As filed with the Securities and Exchange Commission on June 27, 2024

Registration Statement No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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
Tel: (919) 328-4400

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Roger A. Jeffs, Ph.D.
Chief Executive Officer
Liquidia Corporation
419 Davis Drive, Suite 100
Morrisville, North Carolina 27560
Tel: (919) 328-4400

(Name, address, including zip code, and telephone number including area code, of agents for service)

Copies to:
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51 John F. Kennedy Parkway
Short Hills, NJ 07078
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Approximate date of commencement of proposed sale to the public: From time to time after the effectiveness of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Subject to Completion, dated June 27, 2024

PROSPECTUS

7,322,197 Shares of Common Stock

This prospectus relates to the resale or other disposition by the selling stockholders identified in this prospectus (the "Selling Stockholders"), from time to time, of up to 7,322,197 shares of common stock, par value $0.001 per share (the "Common Stock") of Liquidia Corporation (the "Company," "we" or "us").

We are not selling any shares of Common Stock under this prospectus and will not receive any of the proceeds from the sale or other disposition of Common Stock by the Selling Stockholders.

The Selling Stockholders or their pledgees, assignees, permitted transferees or other successors-in-interest may offer and sell or otherwise dispose of the shares of Common Stock described in this prospectus from time to time through public or private transactions at fixed prices, at prevailing market prices, at prices related to prevailing market prices, at varying prices determined at time of sale, or at privately negotiated prices. The Selling Stockholders will bear all commissions and discounts, if any, attributable to the sales of shares. We will bear all costs, expenses and fees in connection with the registration of the shares. See "Plan of Distribution" beginning on page 65 for more information about how the Selling Stockholders may sell or dispose of their shares of Common Stock.

Our Common Stock is listed on The Nasdaq Capital Market under the symbol "LQDA." On June 26, 2024, the last reported sale price of our Common Stock was $12.32 per share.

Investing in our securities involves risk. See "Risk Factors" beginning on page 19 of this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as the documents incorporated by reference herein and therein, before you invest in any of our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2024

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the U.S. Securities and Exchange Commission (the "SEC"), using a "shelf" registration process. Under a shelf registration process, the Selling Stockholders may from time to time sell the shares of Common Stock described in this prospectus in one or more offerings.

This prospectus provides you with a general description of the securities we may offer. Each time the Selling Stockholders sell the securities, to the extent required by law, a prospectus supplement will be provided that will contain specific information about the terms of the offering. One or more free writing prospectuses may also be provided to you in connection with the offering. The prospectus supplement and any related free writing prospectus may add, update or change information contained in this prospectus. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. You should carefully read this prospectus, the applicable prospectus supplement, and any applicable free writing prospectus, as well as the information and documents incorporated herein and therein by reference and the additional information under the heading "Where You Can Find More Information," before making an investment decision.

Neither we nor the Selling Stockholders have authorized any dealer, salesman or other person to give any information or to make any representation other than those contained in, or incorporated by reference into, this prospectus and the applicable prospectus supplement, and any free writing prospectus authorized for use in connection with a specific offering. Neither we nor the Selling Stockholders take any responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

This prospectus and any accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and any accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus, any accompanying prospectus supplement and any applicable free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus, any accompanying prospectus supplement or any applicable free writing prospectus is delivered, or securities sold, on a later date.

This prospectus may not be used to consummate sales of securities unless it is accompanied by a prospectus supplement. To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

This prospectus includes our trademarks, trade names and service marks, such as Liquidia, the Liquidia logo, RareGen, the RareGen logo, YUTREPIA and PRINT, or Particle Replication In Non-wetting Templates, which are protected under applicable intellectual property laws and are the property of our company. This prospectus 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 prospectus 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus and any prospectus supplement or free writing prospectus may contain "forward-looking statements" within the meaning of the safe harbor provisions of Section 27A of the Securities Act, and Section 21E of the Exchange Act. These forward-looking statements only provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should", "could", "predicts" or the negative thereof, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans and our expectations and timing related to the FDA approval and commercialization of our product candidates, including YUTREPIA. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995.

