capabilities during the term of the agreement. We agreed to pay future contingent

milestones and royalties, totaling no more than $1.5 million, $0.2 million of which was accrued as of December 31, 2024.

In December 2022, we entered into a Pump Development Agreement with Mainbridge and 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 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 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.

In June 2023, we entered into a License Agreement with Pharmosa pursuant to which we were granted an exclusive license in North America to develop and commercialize L606, an inhaled, sustained-release liposomal formulation of treprostinil currently being evaluated in a clinical trial for the treatment of PAH and PH-ILD. In October 2024, we and Pharmosa amended the agreement to expand our licensed territory to include key markets in Europe, Japan and elsewhere, in addition to licensing proprietary nebulizers controlled by Pharmosa and being evaluated for use in a planned global pivotal study for the treatment of PH-ILD. In consideration for these exclusive rights, we will pay Pharmosa potential development milestone payments tied to clinical development and approvals in PAH and/or PH-ILD of up to $37.75 million, potential sales milestones of up to $185 million in North America and $150 million outside North American and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication approved by the FDA after PAH and PH-ILD and each additional product approved by the FDA under the license, a $2 million milestone payment for each additional indication approved by the EMA after PAH and PH-ILD, and a $0.5 million milestone payment for each additional indication approved by the PMDA after PAH and PH-ILD.

Purchase Obligations

We enter into contracts in the normal course of business with contract third-party 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, we can elect to discontinue the work under these agreements at any time.

On July 14, 2023, we entered into an Amended and Restated Commercial Manufacturing Services and Supply Agreement with Lonza, which was amended on January 7, 2025 (collectively, the "CSA"). Pursuant to the terms of the CSA, we deliver bulk treprostinil powder, manufactured using our proprietary PRINT® technology, and Lonza encapsulates and packages it. The CSA was effective upon signing and will be in effect until December 31, 2028 and may thereafter be extended upon the mutual written agreement of the parties in accordance with the terms of the CSA. We may terminate the CSA upon 60 days' written notice to Lonza in the event that the application for regulatory approval of YUTREPIA is rejected by the FDA and such FDA decision is not caused by the fault of the Company (the "Termination for FDA Rejection"). Lonza may terminate the CSA upon 120 days written notice if we do not receive regulatory approval of YUTREPIA from the FDA by December 31, 2025 (the "Termination for FDA Delay"). Upon any Termination for FDA Rejection or Termination for FDA Delay, we would reimburse Lonza for 50% of its documented out-of-pocket expenditures for any capital equipment that is purchased by Lonza after the effective date of the Agreement to perform the services for us, not to exceed $2.5 million in the aggregate. We are required to provide Lonza with quarterly forecasts of our expected production requirements for the following 24-month period, the first twelve months of which is considered a binding, firm order. We are required to purchase certain minimum annual order quantities, which may be adjusted by us after the thirteenth month after receipt of regulatory approval of YUTREPIA. The CSA provides for tiered pricing depending upon the batch size ordered.

In addition, on January 10, 2020, we entered into a multi-year supply agreement with LGM to supply active pharmaceutical ingredients for YUTREPIA. Under the 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.

As of December 31, 2024, we have non-cancelable commitments for product manufacturing and supply costs of approximately $12.8 million.

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 December 2031. Minimum operating lease payments are $1.4 million in 2025, $1.4 million in 2026, $1.6 million in 2027, $1.7 million in 2028, $1.7 million in 2029, and $3.6 million thereafter.

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 have agreements with certain employees and an Executive Severance and Change in Control Plan which covers certain other employees which require 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 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.

Long-term Debt

We recognized a liability related to amounts received in January 2023, July 2023, January 2024, and September 2024 pursuant to the HCR Agreement under ASC 470-10, *Debt* and ASC 835-30, *Interest – Imputation of Interest*. The liability will be accreted under the effective interest method based upon the amount of contractual future payments to be made pursuant to the HCR Agreement. Amendments are assessed under ASC 470 to determine the appropriate treatment as troubled debt restructurings, extinguishments or modifications. If the timing or amounts of any future payments change, we will prospectively adjust the effective interest and the related amortization of the liability. See Note 13 to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for additional information.

Prelaunch Inventory

We capitalize prelaunch inventory prior to receiving regulatory approval if regulatory approval and subsequent commercialization of a product is probable and we also expect future economic benefit from the sales of the product to be realized. Prior to this conclusion, we expense prelaunch inventory as research and development expense in the period incurred. For prelaunch inventory that is capitalized, we consider a number of specific facts and circumstances, including the product's historical shelf life, the product's current status in the development and regulatory approval process, results from related clinical trials, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, potential obstacles to the approval process, viability of commercialization and market trends. In late 2023, based on our assessment of the legal and regulatory process related to YUTREPIA, we concluded that we met the criteria to capitalize expenditures for prelaunch inventory. We capitalized $10.8 million of prelaunch inventory as of December 31, 2024 and none as of December 31, 2023. We do not have an allowance for inventory obsolescence as of December 31, 2024. If either regulatory approval or market acceptance post-approval of YUTREPIA do not occur at all or on a timely basis prior to the inventory shelf-life expiration, we may be required to write-off some or all prelaunch inventory, which could affect our financial condition and financial results.

Smaller Reporting Company

As a "smaller reporting company," as defined under Rule 12b-2 of 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.

We will be able to take advantage of these scaled disclosures for so long as (i) our common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. To the extent we take advantage of any reduced disclosure obligations, it may make it harder for investors to analyze the Company's results of operations and financial prospectus in comparison with other public companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our SEC filings will result in less information about our company being available than for other public companies.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements and the notes thereto required to be filed pursuant to this Item 8 are included in Part IV, Item 15 of this Annual Report on Form 10-K and are incorporated herein by this reference.

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, 2024, 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, 2024, 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, 2024 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, 2024 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, 2024.

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 smaller reporting companies.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the fourth quarter of 2024, the following Rule 10b5-1 trading arrangements (as defined in Item 408(a)(1)(i) of Regulation S-K) and non-Rule 10b5-1 trading arrangements (as defined in Item 408(c) of Regulation S-K) intended to satisfy the affirmative defense of Rule 10b5-1(c) of the Exchange Act were adopted or terminated by our directors and/or executive officers (as defined in Section 16 of the Exchange Act):

Name	Title	Date of Adoption of Rule 10b5-1 Trading Arrangement[1]	Scheduled Expiration Date of Rule 10b5-1 Trading Arrangement	Aggregate Number of Securities to Be Sold
Michael Kaseta	Chief Operating Officer and Chief Financial Officer	12/9/2024[2]	8/31/2026	50,000
Jason Adair	Chief Business Officer	12/13/2024[2]	8/31/2026	26,057

(1) Date of adoption of Rule 10b5-1 trading arrangements is in accordance with both the Company's insider trading policy and applicable SEC rules and regulations.

(2) The first trade pursuant to the Rule 10b5-1 trading arrangement will be, in accordance with both the Company's insider trading policy and applicable SEC rules and regulations, on a date after the date of adoption of the Rule 10b5-1 trading arrangement.

During the fourth quarter of 2024, the Company did not adopt or terminate a Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K).

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 I Director Election Proposal" contained in our definitive proxy statement for our 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, if applicable, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 (the "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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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.

We have adopted an insider trading policy, which governs the purchase, sale and/or other dispositions of our securities by our directors, officers and employees, their immediate family members and entities owned or controlled by them as well as consultants that have access to material nonpublic information, which we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations as well as the listing standards of The Nasdaq Stock Market LLC applicable to us.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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, 2024:

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	7,343,056 (2)	$ 5.12	1,481,649 (3)
Equity compensation plans not approved by security holders	1,665,949 (4)	$ 3.21	27,608
Total	9,009,005	$ 4.76	1,509,257

(1) Represents the weighted-average exercise price of outstanding stock options only.

(2) Includes an aggregate of (i) 343,033 option shares assumed by Liquidia Corporation under the Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan, (ii) 90,114 option shares assumed by Liquidia Corporation under the Liquidia Technologies, Inc. 2016 Equity Incentive Plan, as amended, and (iii) 36,547 option shares assumed by Liquidia Corporation under the Liquidia Technologies, Inc. Stock Option Plan, as amended.

(3) Includes an aggregate of (i) 946,907 shares available for issuance under the Liquidia Corporation 2020 Long-Term Incentive Plan (the "2020 Plan"). On January 1, 2025, an additional 3,387,323 shares of common stock were added to the shares authorized for issuance under 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 and (ii) 534,742 shares available for issuance under the Liquidia Corporation 2020 Employee Stock Purchase Plan ("ESPP"). On January 1, 2025 an additional 150,000 shares of common stock were added to the shares authorized for issuance under the ESPP, 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 ESPP is automatically increased by the lesser of (a) 1.0% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, (b) 150,000 shares, or (c) an amount determined by the Board of Directors.

(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, which remain outstanding and exercisable during Mr. deGoa's Board tenure, and (ii) 273,587 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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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 2025 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2024.

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, 2024 and 2023	F-4
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2024 and 2023	F-5
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2024 and 2023	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2024 and 2023	F-7
Notes to Financial Statements	F-8

(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 INDEX

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).
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	Certificate of Amendment of Certificate of Incorporation of Liquidia Corporation (incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023).
3.3	Certificate of Second Amendment of Certificate of Incorporation of Liquidia Corporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed with the SEC on June 21, 2024).
3.4	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 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	Warrant to Purchase Stock, issued February 26, 2021, by Liquidia Corporation to Silicon Valley Bank (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 3, 2021).
4.4	Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and Silicon Valley Bank (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022).
4.5	Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and SVB Innovation Credit Fund VIII, L.P. (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022).
4.6	Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and Innovation Credit Fund VIII-A L.P. (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022).
4.7	Description of Securities of the Company. (incorporated herein by reference to Exhibit 4.7 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.1#	Liquidia Technologies, Inc. Stock Option Plan (2004), as amended, and forms of award agreements thereunder (incorporated 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 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 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. (incorporated herein by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.5#	Amendment to the Liquidia Corporation 2020 Long-Term Incentive Plan (incorporated 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#	Form of Restricted Stock Units Agreement under the Liquidia Corporation 2020 Long-Term Incentive Plan. (incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.7#	Form of Restricted Stock Units Agreement (Performance-Based) under the Liquidia Corporation 2020 Long-Term Incentive Plan. (incorporated herein by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.8#	Form of Incentive Stock Option Agreement under the Liquidia Corporation 2020 Long-Term Incentive Plan. (incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.9#	Form of Non-Qualified Stock Option Agreement under the Liquidia Corporation 2020 Long-Term Incentive Plan. (incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.10#	Liquidia Corporation 2022 Inducement Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 31, 2022).
10.11#	Form of Stock Option Grant Notice and Stock Option Agreement under the Liquidia Corporation 2022 Inducement Plan (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 31, 2022).
10.12#	Form of Indemnification Agreement with the Company's executive officers and directors (incorporated by reference to Exhibit 10.2 to the Company's Current Report on 8-K12B, filed with the SEC on November 18, 2020).
10.13	Litigation Funding and Indemnification Agreement, dated as of November 17, 2020, by and between RareGen, LLC and PBM RG Holdings, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K12B, filed with the SEC on November 18, 2020).

10.14	Purchase Agreement by and between Liquidia Corporation and Roger Jeffs, dated December 12, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on December 14, 2023).
10.15	Common Stock Purchase Agreement, dated as of January 4, 2024, by and between Liquidia Corporation and the Purchaser (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 8, 2024).
10.16	Registration Rights Agreement, dated as of January 4, 2024, by and between Liquidia Corporation and the Purchaser (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on January 8, 2024).
10.17	Common Stock Purchase Agreement by and among Liquidia Corporation and the Purchasers, dated September 10, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on September 12, 2024).
10.18	Registration Rights Agreement by and among Liquidia Corporation and the Purchasers, dated September 10, 2024 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on September 12, 2024).
10.19++	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 (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, filed with the SEC on March 20, 2023).
10.20	First Amendment to Revenue Interest Financing Agreement, dated as of April 17, 2023, by and among Liquidia Technologies, Inc., Healthcare Royalty Partners IV, L.P., and HCR Collateral Management, LLC. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2023).
10.21++	Second Amendment to Revenue Interest Financing Agreement, dated as of June 28, 2023, by and between Liquidia Technologies, Inc. and Healthcare Royalty Partners IV, L.P. (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.22++	Third Amendment to Revenue Interest Financing Agreement, dated as of July 27, 2023, by and between Liquidia Technologies, Inc. and Healthcare Royalty Partners IV, L.P. (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.23++	Fourth Amendment to Revenue Interest Financing Agreement, dated as of January 3, 2024, by and between Liquidia Technologies, Inc. and Healthcare Royalty Partners IV, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 8, 2024).
10.24++	Fifth Amendment to Revenue Interest Financing Agreement, dated as of September 11, 2024, by and between Liquidia Technologies, Inc. and Healthcare Royalty Partners IV, L.P. (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed with the SEC on September 12, 2024).
10.25++**	Sixth Amendment to Revenue Interest Financing Agreement, dated as of March 17, 2025, by and between Liquidia Technologies, Inc. and Healthcare Royalty Partners IV, L.P.
10.26	Research License Agreement, dated as of March 31, 2023, by and between Liquidia Technologies, Inc. and Glaxo Group Limited. (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2023).
10.27+	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).
10.28+	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).

10.29	Sixth 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).
10.30+	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).
10.31+	First 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).
10.32#	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).
10.33#	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).
10.34#	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).
10.35#	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).
10.36#	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).
10.37	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).
10.38	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).
10.39#	Liquidia Corporation 2020 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
10.40#	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).
10.41#	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).
10.42#	Liquidia Corporation Amended and Restated Executive Severance and Change in Control Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 14, 2024).
10.43	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 10.21 to the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
10.44++	Eighth Amendment to Lease Agreement, dated November 22, 2024, by and between Durham Keystone Tech 4, LLC and Liquidia Technologies, Inc. (incorporated herein by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 26, 2024).

10.45++	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).
10.46++	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).
10.47	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).
10.48++	Third Amendment to Promotion Agreement, dated as of November 18, 2022 by and between Liquidia PAH, LLC and Sandoz Inc. (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K, filed with the SEC on March 20, 2023).
10.49	Fourth Amendment to Promotion Agreement, dated as of March 10, 2023, by and between Liquidia PAH, LLC and Sandoz Inc (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2023).
10.50	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).
10.51++	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).
10.52++	Amended and Restated Commercial Manufacturing Services and Supply Agreement, dated July 13, 2023, by and between Liquidia Technologies, Inc. and Lonza Tampa LLC. (incorporated herein by reference to Exhibit 10.47 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.53**	First Amendment to Amended and Restated Commercial Manufacturing Services and Supply Agreement, dated January 7, 2025, by and between Liquidia Technologies, Inc. and Lonza Tampa LLC.
10.54++	Device Development and Supply Agreement, dated as of December 1, 2022, by and among Mainbridge Health Partners, LLC, Sandoz Inc. and Liquidia PAH, LLC (incorporated by reference to Exhibit 10.43 to the Company's Annual Report on Form 10-K, filed with the SEC on March 20, 2023).
10.55++	License Agreement, dated as of June 28, 2023, by and between Liquidia Technologies, Inc. and Pharmosa Biopharm Inc. (incorporated herein by reference to Exhibit 10.49 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
10.56++	First Amendment to the License Agreement, dated as of October 2, 2024, by and between Liquidia Technologies, Inc. and Pharmosa Biopharm Inc. (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 13, 2024).
10.57++	Device License Agreement, dated as of October 2, 2024, by and between Liquidia Technologies, Inc. and Pharmosa Biopharm Inc. (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 13, 2024).
10.58++	Supply Agreement, dated May 22, 2023, by and between Liquidia Technologies, Inc. and Plastiape SpA. (incorporated herein by reference to Exhibit 10.51 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
14.1	Liquidia Corporation Code of Conduct. (incorporated herein by reference to Exhibit 14.1 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
19.1	Liquidia Corporation Insider Trading Policy (included in Exhibit 14.1).
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.
97.1#	Liquidia Corporation Policy for Recovery of Erroneously Awarded Incentive Compensation (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 7, 2023).
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 19, 2025

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.	Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2025
/s/ Michael Kaseta Michael Kaseta	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2025
/s/ Dr. Stephen Bloch Dr. Stephen Bloch	Chairman of the Board of Directors	March 19, 2025
/s/ Damian deGoa Damian deGoa	Director	March 19, 2025
/s/ Katherine Rielly-Gauvin Katherine Rielly-Gauvin	Director	March 19, 2025
/s/ Dr. Joanna Horobin Dr. Joanna Horobin	Director	March 19, 2025
/s/ David Johnson David Johnson	Director	March 19, 2025
/s/ Arthur Kirsch Arthur Kirsch	Director	March 19, 2025
/s/Paul B. Manning Paul B. Manning	Director	March 19, 2025
/s/ Raman Singh Raman Singh	Director	March 19, 2025

LIQUIDIA CORPORATION

FINANCIAL STATEMENTS
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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Liquidia Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Liquidia Corporation and its subsidiaries (the "Company") as of December 31, 2024 and 2023, 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, 2024 and 2023, 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.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations since inception and expects to continue to incur operating losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audits 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical

audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Long-term Debt

As described in Notes 2 and 13 to the consolidated financial statements, during 2023 the Company entered into a revenue interest financing agreement ("HCR Agreement") with HealthCare Royalty Partners IV, L.P. (HCR) and HealthCare Royalty Management, LLC, for an aggregate investment amount of up to $100.0 million in four tranches.
During 2024, the Company entered into the Fourth and Fifth Amendments to the HCR Agreement pursuant to which HCR funded an additional $25.0 million from the second tranche on January 5, 2024 and an additional $32.5 million from the second tranche on September 12, 2024, and eliminated the third and fourth tranches. Amendments are assessed by management to determine appropriate treatment as troubled debt restructurings, extinguishments or modifications. The Fourth Amendment to the HCR Agreement qualifies as a debt extinguishment and issuance of a new debt instrument. Management recorded a loss on extinguishment during the quarter ended March 31, 2024 of $11.5 million, equal to the fair value of the amended HCR Agreement less the carrying value of the existing HCR Agreement on January 5, 2024. The Fifth Amendment to the HCR Agreement also qualifies as a debt extinguishment and issuance of a new debt instrument. Management recorded a gain on extinguishment during the quarter ended September 30, 2024 of $7.2 million, equal to the fair value of the amended HCR Agreement less the carrying value of the existing HCR Agreement on September 12, 2024. Aggregate payments to HCR are capped at 175% of funded portion of the investment amount (the "Hard Cap"), plus an amount, if any, that HCR would need to receive to yield an internal rate of return of (i) 18% on the first $67.5 million funded and (ii) 16% on the next $32.5 million funded (the "IRR True-Up Payment"), unless the HCR Agreement is earlier terminated. If a change of control occurs or upon the occurrence of an event of default, HCR may accelerate payments due under the HCR Agreement up to the Hard Cap, plus the IRR True-Up Payment, plus any other obligations payable under the HCR Agreement. Management recorded the total funds received from HCR under the terms of the HCR Agreement as a liability. Management uses the contractual payment schedule to determine the interest expense to record to accrete the liability to the amount ultimately due. For the year ended December 31, 2024, management estimated an effective annual interest rate of approximately 15.2%. Over the course of the HCR Agreement, the effective annual interest rate may be affected by potential changes in contractual payments. The Company recognized accretion of $12.5 million for the year ended December 31, 2024. The current and long-term portions of the HCR Agreement payable recognized as of December 31, 2024, were $18.0 million and $97.4 million, respectively.