You should read carefully the risks described in the section entitled "Risk Factors" beginning on page 19 of this prospectus, and in any accompanying prospectus supplement or related free writing prospectus, together with all information incorporated by reference herein and therein, to better understand the significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these risks, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this prospectus or in any accompanying prospectus supplement or related free writing prospectus, or incorporated by reference herein and therein, and you should not place undue reliance on any forward-looking statements.

In addition to the risks described in the section entitled "Risk Factors" beginning on page 19 of this prospectus, many important factors may affect our ability to achieve our plans and objectives and to successfully develop and commercialize our product candidates. 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 YUTREPIA, the potential for, and timing regarding, eventual final approval by the FDA (as defined below) of and our ability to commercially launch YUTREPIA, 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, the inter partes reviews with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, our trade secret litigation with United Therapeutics that was filed in the Superior Court for Durham County, North Carolina, the lawsuit filed by United Therapeutics against the FDA in the U.S. District Court for the District of Columbia, or any future litigation with United Therapeutics or any other third party, including any related rehearings or appeals;
- the timing and our business partners' ability to obtain and maintain regulatory clearance for the infusion pump that we are developing with Sandoz Inc. ("Sandoz") and Mainbridge Health Partners LLC ("Mainbridge");
- the timing and our ability to obtain and maintain regulatory approval for L606, an investigational, liposomal formulation of treprostinil that we licensed from Pharmosa Biopharm Inc. ("Pharmosa");
- our ability to continue operations as a going concern without obtaining additional funding;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for those drug products that we commercialize in collaboration with third parties, including Sandoz's first-to-file fully substitutable generic treprostinil injection;

- the availability and market acceptance of medical devices and components of medical devices used to administer our drug products and drug products that we commercialize with third parties, including Smiths Medical's CADD-MS 3 infusion pump, the RG 3ml Medication Cartridge that we developed in collaboration with Chengdu Shifeng Medical Technologies LTD ("Chengdu") used for the subcutaneous administration of Sandoz's generic treprostinil injection, Smiths Medical ASD, Inc.'s ("Smiths Medical") CADD Legacy and CADD-Solis infusion pumps used for the intravenous administration of Sandoz's generic treprostinil injection, the infusion pump that we are developing with Sandoz and Mainbridge for the subcutaneous administration of Sandoz's generic treprostinil injection, Plastiape S.p.A.'s ("Plastiape") 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 ability to draw down on our financing facility with HealthCare Royalty Partners IV, L.P. ("HCR") and our ability to satisfy the covenants contained in the Revenue Interest Financing Agreement dated January 9, 2023, as amended (the "RIFA") with HCR;
- our ability to retain, attract and hire key personnel;
- prevailing economic, market and business conditions;
- our ability to predict, foresee, and effectively address or mitigate future developments resulting from health epidemics, such as the COVID-19 pandemic, or other global shutdowns, which could include a negative impact on the availability of key personnel, the temporary closure of our facility or the facilities of our business partners, suppliers, third-party service providers or other vendors, or delays in payments or purchasing decisions, or the interruption of domestic and global supply chains, the economy and capital or financial markets;
- the cost and availability of capital and any restrictions imposed by lenders or creditors;
- changes in the industry in which we operate;
- the failure to renew, or the revocation of, any license or other required permits;
- unexpected charges or unexpected liabilities arising from a change in accounting policies, including any such changes by third parties with whom we collaborate and from whom we receive a portion of their net profits, or the effects of acquisition accounting varying from our expectations;
- the risk that the credit ratings of our company or our subsidiaries may be different from what the companies expect, which may increase borrowing costs and/or make it more difficult for us to pay or refinance our debts and require us to borrow or divert cash flow from operations in order to service debt payments;
- fluctuations in interest rates;
- adverse outcomes of pending or threatened litigation or governmental investigations, including our ongoing litigation involving United Therapeutics and the FDA and any future litigation with United Therapeutics, the FDA or any other third party;
- the effects on our company or our subsidiaries of future regulatory developments or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we are subject;
- conduct of and changing circumstances related to third-party relationships on which we rely, including the level of credit worthiness of counterparties;
- the volatility and unpredictability of the stock market and credit market conditions;
- conditions beyond our control, such as natural disasters, global pandemics (including COVID-19), or acts of war or terrorism;
- variations between the stated assumptions on which forward-looking statements are based and our actual experience;
- other legislative, regulatory, economic, business, and/or competitive factors;