The principal considerations for our determination that performing procedures relating to long-term debt is a critical audit matter are (i) the significant judgment by management when determining the appropriate accounting treatment for the amendments; and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence related to management's determination of the accounting treatment of the amendments.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) reading the HCR Agreement and related amendments; (ii) evaluating the appropriateness of the classification of the debt; and (iii) evaluating management's assessment related to determining the accounting treatment of the amendments. Evaluating management's assessment related to determining the accounting treatment of the amendments included (i) evaluating the impact of the contractual terms of the amendments; (ii) assessing whether the Company's creditworthiness had deteriorated since the debt was issued; (iii) evaluating whether the change in debt terms is considered substantially different by calculating the present value of the cash flows under the terms of the amendments and comparing it to the present value of the remaining cash flows under the terms of the original HCR Agreement; (iv) considering whether the conclusions reached by management were consistent with the terms of the arrangements and evidence obtained in other areas of the audit; and (v) evaluating the presentation of the related financial statement disclosures.

/s/ PricewaterhouseCoopers LLP
Raleigh, North Carolina
March 19, 2025

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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 176,479	$ 83,679
Accounts receivable, net	2,719	4,061
Inventory	241	—
Prepaid expenses and other current assets	5,666	2,159
Total current assets	185,105	89,899
Property, plant and equipment, net	8,298	4,480
Operating lease right-of-use assets, net	4,187	1,704
Indemnification asset, related party	7,460	6,707
Contract acquisition costs, net	7,286	7,922
Intangible asset, net	3,156	3,430
Goodwill	3,903	3,903
Other assets	10,918	287
Total assets	$ 230,313	$ 118,332
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,689	$ 1,396
Accrued expenses and other current liabilities	18,659	13,400
Long-term debt, current	18,016	2,615
Operating and finance lease liabilities, current	417	1,139
Total current liabilities	41,781	18,550
Litigation finance payable	7,300	6,707
Long-term debt, noncurrent	97,371	43,418
Operating and finance lease liabilities, noncurrent	6,586	2,364
Total liabilities	153,038	71,039
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock — 10,000,000 shares authorized, none outstanding	—	—
Common stock — $0.001 par value, 115,000,000 and 100,000,000 shares authorized as of December 31, 2024 and December 31, 2023, respectively, 84,683,063 and 68,629,575 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	85	69
Additional paid-in capital	636,682	476,322
Accumulated deficit	(559,492)	(429,098)
Total stockholders' equity	77,275	47,293
Total liabilities and stockholders' equity	$ 230,313	$ 118,332

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 Year Ended December 31,	
	2024	2023
Revenue	$ 13,996	$ 17,488
Costs and expenses:		
Cost of revenue	5,879	2,888
Research and development	47,842	43,242
General and administrative	81,569	44,742
Total costs and expenses	135,290	90,872
Loss from operations	(121,294)	(73,384)
Other income (expense):		
Interest income	7,654	3,466
Interest expense	(12,486)	(6,273)
Loss on extinguishment of debt	(4,268)	(2,311)
Total other expense, net	(9,100)	(5,118)
Net loss and comprehensive loss	$ (130,394)	$ (78,502)
Net loss per common share, basic and diluted	$ (1.66)	$ (1.21)
Weighted average common shares outstanding, basic and diluted	78,707,503	64,993,476

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, 2022	64,517,912	$ 64	$ 440,954	$ (350,596)	$ 90,422
Issuance of common stock upon exercise of stock options	137,576	—	495	—	495
Issuance of common stock upon vesting of restricted stock units	201,880	1	(1)	—	—
Issuance of common stock under employee stock purchase plan	140,922	—	683	—	683
Sale of common stock, net	3,631,285	4	24,102	—	24,106
Stock-based compensation	—	—	10,089	—	10,089
Net loss	—	—	—	(78,502)	(78,502)
Balance as of December 31, 2023	68,629,575	$ 69	$ 476,322	$ (429,098)	$ 47,293
Issuance of common stock upon exercise of stock options	380,096	1	1,770	—	1,771
Issuance of common stock upon vesting of restricted stock units	725,038	—	—	—	—
Issuance of common stock under employee stock purchase plan	172,395	—	1,248	—	1,248
Issuance of common stock upon exercise of warrants	9,158	—	—	—	—
Sale of common stock, net	14,766,801	15	138,536	—	138,551
Stock-based compensation	—	—	18,806	—	18,806
Net loss	—	—	—	(130,394)	(130,394)
Balance as of December 31, 2024	84,683,063	$ 85	$ 636,682	$ (559,492)	$ 77,275

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,	
	2024	**2023**
Operating activities		
Net loss	$ (130,394)	$ (78,502)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	3,500	10,000
Stock-based compensation	18,806	10,089
Depreciation and amortization	2,197	2,178
Non-cash lease expense	468	397
Loss (gain) on disposal of property and equipment	46	(2)
Loss on extinguishment of debt	4,268	2,311
Accretion and non-cash interest expense	12,479	6,093
Changes in operating assets and liabilities:		
Accounts receivable, net	1,342	956
Inventory	(241)	—
Prepaid expenses and other current assets	(1,881)	(798)
Other noncurrent assets	(10,631)	20
Accounts payable	2,330	(1,152)
Accrued expenses and other current liabilities	5,259	7,746
Operating lease liabilities	(970)	(900)
Net cash used in operating activities	(93,422)	(41,564)
Investing activities		
Purchase of in-process research and development	(3,500)	(10,000)
Purchases of property, plant and equipment	(4,949)	(1,290)
Proceeds from the sale of property, plant and equipment	8	2
Net cash used in investing activities	(8,441)	(11,288)
Financing activities		
Proceeds from long-term debt, net of fees	57,460	41,744
Payments on long-term debt	(4,853)	(21,654)
Payments for debt prepayment and extinguishment costs	—	(2,190)
Principal payments on finance leases	(107)	(181)
Receipts from litigation financing	593	113
Proceeds from sale of common stock, net of issuance costs	138,551	24,238
Proceeds from issuance of common stock under stock incentive plans	3,019	1,178
Net cash provided by financing activities	194,663	43,248
Net increase (decrease) in cash and cash equivalents	92,800	(9,604)
Cash and cash equivalents, beginning of period	83,679	93,283
Cash and cash equivalents, end of period	$ 176,479	$ 83,679
Supplemental disclosure of cash flow information		
Cash paid for interest	$ —	$ 360
Cash paid for operating lease liabilities	$ 1,322	$ 1,283
Offering costs incurred, but not paid included in accrued expenses	$ —	$ 132
Non-cash increase in right-of-use assets due to remeasurement of lease liabilities	$ 4,577	$ —
Non-cash increase in property, plant and equipment through accounts payable	$ 210	$ 239
Non-cash increase in indemnification asset through accounts payable	$ 753	$ 112

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

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

1. Business

Description of the Business

We are a biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards rare cardiopulmonary diseases such as pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). We operate through our wholly owned operating subsidiaries, Liquidia Technologies, Inc. ("Liquidia Technologies") and Liquidia PAH, LLC ("Liquidia PAH"), formerly known as RareGen, LLC ("RareGen").

We currently generate revenue 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. We employ a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of PAH and PH-ILD in the United States, as well as key stakeholders involved in the distribution and reimbursement of medicines to treat these patients. We established our commercial presence in the field to support Treprostinil Injection and have since expanded our presence to support the potential launch of YUTREPIA (treprostinil) inhalation powder ("YUTREPIA"), further validating our reputation as a company committed to supporting PAH and PH-ILD 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, to enable 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 and PH-ILD. 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 effort dry-powder inhaler ("DPI") and by achieving higher dose levels than the labeled doses of current inhaled therapies. On August 16, 2024, the United States Food and Drug Administration (the "FDA") (i) granted tentative approval for our New Drug Application ("NDA") for YUTREPIA for the treatment of PAH and PH-ILD and (ii) simultaneously determined that Tyvaso DPI, approved on May 23, 2022, qualifies for a three-year New Clinical Investigation exclusivity for the chronic use of dry powder formulations of treprostinil for the approved indications. As a result, final approval of YUTREPIA for PAH and PH-ILD is delayed until after expiry of the three-year regulatory exclusivity for Tyvaso DPI on May 23, 2025.

We are also developing L606, an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, which we licensed from Pharmosa Biopharm Inc. ("Pharmosa"). L606 is currently being evaluated in an open-label study in the United States for treatment of PAH and PH-ILD with a planned pivotal study for the treatment of PH-ILD.

Risks and Uncertainties

We are 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, we operate in a dynamic and highly competitive industry and believe that changes in any of the following areas could have a material adverse effect on our 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, market acceptance and third-party payor coverage for our products; development of sales channels; certain strategic relationships; litigation or claims against us, including claims related to intellectual property, product, regulatory, or other matters; and our ability to attract and retain employees necessary to support our growth.

Product candidates we develop require approval from the FDA and/or other international regulatory agencies prior to commercial sales. There can be no assurance that our product candidates will receive the necessary approvals or, if we do, the indications for which our products will be approved. If we are denied approval, approval is delayed, approval is for less than all of the indications we are seeking, or we are unable to maintain approval, it could have a material adverse impact on our business, financial position and results of operations.

We rely on single source manufacturers and suppliers for the supply of our product candidates, adding to the manufacturing risks we face. In the event of any failure by a supplier, we could be left without backup facilities. Any disruption from these manufacturers or suppliers could have a negative impact on our business, financial position and results of operations.

Liquidity and Going Concern

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), we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. 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, bank borrowings with warrants, the issuance of convertible notes and warrants, and other long-term debt. Since inception, we have incurred recurring operating losses, including net losses of $130.4 million and $78.5 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $559.5 million.

We expect to incur significant expenses, operating losses, and negative cash flows from operations for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval of such product candidates and pursue commercialization of any approved product candidates. 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. Additionally, the revenue interest financing agreement with HealthCare Royalty Partners IV, L.P. ("HCR") dated January 9, 2023, as amended (the "HCR Agreement") contains fixed quarterly payments and minimum cash covenants that require us to maintain cash and cash equivalents in an amount at least equal to $15.0 million for the remainder of the payment term, which is expected to conclude in 2031.

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. Based on current operating plans and excluding any external financing, we will not have sufficient cash and cash equivalents to fund operating expenses and capital requirements and to meet our minimum cash covenants beyond one year from the issuance of these consolidated financial statements, and therefore, we have concluded that there is substantial doubt about its ability to continue as a going concern. Accordingly, we will require additional funding over the next twelve months to continue our operations and maintain compliance with debt covenants, and could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or commercialization efforts, which could adversely affect our business prospects, or potentially force us to cease operations.

2. Basis of Presentation, Significant Accounting Policies and Fair Value Measurements

Basis of Presentation

These consolidated financial statements, in the opinion of management, include all adjustments (consisting only of normal recurring adjustments and accruals) necessary for a fair statement of the results for the periods presented in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Our financial position, results of operations and cash flows are presented in U.S. Dollars.

Consolidation

The accompanying consolidated financial statements include our 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 to be reasonable under the circumstances. We evaluate our 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 make changes to the estimates and related disclosures as our experience develops or new information becomes known. Actual results will most likely differ from those estimates.

Summary of Significant Accounting Policies

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Subtopic 280)*. This guidance improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The Company adopted ASU 2023-07 during the year ended December 31, 2024 and applied it retrospectively for all prior periods presented. See Note 17-Segment Information.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*. This guidance requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. This standard also includes certain other amendments to improve the effectiveness of income tax disclosures. The guidance is effective for annual reporting periods beginning after December 15, 2024, with early adoption permitted. Except for expanding disclosures, we do not expect the adoption of ASU 2023-09 to have a material effect on our consolidated financial statements taken as a whole.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses (DISE)*. This guidance requires disaggregated disclosure of income statement expenses for public business entities. ASU 2024-03 does not change the expense captions an entity presents on the face of the income statement; rather, it requires disaggregation of certain expense captions into specified categories in disclosures within the footnotes to the financial statements. As revised by ASU 2025-01, *Income Statement —Reporting Comprehensive Income—Expense Disaggregation Disclosures*, the provisions of ASU 2024-03 are effective for fiscal years beginning after December 15, 2026, with early adoption permitted. Except for expanding disclosures to include more granular income statement expense categories, we do not expect the adoption of ASU 2024-03 to have a material effect on our consolidated financial statements taken as a whole.

Cash, Cash Equivalents, and Concentration of Credit Risk

We consider 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 us to concentrations of credit risk consist of cash and cash equivalents. We are exposed to credit risk, subject to federal deposit insurance, in the event of default by the financial institutions holding our cash and cash equivalents to the extent of amounts recorded on the consolidated balance sheet. Our cash and cash equivalents are held at multiple accredited financial institutions. We have not experienced any losses on such accounts and do not believe that we are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Such deposits have exceeded 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 95% and 99% of our accounts receivable, net as of December 31, 2024 and December 31, 2023, respectively. As of December 31, 2024 and 2023, we have not recorded an allowance for credit losses.

Prelaunch Inventory

We capitalize prelaunch inventory prior to receiving regulatory approval if regulatory approval and subsequent commercialization of a product is probable and we also expect future economic benefit from the sales of the product to be realized. Prior to this conclusion, we expense prelaunch inventory as research and development expense in the period incurred. For prelaunch inventory that is capitalized, we consider a number of specific facts and circumstances, including the product's shelf life, the product's current status in the development and regulatory approval process, results from related clinical trials, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, potential obstacles to the approval process, viability of commercialization and market trends. In late 2023, based on our assessment of the legal and regulatory process related to YUTREPIA, we concluded that we met the criteria to capitalize expenditures for prelaunch inventory. We capitalized $10.8 million of prelaunch inventory as of December 31, 2024 and none as of December 31, 2023. If either regulatory approval or market acceptance post-approval of YUTREPIA do not occur at all or on a timely basis prior to the inventory shelf-life expiration, we may be required to write-off some or all prelaunch inventory, which could affect our financial condition and financial results.

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

We review long-lived assets, including definite-life intangible 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. We also review for impairment when conditions exist that indicate the carrying amount of the assets may not be fully recoverable. In those circumstances, we perform undiscounted operating cash flow analyses to determine if an impairment exists. When testing for asset impairment, we group 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

We assess 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 at an interim date. We have one reporting unit. We have 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.

We completed our annual goodwill impairment test as of July 1, 2024 and concluded that no impairments had occurred. There have been no significant events or changes in circumstances which indicated that the carrying amount of goodwill was not recoverable subsequent to the assessment.

Long-term Debt

We recognized a liability related to amounts received in January 2023, July 2023, January 2024, and September 2024 pursuant to the HCR Agreement under ASC 470-10, *Debt* and ASC 835-30, *Interest – Imputation of Interest*. The liability will be accreted under the effective interest method based upon the amount of contractual future payments to be made pursuant to the HCR Agreement. Amendments are assessed under ASC 470 to determine the appropriate treatment as troubled debt restructurings, extinguishments or modifications. If the timing or amounts of any future payments change, we will prospectively adjust the effective interest and the related amortization of the liability.

Revenue Recognition

We recognize revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). The core principle of ASC 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, we assess the promised goods or services in the contract and identify 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. We evaluate 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. We recognize 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.

Research and Development Expense

Research and development costs are expensed as incurred in accordance with ASC 730, *Research and Development* and include facility-related costs related to research and development activities, direct costs from third parties, such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and consultants, as well as employee-related expenses, including salaries, benefits, and stock-based compensation. Research and development expenses also include costs of acquired product licenses and related technology rights where there is no alternative future use.

Accrued Research and Development Expenses

As part of the process of preparing the consolidated financial statements, we are required to estimate accrued 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 these 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. The financial terms of our agreements with CROs and CMOs 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 such 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.

Patent Maintenance

We are responsible for all patent costs, past and future, associated with the preparation, filing, prosecution, issuance, maintenance, enforcement and defense of United States patent applications to which we have rights other than those patents that we license from Pharmosa that are not specific to L606. Such costs are recorded as general and administrative expenses as incurred. To the extent that our licensees share these costs, such benefit is recorded as a reduction of the related expenses.

Stock-Based Compensation

We estimate the grant date fair value of stock-based awards and amortize this fair value to compensation expense over the requisite service period or the vesting period of the respective award. In arriving at stock-based compensation expense, we estimate the number of stock-based awards that will be forfeited due to employee turnover. The forfeiture assumption is based primarily on turnover historical experience. If the actual forfeiture rate is higher than the estimated forfeiture rate, then an adjustment will be made to increase the estimated forfeiture rate, which will result in a decrease to the expense recognized in our financial statements. If the actual forfeiture rate is lower than the estimated forfeiture rate, then an adjustment will be made to lower the estimated forfeiture rate, which will result in an increase to expense recognized in our financial statements. The expense we recognize in future periods will be affected by changes in the estimated forfeiture rate and may differ from amounts recognized in the current period. See Note 9.

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,	
	2024	2023
Stock Options	9,288,028	9,513,039
Restricted Stock Units	3,049,830	1,685,532
Warrants	450,000	450,000
Total	12,787,858	11,648,571

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

Income Taxes

The asset and liability method is used in our 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. We record 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.

We 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.

Fair Value Measurements

ASC 825, *Financial Instruments* defines fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants (an exit price). As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. ASC 825 establishes a three-tiered approach for valuation of financial instruments, which requires that fair value measurements be classified and disclosed in one of three tiers, whether or not recognized on our consolidated balance sheets at fair value. 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 — Inputs other than quoted prices included in active markets 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 table presents the placement in the fair value hierarchy of financial assets and liabilities measured at fair value as of December 31, 2024 and December 31, 2023:

December 31, 2024	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
Money market funds (cash equivalents)	$ 170,672	$ —	$ —	$ 170,672

December 31, 2023	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
Money market funds (cash equivalents)	$ 79,912	$ —	$ —	$ 79,912

Money market funds are included in cash and cash equivalents on our consolidated balance sheet and are classified within Level 1 of the fair value hierarchy since they are valued using quoted market prices.

The carrying amounts reflected in our consolidated balance sheets for cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to their short-term nature. The carrying value of long-term debt approximates fair value as the respective interest rates are reflective of current market rates on debt with similar terms and conditions.

3. Inventory

Inventories are stated at the lower of average cost or net realizable value and consist of the following:

	December 31, 2024	December 31, 2023
Raw materials	$ 3,737	$ —
Work in process	7,069	—
Inventory	$ 10,806	$ —
Recognized as:		
Inventory	$ 241	$ —
Other assets	10,565	—

Prelaunch Inventory

As of December 31, 2024, we capitalized costs of $10.8 million associated with the production of YUTREPIA as a result of our determination that regulatory approval and subsequent commercialization is probable, and we also expect future economic benefit from the sales of YUTREPIA to be realized.