- our plans to develop and commercialize our product candidates;
- our planned clinical trials for our product candidates;
- the timing of the availability of data from our clinical trials;
- the timing and related contents of our planned regulatory filings and/or applications;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our product candidates and their potential advantages compared to other treatments;
- our commercialization, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates and the 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;
- our estimates regarding the market opportunities for our product candidates;
- our intellectual property position and the duration of our patent rights;
- fluctuations in the trading price of our common stock;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and
- our expected use of proceeds from prior public offerings and the period over which such proceeds, together with our available cash, will be sufficient to meet our operating needs.

Therefore, current and prospective security holders are cautioned that there can be no assurance that the forward-looking statements included in this document will prove to be accurate. You should read and interpret any forward-looking statements together with the following documents:

- Our most recent Annual Report on Form 10-K, including the sections entitled “Business”, “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”;
- the risk factors contained in this prospectus under the caption “Risk Factors”; and
- our other filings with the SEC.

Any forward-looking statements that we make in this prospectus speak only as of the date of such statements and we undertake no obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus or incorporated by reference into this prospectus. This summary does not contain all the information that you should consider before investing in our securities. You should carefully read this entire prospectus, the applicable prospectus supplement and any related free writing prospectus, including each of the documents incorporated herein or therein by reference, before making an investment decision. Unless the context otherwise requires, references in this prospectus to "Liquidia," "we," "us," "our," "our company," "the Company" and "our business" refer to Liquidia Corporation and its subsidiaries.

About Liquidia Corporation

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, 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, 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 upon final approval, 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. In November 2021, the United States Food and Drug Administration ("FDA") tentatively approved our New Drug Application ("NDA") for YUTREPIA for the treatment of PAH. In July 2023, we filed an amendment to our NDA to add PH-ILD to the label for YUTREPIA. We are currently awaiting final action by the FDA with respect to our NDA.

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.

Our Products and Product Candidates

YUTREPIA™ (treprostinil) Inhalation Powder to Treat PAH

Our lead investigational drug, YUTREPIA™ (treprostinil) inhalation powder was tentatively approved by the FDA in November 2021. In July 2023, we filed an amendment to our NDA to add

PH-ILD to the label for YUTREPIA. We are currently awaiting final action by the FDA with respect to our NDA. YUTREPIA is an inhaled dry powder formulation of treprostinil designed to improve the therapeutic profile of treprostinil by enhancing deep lung delivery and achieving higher dose levels than the labeled doses of current inhaled therapies while using a convenient, easy-to-use dry-powder inhaler, the RS00 Model 8 DPI. This device and its variants have been used in at least eight marketed products globally since 2001, including Novartis's Foradil Aerolizer® for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

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

The different combinations of YUTREPIA's four proposed capsule-strengths, if approved, would allow customized dosing and easier titration based on a patient's disease progression. YUTREPIA can be safely titrated to doses far beyond the target dose of nebulized Tyvaso (9-12 breaths) and the doses described in the label for Tyvaso DPI (up to 64 mcg QID). YUTREPIA has been studied up to 318 mcg QID, which is comparable to 30 breaths of nebulized Tyvaso. By expanding the dose range of inhaled treprostinil, YUTREPIA may be able to keep patients on therapy longer before transitioning to parenteral therapies.