Amounts recognized as *Other Assets* are comprised entirely of raw materials and work in process inventories not expected to be sold within one year of the balance sheet date.

4. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

	December 31, 2024	December 31, 2023
Lab and build-to-suit equipment	$ 6,918	$ 6,834
Office equipment	7	19
Furniture and fixtures	481	241
Computer and other equipment	741	487
Leasehold improvements	12,959	11,409
Construction-in-progress	3,001	804
Total property, plant and equipment	24,107	19,794
Accumulated depreciation and amortization	(15,809)	(15,314)
Property, plant and equipment, net	$ 8,298	$ 4,480

We recorded depreciation and amortization expense related to property, plant and equipment of $0.8 million and $1.2 million for the years ended December 31, 2024 and 2023, respectively. Maintenance and repairs are expensed as incurred and were $0.3 million for both the years ended December 31, 2024 and 2023.

5. Contract Acquisition Costs and Intangible Asset, and Goodwill

Contract acquisition costs and intangible asset are summarized as follows:

	December 31, 2024			December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Contract acquisition costs	$ 12,980	$ (5,694)	$ 7,286	$ 12,980	$ (5,058)	$ 7,922
Intangible asset	$ 5,620	$ (2,464)	$ 3,156	$ 5,620	$ (2,190)	$ 3,430

We are amortizing the value of the contract acquisition costs and 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 for our accounting policies). Amortization of contract acquisition costs is recorded as a reduction of revenue, and amortization of the intangible asset is recorded as cost of revenue.

We recorded amortization related to the contract acquisition costs of $0.6 million for both the years ended December 31, 2024 and 2023, respectively. We recorded amortization related to the intangible asset of $0.3 million for both the years ended December 31, 2024 and 2023, respectively. Annual amortization over the next five years is expected to immaterially fluctuate from the 2024 amounts, consistent with changes to net profits to be recognized pursuant to the Promotion Agreement over the period.

During the year ended December 31, 2020, we recorded goodwill of $3.9 million, which primarily represented 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, 2024 and 2023, we concluded that there were no events or changes in circumstances that indicated that the carrying amount of goodwill was not recoverable.

6. 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") (the "RareGen Litigation"). 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 (as defined below), 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 RG Holdings, LLC ("PBM"). PBM is considered to be a related party as it is controlled by a major stockholder (which beneficially owns approximately 7.8% of Liquidia Corporation common stock as of March 10, 2025), who is also a member of our Board of Directors.

Under the terms of the Indemnification Agreement, PBM now controls the litigation, with Liquidia PAH's primary 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 RareGen 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 we record third party legal and litigation expenses related to the RareGen litigation.

As of December 31, 2024, the Indemnification Asset and Litigation Finance Payable were classified as long-term assets and liabilities, respectively, as it is considered unlikely that the RareGen Litigation would conclude prior to December 31, 2025.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2024	December 31, 2023
Accrued compensation	$ 10,251	$ 8,544
Accrued research and development expenses	2,495	2,902
Accrued inventory costs	1,641	—
Accrued other expenses	4,272	1,954
Total accrued expenses and other current liabilities	$ 18,659	$ 13,400

8. Stockholders' Equity

Authorized Capital

As of December 31, 2024, the authorized capital of the Company consists of 125,000,000 shares of capital stock, $0.001 par value per share, of which 115,000,000 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 September 11, 2024 from an Underwritten Public Offering and Private Placement

In September 2024, we sold 6,460,674 shares of our common stock in an underwritten registered public offering at an offering price of $8.90 per share (the "2024 Offering") for gross proceeds of approximately $57.5 million, before deducting offering costs of approximately $3.8 million.

A fund affiliated with Paul B. Manning, a member of our Board of Directors, participated in the 2024 Offering and purchased shares of common stock in an aggregate amount of approximately $3.0 million at the public offering price per share and on the same terms as the other purchasers in the 2024 Offering.

Concurrently with the 2024 Offering referenced above, we entered into a common stock purchase agreement with funds managed by Caligan Partners LP ("Caligan"), our largest stockholder, for the sale by us in a private placement of an aggregate of 1,123,595 shares of our common stock at a purchase price of $8.90 per share for gross and net proceeds of approximately $10.0 million.

Issuance of Common Stock on January 4, 2024 from a Private Placement

On January 4, 2024, we entered into a common stock purchase agreement with Legend Aggregator, LP for the sale by us in a private placement (the "2024 Private Placement") of an aggregate of 7,182,532 shares of our common stock at a purchase price of $10.442 per share. The 2024 Private Placement closed on January 8, 2024, and we received gross proceeds of approximately $75.0 million, before deducting offering costs of less than $0.1 million.

Issuance of Common Stock on December 12, 2023 from an Underwritten Public Offering and Private Placement

In December 2023, we sold 3,491,620 shares of our common stock in an underwritten registered public offering at an offering price of $7.16 per share (the "2023 Offering") for net proceeds of approximately $25.0 million, before deducting offering costs of approximately $1.9 million.

Caligan and Paul B. Manning, participated in the 2023 Offering and purchased shares of common stock in an aggregate amount of approximately $10.0 million at the public offering price per share and on the same terms as the other purchasers in the 2023 Offering. Caligan purchased 1,117,318 shares of common stock in the 2023 Offering for an aggregate purchase price of $8.0 million and Paul B. Manning purchased 279,330 shares of common stock in the 2023 Offering for an aggregate purchase price of $2.0 million.

Concurrently with the 2023 Offering referenced above, we entered into a common stock purchase agreement with Roger Jeffs, our Chief Executive Officer, for the sale by us in a private placement of an aggregate of 139,665 shares of our common stock at a purchase price of $7.16 per share for gross proceeds of approximately $1.0 million.

Warrants

During the years ended December 31, 2024 and 2023, 9,175 and no warrants to purchase shares of common stock were exercised, respectively. Outstanding warrants consisted of the following as of December 31, 2024:

Number of warrants		Exercise Price	Expiration Date
250,000	$	5.14	January 6, 2032
100,000	$	3.05	February 26, 2031
100,000	$	n/a[1]	February 26, 2031
56,397	$	0.02	December 31, 2026

1 These warrants were issued on February 26, 2021, in connection with our previously outstanding debt with Silicon Valley Bank. These warrants only became exercisable if there was additional funding under the loan agreement, and the exercise price of these warrants was to be set upon such potential additional funding. The additional funding never occurred, and the loan agreement has since been repaid and terminated. While these warrants technically remain outstanding, they are not, and will never be, exercisable.

9. Stock-Based Compensation

2020 Long-Term Incentive Plan

Our 2020 Long-Term Incentive Plan (the "2020 Plan") provides for the granting of stock 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 our 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, 2025, the number of shares of common stock available for issuance under the 2020 Plan automatically increased by 3,387,323 shares pursuant to the Evergreen Provision. As of December 31, 2024, there were 946,907 shares available for future grants under the 2020 Plan.

The 2020 Plan replaced all prior equity award plans and such plans have been discontinued. However, the awards outstanding under the prior equity award plans will continue to remain in effect in accordance with their terms. Awards that are forfeited under these prior plans upon cancellation, termination or expiration will not be available for grant under the 2020 Plan. As of December 31, 2024, a total of 469,694 shares of common stock were reserved for issuance related to the remaining outstanding equity awards granted under the prior plans.

2022 Inducement Plan

On January 25, 2022, the Board of Directors approved the adoption of our 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 of Directors without stockholder approval pursuant to Rule 5635(c)(4) of the rules and regulations of The Nasdaq Stock Market, LLC (the "Nasdaq Listing Rules").

310,000 shares of our common stock were reserved for issuance pursuant to equity awards that may be 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 of Directors, or following a bona fide period of non-employment by us, if he or she is granted such equity awards in connection with his or her commencement of employment with us and such grant is an inducement material to his or her entering into employment with us. As of December 31, 2024, a total of 27,608 shares were available for issuance 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 number of shares of our common stock available for issuance under the ESPP will automatically increase on January 1 of each year through 2030, by the lesser of (a) 1.0% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, (b) 150,000 shares, or (c) an amount determined by the Board of Directors. On January 1, 2025, the number of shares of common stock available for issuance under the ESPP increased by 150,000 shares. As of December 31, 2024, a total of 534,742 shares of common stock are reserved for issuance under the ESPP. The ESPP allows eligible employees to purchase shares of our common stock at a discount through payroll deductions, subject to plan limitations. Unless otherwise determined by the administrator, the 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 our common stock on the first and last trading day of the offering period. During the years ended December 31, 2024 and 2023, 172,395 and 140,922 shares were issued under the ESPP, respectively.

Stock-Based Compensation Valuation and Expense

We account for employee stock-based compensation plans using the fair value method. The fair value method requires us to estimate the grant-date fair value of stock-based awards and amortize this fair value to compensation expense over the requisite service period or vesting term. The fair value of each option grant is estimated using a Black-Scholes option-pricing model. For restricted stock units ("RSUs") and performance stock units ("PSUs"), the grant-date fair value is based upon the market price of our 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.

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

	Year Ended December 31,	
By Expense Category:	**2024**	**2023**
Cost of revenue	$ 225	$ —
Research and development	3,489	2,294
General and administrative	15,092	7,795
Total stock-based compensation expense	$ 18,806	$ 10,089

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, 2024	
	Unamortized Expense	**Weighted Average Remaining Recognition Period (Years)**
Stock options	$ 8,138	1.4
Restricted and performance stock units	$ 22,615	2.3

Fair Value of Stock Options Granted and Purchase Rights Issued under the ESPP

We use the Black-Scholes option-pricing model to determine the fair value of stock options granted and purchase rights issued under the ESPP.

The following table summarizes the assumptions used for estimating the fair value of stock options granted under the Black-Scholes option-pricing model:

	Year Ended December 31,	
	2024	2023
Expected dividend yield	—	—
Risk-free interest rate	3.98%	3.46% - 4.73%
Expected volatility	90%	90% - 95%
Expected life (years)	6.1	5.8 - 6.1

The following table summarizes the assumptions used for estimating the fair value of purchase rights granted to employees under the ESPP under the Black-Scholes option-pricing model:

	Year Ended December 31,	
	2024	2023
Expected dividend yield	—	—
Risk-free interest rate	4.80% - 5.27%	5.20% - 5.47%
Expected volatility	62% - 72%	60% - 64%
Expected life (years)	0.50	0.50

The following describes our methodology for determining each assumption:

Expected Dividend Yield: The dividend yield percentage is zero because we have not historically paid dividends and do 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 our common stock during the period for which it has traded since the initial public offering. For purposes of identifying peer companies, we 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. Our 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, we estimate the expected term by using the simplified method.

Stock Options

Options generally vest over a four-year period in multiple tranches.

The following table summarizes stock option activity during the year ended December 31, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	9,573,937	$ 4.80		
Granted	7,500	12.86		
Exercised	(380,096)	4.66		
Cancelled	(192,336)	7.24		
Outstanding as of December 31, 2024	9,009,005	$ 4.76	6.8	$ 63,218
Exercisable as of December 31, 2024	7,039,951	$ 4.52	6.6	$ 51,127
Vested and expected to vest as of December 31, 2024	8,806,504	$ 4.74	6.8	$ 62,022

The weighted average fair value for options granted during the years ended December 31, 2024 and 2023 was $9.84 and $5.09 per share, respectively. The aggregate intrinsic value of stock options in the table above represents the difference between the $11.76 closing price of our common stock as of December 31, 2024 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,	
	2024	2023
Cash proceeds from options exercised	$ 1,771	$ 495
Aggregate intrinsic value of options exercised	$ 2,907	$ 468
Fair value of options vested	$ 6,773	$ 10,143

Restricted and Performance Stock Units

RSUs represent the right to receive shares of our common stock at the end of a specified time period and/or upon the achievement of a specific milestone. RSUs can only be settled in shares of our common stock. RSUs generally vest over a four-year period similar to stock options granted to employees. RSUs granted to directors generally vest over a one-year period.

PSUs granted during 2024 included 520,526 performance-based RSUs granted to our executive officers. These PSUs vest upon the later of (a) time-based vesting conditions and (b) the first commercial sale of YUTREPIA in the United States and are considered probable of vesting. The time-based vesting condition means 25% of the performance-based RSUs vest one year after grant date and quarterly thereafter for three years, subject to the executive's continued service.

The tax withholding method used for most RSUs and PSUs is the sell-to-cover method, in which shares with a market value equivalent to the tax withholding obligation are sold on behalf of the holder of the RSUs and PSUs upon vesting and settlement to cover the tax withholding liability and the cash proceeds from such sales are remitted to taxing authorities by us. In circumstances where the sell-to-cover method is not used, the holder of the RSUs or PSUs is required to remit cash to us to cover the tax withholding liability and the cash is then remitted to taxing authorities by us.

The following table summarizes our RSU and PSU activity during the year ended December 31, 2024:

	Number of RSUs	Weighted Average Grant-Date Fair Value (per RSU)
Unvested as of December 31, 2023	1,657,978	$ 6.41
Granted	2,164,377	12.56
Vested	(725,038)	6.48
Forfeited	(149,268)	8.32
Unvested as of December 31, 2024	2,948,049	$ 10.82

10. Revenue From Contracts With Customers

In August 2018, we entered into a Promotion Agreement with Sandoz under which we have the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection for the treatment of patients with PAH in the United States. We paid Sandoz $20 million at the inception of the Promotion Agreement in consideration for these rights. In exchange for conducting these commercial activities, we are entitled to receive a share of Net Profits (as defined within the Promotion Agreement) based on specified profit levels. The share of Net Profits received is subject to adjustments from Sandoz for certain items, such as distributor chargebacks, rebates, inventory returns, inventory write-offs and other adjustments. We expect 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, 2024 and 2023, a $2.0 million and $0.5 million refund liability, respectively, is offset against accounts receivable from Sandoz to expected refund amounts. Approximately 98% and 99% of revenue during the years ended December 31, 2024 and 2023, respectively, was generated from the Promotion Agreement.

11. Income Taxes

No provision for federal and state income tax expense has been recorded for the years ended December 31, 2024 and 2023 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 our deferred tax assets and liabilities are as follows as of December 31, 2024 and 2023:

	2024	2023
Deferred income tax assets:		
Tax loss carryforwards	$ 86,289	$ 66,956
Research and development credits	3,942	3,942
R&D section 174 costs	15,166	9,446
Share-based compensation	1,710	1,520
Lease liability	1,713	863
Compensation	2,235	1,982
Fixed assets	302	404
Patent amortization	280	396
Accrued litigation costs	1,786	1,652
Settlement reserve	496	130
Licensing agreement	3,043	2,367
OID Interest	1,387	383
Other	31	21
Valuation allowance	(115,525)	(87,963)
Total deferred income tax assets	2,855	2,099
Deferred income tax liabilities:		
Intangible assets	1,825	1,652
Right of use asset	1,030	447
Total deferred income tax liabilities	2,855	2,099
Total net deferred tax	$ —	$ —

As of December 31, 2024 and 2023, we established a full valuation allowance against our net deferred tax assets since, at the time, we could not assert that it was more likely than not that our deferred tax assets would be realized. As a result, there was an increase in the valuation allowance in 2024 of approximately $27.5 million.

As of December 31, 2024, we had federal and state income tax loss carryforwards of $388.7 million and $390.9 million, respectively, which begin to expire in 2025 for both federal and state purposes. In addition, we have tax credit carryforwards for federal tax purposes of approximately $4.3 million as of December 31, 2024, which begin to expire in 2026. The utilization of net operating loss and tax credit carryforwards to reduce future income taxes will depend on our 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 our net operating loss carryforwards are limited, and we have taxable income which exceeds the permissible yearly net operating loss carryforwards, we 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, 2024 and 2023 and the amount computed by applying the statutory federal income tax rate to income before income tax are as follows:

	2024		2023	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate	$ (27,383)	21.0 %	$ (16,486)	21.0 %
State income taxes, net of federal tax benefit	(4,139)	3.2	(2,553)	3.3
Non-deductible expenses	896	(0.7)	493	—
Stock-based compensation	1,934	(1.5)	2,015	(2.6)
Credits	—	—	—	—
Deferred tax true-up	417	(0.3)	2,823	(3.6)
Change in state rate	105	(0.1)	260	(0.3)
Other	608	(0.5)	34	—
Change in valuation allowance	27,562	(21.1)	13,414	(17.8)
Provision for income taxes	$ —	— %	$ —	— %

We have determined that there may be a future limitation on our ability to utilize its entire federal R&D credit carryover. Therefore, we recognized an uncertain tax benefit associated with the federal R&D credit carryover during the years ended December 31, 2024 and 2023, as follows:

Balance at December 31, 2022	$ 390
Increases related to 2023	—
Balance at December 31, 2023	390
Decreases related to 2024	—
Balance at December 31, 2024	$ 390

We 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. We have determined that it had no other material uncertain tax benefits for the year ended December 31, 2024. Our policy for recording interest and penalties related to uncertain tax provisions is to record them as a component of the provision for income taxes. We did not have any accrued interest or penalties associated with any unrecognized tax positions as of December 31, 2024 and 2023, and there were no such interest or penalties recognized during the years ended December 31, 2024 and 2023.

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. The Company has 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 in each year is fully offset by a 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.

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

12. Leases

Operating Leases

We are party to a non-cancelable operating lease for our laboratory and office space in Morrisville, North Carolina. On November 22, 2024, the operating lease was amended to extend the expiration date from October 31, 2026 to December 31, 2031, with an option to extend for an additional period of five years with appropriate notice. As a result of the

amendment, we remeasured our operating lease liability using an incremental borrowing rate of 15.2%. We have not included the optional extension period in the measurement of lease liabilities because it is not reasonably certain that we will exercise the option to extend. The payments under this lease are subject to escalation clauses. Operating lease cost is allocated between inventory, research and development, and general and administrative expenses based on the usage of the leased facilities. 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.

Finance Leases

We lease specialized laboratory equipment under finance leases. We do not have access to certain inputs used by our lessors to calculate the rate implicit in our finance leases and, as such, use our estimated incremental borrowing rate at the time of lease inception for the discount rate applied to our finance leases. The incremental borrowing rate used on finance leases was 6.5%. Certain finance leases also include options to purchase the leased property. We recognize all such purchase options as part of our right-of-use assets and lease liabilities if we are reasonably certain that such purchase options will be exercised.

Lease Balances, Costs, and Future Minimum Payments

Leases with an initial term of 12 months or less are not recorded on the balance sheet. As of December 31, 2024, we have not entered into any short-term leases. For lease agreements entered into or reassessed after the adoption of ASC 842 Leases, we combine lease and non-lease components, if any. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Our lease cost is reflected in the accompanying statements of operations and comprehensive loss as follows:

		Year Ended December 31,	
	Classification	2024	2023
Operating lease cost:			
Fixed lease cost	Research and development	$ 740	$ 702
Fixed lease cost	General and administrative	82	78
Finance lease cost:			
Amortization of lease assets	Research and development	89	96
Interest on lease liabilities	Interest expense	7	15
Total Lease Cost		$ 918	$ 891

The weighted average remaining lease term and discount rates as of December 31, 2024 were as follows:

Weighted average remaining lease term (years):	
Operating leases	7.0
Finance leases	0.2
Weighted average discount rate:	
Operating leases	15.2 %
Finance leases	6.5 %

The discount rate for leases was estimated based upon market rates of collateralized loan obligations of comparable companies on comparable terms at the time of lease inception.