In clinical studies required for approval, YUTREPIA has proven to be safe, well-tolerated and effective regardless of a patient's previous exposure to treprostinil. Prostacyclin-naïve patients achieved comparable dosing to the transition patients within 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 the New Drug Application ("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 label for YUTREPIA. We are currently awaiting final action by the FDA with respect to our NDA. However, final FDA approval may be affected by the outstanding litigation described further below in the section entitled "Legal Proceedings," in which United Therapeutics is seeking to enjoin approval and launch of YUTREPIA. The FDA's tentative approval can be subject to change based on new information that may come to FDA's attention between after the tentative approval. A new drug product may not be marketed until the date of final approval.

Our NDA submission was based in part upon the results of our pivotal, open-label Phase 3 clinical trial, Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, for YUTREPIA ("INSPIRE"). The primary objective of the INSPIRE study was to evaluate the long-term safety of YUTREPIA with a primary endpoint to assess safety and tolerability through Month 2. The study enrolled patients who have either (a) been under stable treatment with Tyvaso (nebulizer-delivered treprostinil) for at least three months and transitioned to YUTREPIA under the protocol ("Transition patients"), or (b) patients who had been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and then had their treatment regimen supplemented with

YUTREPIA under the protocol ("Prostacyclin Naïve patients"). Transition patients started at a dose comparable to their prior nebulized treprostinil dose and were titrated to higher doses as warranted by their clinical disease. Prostacyclin Naïve patients started on a dose of 26.5 mcg of YUTREPIA, with most (>80%) titrating to a 79.5 mcg dose or higher within the first two months of treatment. Of the 121 patients enrolled in the study, 55 were Transition patients and 66 were Prostacyclin Naïve patients.

YUTREPIA was observed to be well-tolerated and treatment-emergent adverse events ("TEAEs") were mostly mild to moderate in nature at Month 2 up to doses of 159 mcg, the highest dose studied for the primary endpoint. We continued to treat patients who chose to remain on YUTREPIA beyond the Month 2 timepoint. At the completion of the INSPIRE study, the patient with the longest duration of treatment had been on YUTREPIA therapy for 18 months and the highest dosing reached in the INSPIRE study was 212 mcg of treprostinil given four times per day. Patients from INSPIRE had the option of rolling into the LTI-302 extension study to remain on treatment. Patients in LTI-302 continued to titrate doses upwards as needed with no observed maximum tolerated dose and the highest dose delivered to date being 318 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 breaths of Tyvaso (54 mcg). For reference, the target dose of Tyvaso is 9 to 12 breaths per treatment session, 4 times daily. Clinical results from the PK, 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 2023.

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. We conducted a clinical study, known as LTI 201, at certain investigational sites in France and Germany to characterize the hemodynamic dose-response relationship to YUTREPIA. In December 2020, we decided to terminate the study earlier than planned due to challenges related to the COVID-19 pandemic; however, we did observe acute, hemodynamic responses as expected with inhaled treprostinil.

Treprostinil Injection, a Generic Version of Remodulin®

Remodulin® is treprostinil administered through continuous intravenous and subcutaneous infusion, as approved by the FDA in 2002 and 2004, and marketed by United Therapeutics. Patients must use external pumps manufactured by third parties to deliver Remodulin. Smiths Medical manufactured the pumps used by most patients in the United States to administer Remodulin, including the CADD-MS® 3 pump used to deliver subcutaneous Remodulin, and the CADD-Legacy® pump to deliver intravenous Remodulin. An estimated 3,000 patients are treated annually with parenteral, infused treprostinil split between the two routes of administration. Branded Remodulin generated U.S. revenue of approximately $415 million and $408 million in 2023 and 2022, respectively.

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

Treprostinil Injection contains the same active ingredient, same strength, same dosage forms and same inactive ingredient amounts as Remodulin®, and at the same service and support, but at a lower price.