The future minimum lease payments as of December 31, 2024 were as follows:

Year ending December 31:	Operating Leases	Finance Leases	Total
2025	$ 1,370	$ 64	$ 1,434
2026	1,442	—	1,442
2027	1,643	—	1,643
2028	1,692	—	1,692
2029	1,743	—	1,743
Thereafter	3,644	—	3,644
Total minimum lease payments	11,534	64	11,598
Less: interest	(4,594)	(1)	(4,595)
Present value of lease liabilities	$ 6,940	$ 63	$ 7,003

13. Long-term Debt

On January 9, 2023, we entered into the HCR Agreement pursuant to which and subject to the terms and conditions contained therein, HCR has paid us an aggregate investment amount of $100.0 million (the "Investment Amount").

On January 27, 2023, $32.5 million of the Investment Amount was funded from the first tranche, $22.2 million of which was used to satisfy existing obligations due to Silicon Valley Bank. This repayment resulted in a loss on extinguishment during the year ended December 31, 2023 of $2.3 million.

On June 28, 2023 and July 27, 2023, we entered into the Second Amendment to the HCR Agreement and Third Amendment to the HCR Agreement, respectively, pursuant to which HCR funded $10.0 million from the second tranche on July 27, 2023.

On January 3, 2024, we entered into the Fourth Amendment to the HCR Agreement pursuant to which HCR funded an additional $25.0 million from the second tranche on January 5, 2024.

On September 11, 2024 we entered into the Fifth Amendment to the HCR Agreement pursuant to which HCR funded an additional $32.5 million from the second tranche on September 12, 2024 and eliminated the third and fourth tranches.

As consideration for the Investment Amount and pursuant to the HCR Agreement, we have agreed to pay HCR according to a fixed quarterly payment schedule.

As of December 31, 2024, we were required to pay $18.0 million within one year of the balance sheet date, which is classified as current in our consolidated balance sheet.

Aggregate payments to HCR are capped at 175% of funded portion of the Investment Amount (the "Hard Cap"), plus an amount, if any, that HCR would need to receive to yield an internal rate of return of (i) 18% on the first $67.5 million funded and (ii) 16% on the next $32.5 million funded (the "IRR True-Up Payment"), unless the HCR Agreement is earlier terminated. If a change of control occurs or upon the occurrence of an event of default, HCR may accelerate payments due under the HCR Agreement up to the Hard Cap, plus the IRR True-Up Payment, plus any other obligations payable under the HCR Agreement.

The HCR Agreement 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 HCR Agreement and require us to make payments to HCR equal to the lesser of (a) the Hard Cap, plus any other obligations payable under the HCR Agreement, or (b) the funded portion of the Investment Amount, minus payments received by HCR, 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 we will be required to make payments to HCR equal to 100% of the amount funded by HCR to date, minus payments received by HCR.

The HCR Agreement contains certain restrictions on our ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, dispose of assets, pay dividends and distributions, subject to certain exceptions. In addition, the HCR Agreement contains a financial covenant that requires us to maintain cash and cash equivalents in an amount at least equal to $15.0 million for the remainder of the payment term, which based on amounts funded as of December 31, 2024, concludes in 2031.

As of the filing date of these consolidated financial statements, we are not aware of any breach of covenants, or the occurrence of any material adverse event, nor have we received any notice of event of default from HCR.

The Fourth Amendment to the HCR Agreement qualified as a debt extinguishment and issuance of a new debt instrument in accordance with ASC 405-20, *Extinguishments of Liabilities*. We recorded a loss on extinguishment during the quarter ended March 31, 2024 of $11.5 million, equal to the fair value of the amended HCR Agreement less the carrying value of the existing HCR Agreement on January 5, 2024.

The Fifth Amendment to the HCR Agreement qualified as a debt extinguishment and issuance of a new debt instrument in accordance with ASC 405-20, *Extinguishments of Liabilities*. We recorded a gain on extinguishment during the quarter ended September 30, 2024 of $7.2 million, equal to the fair value of the amended HCR Agreement less the carrying value of the existing HCR Agreement on September 12, 2024.

We recorded the total funds received from HCR under the terms of the HCR Agreement as a liability. We use the contractual payment schedule to determine the interest expense to record to accrete the liability to the amount ultimately due. For the year ended December 31, 2024, we estimated an effective annual interest rate of approximately 15.2%. Over the course of the HCR Agreement, the effective annual interest rate may be affected by potential changes in contractual payments.

The following table presents the changes in the HCR Agreement payable during the year ended December 31, 2024:

Balance as of December 31, 2023	$	46,033
Accretion		107
Amortization of issuance costs		2
Second tranche funding, net of fees		24,975
Balance as of January 5, 2024, prior to extinguishment	$	71,117
Loss on extinguishment		11,483
Balance as of January 5, 2024, after extinguishment	$	82,600
Accretion		7,161
Payments		(2,731)
Second tranche funding, net of fees		32,485
Balance as of September 12, 2024, prior to extinguishment	$	119,515
(Gain) on extinguishment		(7,215)
Balance as of September 12, 2024, after extinguishment	$	112,300
Accretion		5,209
Payments		(2,122)
Balance as of December 31, 2024	$	115,387
Less: current portion of long-term debt		(18,016)
Long-term portion of long-term debt	$	97,371

The expected annual payments on long-term debt as of December 31, 2024 are as follows:

Year ending December 31:		
2025	$	18,017
2026		52,724
2027		32,962
2028		32,962
2029		15,308
Thereafter		16,521
Total	$	168,494

On March 17, 2025, we entered into the Sixth Amendment to the HCR Agreement pursuant to which HCR made an additional $100.0 million available for funding under the second tranche. See Note 17 for further information.

14. Legal Proceedings

YUTREPIA-Related Litigation

In connection with an amendment to the Company's NDA filed in July 2023 to add PH-ILD as an indication for YUTREPIA, the Company provided a notice of the paragraph IV certification to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, in September 2023, United Therapeutics filed a complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware (Case No. 1:23-cv-00975-RGA) (the "New Hatch-Waxman Litigation"), asserting infringement by the Company of U.S. Patent No. 10,716,793, entitled "Treprostinil Administration by Inhalation" (the "'793 Patent"). In November 2023, the U.S. Patent and Trademark Office (the "USPTO") issued U.S. Patent No. 11,826,327, entitled "Treatment for Interstitial Lung Disease" (the "'327 Patent"), to United Therapeutics. On November 30, 2023, United Therapeutics filed an amended complaint in the New Hatch-Waxman Litigation asserting infringement of the '327 Patent by the practice of YUTREPIA based on the amended NDA. In January 2024, the Company filed an answer, counterclaims and a partial motion to dismiss the claims related to the '793 Patent as a result of the decision by the United States Court of Appeals for the Federal Circuit to affirm a finding by the Patent Trial and Appeal Board (the "PTAB") that the '793 Patent is unpatentable. In February 2024, United Therapeutics stipulated to the dismissal of the claims in the New Hatch-Waxman Litigation related to the '793 Patent. In February 2024, United Therapeutics also filed a motion seeking a preliminary injunction to prevent the Company from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. Judge Andrews denied the motion for a preliminary injunction in May 2024. Trial is scheduled for June 2025.

FDA Litigation

In February 2024, United Therapeutics filed a complaint against the FDA in the U.S. District Court for the District of Columbia (the "D.C. District Court"), challenging the FDA's acceptance of the Company's amended NDA for review (the "Original FDA Litigation"). The Company intervened and became a party to the lawsuit in March 2024. In March 2024, United Therapeutics filed a motion for a temporary restraining order and preliminary injunction in the FDA Litigation, seeking to enjoin the FDA from approving the Company's NDA for YUTREPIA with respect to the indication to treat PH-ILD. United Therapeutics' motion was denied in March 2024. In August 2024, United Therapeutics voluntarily dismissed its complaint, without prejudice.

In August 2024, the Company filed a lawsuit in the D.C. District Court to challenge the decision by the FDA to grant three-year regulatory exclusivity to Tyvaso DPI (the "New FDA Litigation"). The D.C. District Court granted the parties' motion for an expedited summary judgment briefing schedule, and a summary judgment hearing was held in December 2024. In February 2025, the D.C. District Court issued a decision denying the Company's motion for summary judgment and simultaneously granting the motions for summary judgment filed by the FDA and United Therapeutics. In so doing, the D.C. District Court affirmed the FDA's award of regulatory exclusivity to Tyvaso DPI. This decision does not affect the expiration of the regulatory exclusivity, which will still occur on May 23, 2025.

In September 2024, United Therapeutics filed a cross claim in the New FDA Litigation, re-asserting its challenge to FDA's acceptance of the Company's amended NDA for review. The Company intervened and became a party with respect to the cross claim in November 2024. Both the Company and the FDA filed motions to dismiss United Therapeutics' cross claim. The motions to dismiss remain pending.

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 (the "Former Employee") conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2024, the Former Employee filed a motion for summary judgment with respect to all claims, but the motion was denied in July 2024. In addition, in July 2024, the Company filed a motion for summary judgment with respect to all claims. A hearing on the Company's motion for summary judgment was held in December 2024. The motion remains pending.

In May 2024, United Therapeutics filed a second complaint in the Superior Court in Durham County, North Carolina, against the Former Employee, alleging that he breached prior employment agreements with United Therapeutics by failing to assign to United Therapeutics his interest in patents obtained by the Company that relied upon or benefitted from certain inventions, discoveries, materials, authorship, derivatives and results developed by the Former Employee while he was employed by United Therapeutics. The Company was also named as a defendant in this new lawsuit. As part of the lawsuit, United Therapeutics alleges that the Former Employee misappropriated certain intellectual property of United Therapeutics which led to the development of YUTREPIA. The complaint also seeks declaratory judgement such that all right, title and interest in and to any patentable or unpatentable inventions, discoveries, and ideas made or conceived by the Former Employee while employed by the Company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. In July 2024, the Company filed a motion to dismiss all claims. A hearing on the Company's motion to dismiss was held in December 2024. The motion remains pending.

RareGen Litigation

In April 2019, Sandoz and Liquidia PAH (then known as RareGen) filed a complaint against United Therapeutics and Smiths Medical (now ICU 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 Settlement Agreement, Smiths Medical 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 cartridge that Smiths Medical developed and manufactures for use with the CADD-MS 3 infusion pump (the "CADD-MS 3 Cartridge") and certain other information for use of the CADD-MS 3 infusion pump and the CADD-MS 3 Cartridges. In connection with the license,

Liquidia PAH and Sandoz agreed, among other things, to indemnify Smiths from certain liabilities related to any cartridge they developed for use with the CADD-MS 3 infusion pumps.

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. A trial to determine the amount of damages due from United Therapeutics to Sandoz with respect to the breach of contract claim was held from late April to early May 2024. In November 2024, the Court entered a judgment in the amount of $70.6 million. United Therapeutics, Sandoz and Liquidia PAH have all appealed the Court's decision to the United States Court of Appeals for the Third Circuit, and briefing is ongoing.

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

Pharmosa License Agreement and Device License Agreement

In June 2023, we entered into a License Agreement with Pharmosa pursuant to which we were granted an exclusive license in North America to develop and commercialize L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of PAH and PH-ILD, and a non-exclusive license for the manufacture, development and use (but not commercialization) of such licensed product in most countries outside North America (the "Pharmosa License Agreement"). On October 2, 2024, we and Pharmosa entered into a First Amendment to the Pharmosa License Agreement (the "First Amendment") which, among other things, expands our licensed territory beyond North America to include key markets in Europe, Japan and elsewhere.

Concurrently with the execution of the First Amendment, we and Pharmosa also entered into a Device License Agreement (the "Device License Agreement"). Pursuant to the terms of the Device License Agreement, Pharmosa will provide (i) an exclusive license to Liquidia Technologies for the right to develop, manufacture, use and commercialize Pharmosa's next-generation smart-technology nebulizers (the "Device") for use with L606 in most countries (subject to certain exceptions) (the "Territory") and (ii) a non-exclusive license to Liquidia Technologies for the right to develop, manufacture and use (but not commercialize) the Device outside of the Territory.

Under the terms of the Pharmosa License Agreement, as amended, we will be responsible for development, regulatory and commercial activities of L606 in the Territory. Pharmosa will manufacture clinical and commercial supplies of the liposomal formulation through its global supply chain and support us in establishing a redundant global supply chain. In consideration for these exclusive rights, we paid Pharmosa an upfront license fee of $10 million and paid an additional $3.5 million upfront license fee in October 2024 in connection with the rights granted in the First Amendment and the Device License Agreement. In addition to the upfront fees, we will pay Pharmosa potential development milestone payments tied to clinical development and approvals in PAH and/or PH-ILD of up to $37.75 million, potential sales milestones of up to $185 million in North America and $150 million outside North American and two tiers of low, double-digit royalties on all net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication approved by the FDA after PAH and PH-ILD and each additional product approved by the FDA under the license, a $2 million milestone payment for each additional indication approved by the EMA after PAH and PH-ILD, and a $0.5 million milestone payment for each additional indication approved by the PMDA after PAH and PH-ILD. We also retain the first right to negotiate for development and commercialization of L606 in Europe and other territories should Pharmosa seek a partner, subject to satisfaction of certain conditions as set forth in the Pharmosa License Agreement.

Mainbridge Health Care Device Development and Supply Agreement

In December 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 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 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.

UNC License Agreement

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 Agreement"). As part of the UNC License Agreement, we hold an exclusive license to certain research and development technologies and processes in various stages of patent pursuit, for use in our 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, we are 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. We 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, we entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to our manufacturing capabilities during the term of the agreement. We agreed to pay future contingent milestones and royalties on net sales totaling no more than $1.5 million, $0.2 million of which has been accrued as of December 31, 2024.

Employment Agreements and Executive Severance and Change in Control Plan

We have agreements with certain employees and an Executive Severance and Change in Control Plan which covers certain other employees which require payments if certain events, such as a change in control or termination without cause, occur.

Purchase Obligations

We enter 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, we can elect to discontinue the work under these agreements at any time.

On July 14, 2023, we entered into an Amended and Restated Commercial Manufacturing Services and Supply Agreement with Lonza Tampa LLC ("Lonza") (as amended, the "CSA"). Lonza is our sole supplier for encapsulation and packaging services for YUTREPIA. Pursuant to the terms of the CSA, we deliver bulk treprostinil powder, manufactured using our proprietary PRINT® technology, and Lonza encapsulates and packages it. The CSA was effective upon signing, will be in effect until December 31, 2028 and may thereafter be extended upon the mutual written agreement of the parties in accordance with the terms of the CSA. We may terminate the CSA upon 60 days' written notice to Lonza in the event that the application for regulatory approval of YUTREPIA is rejected by the FDA and such FDA decision is not caused by the fault of the Company (the "Termination for FDA Rejection"). Lonza may terminate the CSA upon 120 days written notice if we do not receive regulatory approval of YUTREPIA from the FDA by December 31, 2025 (the "Termination for FDA Delay"). Upon any Termination for FDA Rejection or Termination for FDA Delay, we would reimburse Lonza for 50% of its documented out-of-pocket expenditures for any capital

equipment that is purchased by Lonza after the effective date of the Agreement to perform the services for us, not to exceed $2.5 million in the aggregate.

We are required to provide Lonza with quarterly forecasts of our expected production requirements for the following 24-month period, the first twelve months of which is considered a binding, firm order. We are required to purchase certain minimum annual order quantities, which may be adjusted by us after the thirteenth month after receipt of regulatory approval of YUTREPIA. The CSA provides for tiered pricing depending upon the batch size ordered.

In addition, we entered into a multi-year supply agreement with LGM Pharma, LLC ("LGM") to supply active pharmaceutical ingredients for YUTREPIA. Under the 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.

As of December 31, 2024, we have non-cancelable commitments for product manufacturing and supply costs of approximately $12.8 million.

Other Contingencies and Commitments

From time-to-time we are subject to claims and litigation in the normal course of business, none of which do we believe 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, we are party to other commitments, including non-cancelable leases and long-term debt, which are described elsewhere in these notes to the consolidated financial statements.

16. Segment Information

We operate as a single business segment focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards rare cardiopulmonary diseases such as PAH and PH-ILD. The determination of a single business segment is consistent with the consolidated financial information regularly reviewed by our Chief Executive Officer, the chief operating decision maker ("CODM"), in assessing segment performance and deciding how to allocate resources on a consolidated basis. The accounting policies of the segment are the same as those described in the summary of significant accounting policies.

The CODM measures segment profit and loss by net loss as reported in the consolidated income statements. The CODM uses net loss to monitor budget and forecast versus actual results to assess segment performance and to allocate resources across the organization. The measure of segment assets is reported on the consolidated balance sheet as total assets.

The following table summarizes segment revenue, segment loss, and significant segment expenses regularly reported to the CODM during the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Revenue	13,996	17,488
Cost of revenue	5,879	2,888
Program expenses (1)		
YUTREPIA	37,352	23,487
L606	12,052	12,551
Generic Treprostinil	720	308
Total program expenses	50,124	36,346
Non-program expenses (2)	15,530	12,854
Personnel, including stock-based compensation	63,757	38,784
Loss from operations	(121,294)	(73,384)
Other income (expense), net	(9,100)	(5,118)
Net loss	(130,394)	(78,502)

(1) Includes external research and development and general and administrative expenses

(2) Includes professional service fees, facilities & infrastructure expenses, insurance, depreciation & amortization, and other corporate expenses.

17. Subsequent Event

Sixth Amendment to the HCR Agreement

On March 17, 2025, we entered into the Sixth Amendment to the HCR Agreement pursuant to which HCR made an additional $100.0 million available for funding under the second tranche, $25.0 million of which was funded on March 17, 2025. An additional $50.0 million may be funded upon the first commercial sale of YUTREPIA following receipt of final FDA approval for the treatment of PAH and PH-ILD, so long as no injunction has been issued prohibiting Liquidia from commercializing YUTREPIA for either or both of PAH and PH-ILD, and an additional $25.0 million upon the mutual agreement of the parties after achieving aggregate net sales of YUTREPIA in excess of $100 million any time on or prior to June 30, 2026. As consideration for the additional $25.0 million funded at closing, Liquidia has agreed to a fixed payment schedule that terminates in 2032. Payments on the last two tranches, when funded, would also follow a fixed payment schedule. As further discussed in Note 13, aggregate payments to HCR are capped at 175% of the total amounts advanced by under the HCR Agreement plus a potential true-up payment to be made by us if HCR's internal rate of return is less than a minimum rate of return on the date the cap is reached. The minimum rates of return for the three new tranches are 16%, 13% and 12%, respectively.