The treprostinil is supplied in 20 mL multi-dose vials in four strengths — containing 20 mg, 50 mg, 100 mg, or 200 mg (1 mg/mL, 2.5 mg/mL, 5 mg/mL or 10 mg/mL) of treprostinil, respectively. Treprostinil Injection is available for intravenous and subcutaneous administration at the same specialty pharmacies that dispense the brand name medicine.

When first launched in April 2019, Treprostinil Injection was only available for intravenous administration. The cartridges required to operate the CADD-MS 3 pump for subcutaneous administration were not available to patients using Treprostinil Injection due to restrictions imposed by other companies. In May 2021, Liquidia PAH's manufacturing partner, Chengdu began selling the RG 3ml Medication Cartridge, which now may be used to supply Treprostinil Injection to PAH patients with the CADD-MS 3 pump manufactured by Smiths Medical.

Smiths Medical no longer manufactures the CADD-MS 3 infusion pump and has indicated that it will no longer support the CADD-MS 3 infusion pumps after November 2024. 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. 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 a collaboration with Sandoz and Mainbridge to support the development of a new subcutaneous pump for infusion of Treprostinil Injection in order to replace the existing CADD-MS 3 system. Mainbridge is performing all development, validation and testing activities required for the pump and related consumables in anticipation of submitting a 510(k) in 2025 for FDA clearance. We and Sandoz are splitting the development costs 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 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. 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. 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 a mesh-vibrating nebulizer. Before each treatment session, a L606 ampule would be opened and the suspension would be transferred into the medication chamber of the L606 nebulizer for oral inhalation. The inhalation system used to administer L606 consists of an electronic, lightweight, and virtually silent mesh-vibrating nebulizer which can deliver a dose in less than two 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. 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.

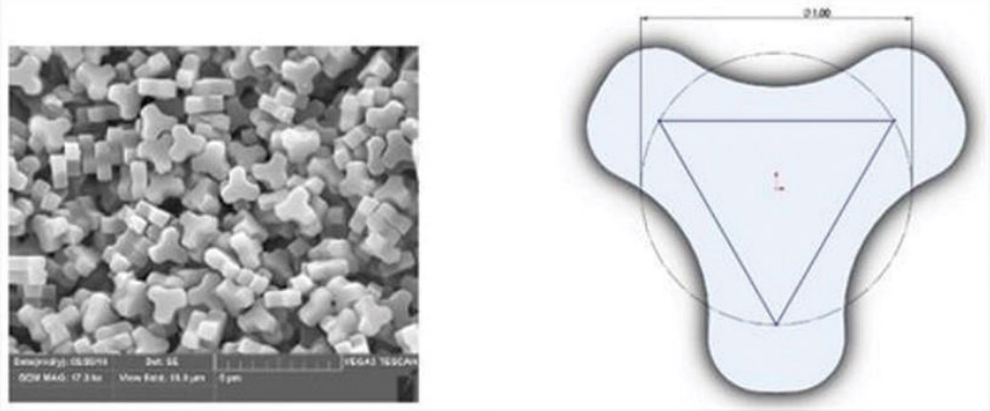
Comparable bioavailability was established in a Phase 1, randomized, 2-part study that was conducted by Pharmosa at a clinical research unit in the USA. The systemic exposures of a single dose of L606, 51 µg, and, Tyvaso, 54 µg, were compared. L606 resulted in a similar systemic exposure (AUCinf) compared 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 U.S. an open-label study to assess the safety of L606 in up to 60 patients with PAH and patients with PH-ILD transitioning from Tyvaso (nebulizer or dry-powder inhaler) or patients with PAH naïve to prostacyclins. As of January 2024, the open-label study was more than one third enrolled and includes some patients who have been successfully treated with L606 for longer than one year. In May 2024, we presented interim data at the American Thoracic Society Annual Conference on the first 24 patients enrolled which described a favorable tolerability and titratability profile of L606. To date, patients have titrated to our maximum dose allowed in the study of 378 mcg twice daily, a dosage that would be comparable to 26 to 28 breaths of Tyvaso administered four times daily. We anticipate that the open-label study will be fully enrolled in 2024. We are preparing to initiate a global placebo-controlled efficacy study in PH-ILD in late 2024.

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 U.S. The 505(b)(2) regulatory pathway can be capital efficient and potentially enable a shorter time to approval, subject to certain risks associated with this regulatory pathway. If our product candidates receive marketing approval, we plan to commercialize them in the U.S. either by ourselves or through partnership or licensing arrangements with other pharmaceutical companies. Outside of the U.S., we may pursue regulatory approval and commercialization of our product candidates in collaboration with pharmaceutical companies with regional expertise.

We intend to manufacture our product candidates using 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 for Treprostinil Injection, calling on physicians involved in the treatment of PAH in the U.S., as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient launch of YUTREPIA if and when we obtain final approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH 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, for treprostinil, the active pharmaceutical ingredient of YUTREPIA, and we currently rely on a sole supplier, Plastiape, for RS00 Model 8 DPI, the device used to administer YUTREPIA. We also rely on a sole supplier, Lonza Tampa LLC, for encapsulation and packaging services for YUTREPIA. If and when we receive final marketing approval for YUTREPIA, we may, from time to time, 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 (MS-3) ambulatory infusion pumps and enable subcutaneous administration of Treprostinil Injection. In addition, the pumps used to administer Treprostinil Injection are currently all manufactured by Smiths Medical, with whom we have no contractual relationship other than an agreement to continue to support the CADD-MS 3 pump, which we expect them to discontinue in November 2024. We have also entered into an 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 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.

Summary of Private Placements

December 2023 Common Stock Purchase Agreement

On December 12, 2023, the Company entered into a common stock purchase agreement (the "December 2023 Purchase Agreement") with Roger Jeffs, the Chief Executive Officer of the Company, pursuant to which the Company issued and sold to Dr. Jeffs in a private placement 139,665 shares of the Company's Common Stock, at a purchase price of $7.16 per share for an aggregate investment amount of approximately $1 million (the "December 2023 Private Placement"). The December 2023 Private Placement closed on December 14, 2023.

January 2024 Common Stock Purchase Agreement

On January 4, 2024, the Company entered into a common stock purchase agreement (the "January 2024 Purchase Agreement") with Legend Aggregator, LP ("Legend"), pursuant to which the Company issued and sold to Legend in a private placement 7,182,532 shares (the "January 2024 Private Placement") of the Company's Common Stock, at a purchase price of $10.442 per share. The January 2024 Private Placement closed on January 8, 2024.

Registration Rights

The December 2023 Purchase Agreement contained certain registration rights such that, upon the written request of Dr. Jeffs, the Company shall promptly file with the SEC a resale registration statement on Form S-3 or such other appropriate form for an offering to be made on a delayed or continuous basis pursuant to Rule 415 of the Securities Act of 1933, as amended (the "Securities Act") pursuant to which all of the shares of Common Stock sold at the closing of the December 2023 Private Placement shall be registered for resale.

In connection with the January 2024 Private Placement, on January 4, 2024, we entered into a registration rights agreement (the "Registration Rights Agreement") with Legend. Pursuant to the Registration Rights Agreement, we agreed to file a shelf registration statement (the "Registration Statement") with the SEC within 180 days following the date of entry into the Registration Rights Agreement to register the shares issued in the January 2024 Private Placement for resale and use our best efforts to cause the Registration Statement to be declared effective by the SEC or otherwise become effective under the Securities Act as soon as practicable after the filing thereof. We also agreed, among other things, to indemnify the selling holders under the Registration Statement from certain liabilities and to pay all fees and expenses incident to our performance of or compliance with the Registration Rights Agreement.

Liquidity

In accordance with Accounting Standards Update 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 condensed 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 revenue interest financing. Since inception, we have incurred recurring losses, including a net loss of $40.9 million for the three months ended March 31, 2024. As of March 31, 2024, we had an accumulated deficit of $470.0 million.

We expect to incur significant expenses and operating losses for the foreseeable future as we conduct clinical development of product candidates and seek regulatory approval and prepare for commercialization of any approved product candidates. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. Additionally, the RIFA with HCR contains fixed quarterly payments and minimum cash covenants that require us to maintain cash and cash equivalents in an amount at least equal to $7.5 million during the calendar year beginning on January 1, 2024 and at least equal to $15.0 million for the remainder of the payment term after the calendar year ended December 31, 2024. In addition, as a result of the fourth amendment to the RIFA, we expect that the quarterly fixed payment will increase from $1.1 million to $5.8 million, beginning in the third quarter of 2025 through 2028, and an incremental one-time fixed payment of $23.8 million will be due on July 30, 2025.

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. We may require additional capital to fund operations as well as to pursue in-licenses or acquisitions of other product candidates. If we determine we require but are unable to obtain additional funding, we could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations.

Although we expect to continue to generate operating losses for the foreseeable future, we believe that based on our current operating plan, excluding any future YUTREPIA product revenue, our cash and cash equivalents will be sufficient to fund operations, capital expenditures, and RIFA quarterly fixed payment requirements and allow us to remain in compliance with our minimum cash covenants pursuant to the RIFA for at least twelve months from the filing of this registration statement. If we have not received full FDA approval for both PAH and PH-ILD and begun product sales of YUTREPIA or are unable to access

additional capital by the date of issuance of our second quarter 2024 financial statements, there could be substantial doubt about our ability to continue as a going concern as of that date. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Legal Proceedings

YUTREPIA-Related Litigation

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

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

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

Trial proceedings in the Original Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Original Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the '066 Patent were invalid, that the remaining asserted claims of the '066 Patent were not infringed by the Company, and that all of the asserted claims of the '793 Patent were both valid and infringed by the Company, based on the arguments presented by the Company in the Original Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Original Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent, which will be in 2027. Both the Company and United Therapeutics appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. On July 24, 2023, the United States Court of Appeals for the Federal Circuit affirmed Judge Andrews' decision with respect to both the '066 patent and the '793 patent.

In March 2020, the Company filed a petition for inter partes review with the Patent Trial and Appeal Board (the "PTAB") of the USPTO with respect to the '901 Patent seeking a determination that the claims in the '901 Patent are invalid. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the inter partes review of the '901 Patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the '901 Patent to the United States Court of Appeals for the Federal Circuit. On June 27, 2024, the United States Court of Appeals for the Federal Circuit affirmed the PTAB's decision with respect to the '901 patent.

In January 2021, the Company filed a petition for inter partes review with the PTAB relating to the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. In July 2022, the PTAB ruled in the Company's favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a

rehearing request with respect to the PTAB's decision in the inter partes review of the '793 Patent. The rehearing request was denied in February 2023. In April 2023, United Therapeutics appealed the decision of the PTAB with respect to the '793 Patent to the United States Court of Appeals for the Federal Circuit. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in inter partes review proceedings. In January 2024, United Therapeutics filed a request for rehearing of the decision by the United States Court of Appeals for the Federal Circuit. The request for rehearing was denied in March 2024. On June 10, 2024, United Therapeutics filed a petition for a writ of certiorari to seek an appeal with the United States Supreme Court. The petition remains pending.

As a result of this decision by the United States Court of Appeals for the Federal Circuit with respect to the invalidity of the '793 Patent, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch-Waxman Litigation. The motion was granted in March 2024, and the injunction on final approval by the FDA of YUTREPIA was set aside. United Therapeutics has appealed Judge Andrews' decision to set aside the injunction to the Federal Circuit. Briefing in the appeal remains ongoing, and the Federal Circuit has stated that it will schedule oral argument for September 2024.

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 second 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"), again asserting infringement by the Company of the '793 Patent. In November 2023, the U.S. Patent and Trademark Office (the USPTO) issued U.S. Patent No. 11,826,327, or the '327 Patent, entitled "Treatment for Interstitial Lung Disease", 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, we 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 the PTAB's finding 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 us 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. Discovery in the case remains ongoing.

FDA Litigation

In February 2024, United Therapeutics filed a complaint against the FDA in the U.S. District Court for the District of Columbia, challenging the FDA's acceptance of our amended NDA for review (the "FDA Litigation"). We intervened and became a party to the lawsuit in March 2024. In March 2024, United Therapeutics filed a motion for a temporary restraining order in the 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 the Company and the FDA filed motions to dismiss United Therapeutics' complaint. Briefing on the motions to dismiss has been completed.

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 Robert Roscigno ("Dr. Roscigno"), a former United Therapeutics employee who later joined the Company as an employee many years after terminating his employment with United Therapeutics, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2024, Dr. Roscigno filed a motion to dismiss all claims. The motion has been briefed and oral argument was held in May 2024. The motion remains pending.

In May 2024, United Therapeutics filed a second complaint in the Superior Court in Durham County, North Carolina, against Dr. Roscigno, 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 Dr. Roscigno 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 Dr. Roscigno 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 Dr. Roscigno while employed by the company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. The Company intends to vigorously defend itself against these allegations.

RareGen Litigation

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

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

In September 2021, United Therapeutics filed a motion for summary judgment with respect to all of the claims brought by Sandoz and Liquidia PAH against United Therapeutics. At the same time, Sandoz filed a motion for summary judgment with respect to the breach of contract claim. In March 2022, the Court issued an order granting partial summary judgment to United Therapeutics with respect to the antitrust and unfair competition claims, denying summary judgment to United Therapeutics with respect to the breach of contract claim, and granting partial summary judgment to Sandoz with respect to the breach of contract claim. 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 and closing arguments were held on June 4, 2024. The parties are awaiting a decision from the Court.

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.

Summary Risk Factors

Our business is subject to a number of risks and uncertainties. The following is a summary of the principal risk factors described further under "Risk Factors" beginning on page 19 of this prospectus:

- We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company may depend on our ability to raise additional capital to finance our future operations.
- We have a history of losses and our future profitability remains uncertain.
- 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, separate lawsuits against us that we and a former United Therapeutics employee, who later joined us as an employee, conspired to misappropriate and use certain trade secrets and confidential information of United Therapeutics and engaged in unfair or deceptive trade practices, and a separate lawsuit against the FDA seeking to challenge the FDA's acceptance of our amended NDA for YUTREPIA. United Therapeutics is currently seeking injunctive relief in several of these lawsuits. 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, may limit the indications for which YUTREPIA is approved or may result in substantial damage claims against us if we launch YUTREPIA and we are later found to infringe.
- 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 Smiths Medical's CADD-MS 3 infusion pump. Smiths Medical no longer manufactures the CADD-MS 3 infusion pump and has indicated its intention to discontinue service and maintenance of CADD-MS 3 infusion pumps in November 2024. In addition, should components of the CADD-MS 3 pump become unavailable before November 2024, Smiths Medical's ability to service and maintain such pumps may terminate earlier than anticipated. For instance, we are aware of a shortage of a critical component of the CADD-MS 3 infusion pump that may cause the number of CADD-MS 3 infusion pumps available for the administration of Treprostinil Injection to be depleted prior to November 2024. In the event the specialty pharmacies are unable to access sufficient quantities of operable pumps or in the event we are unable to identify or develop a new pump prior to the current pumps becoming unavailable, the commercial success of Treprostinil Injection may be adversely affected.
- Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration and the medical devices used for administration of Treprostinil Injection, including the Smiths Medical infusion pumps, any future pumps that we develop, and the RG Cartridge, by patients, health care providers and by third-party payors, while interactions with these persons and entities are subject to compliance requirements. The

commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection.

- We expect that we will need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA 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., or HCR, requires mutual agreement of both HCR and us in order to draw down on the facility. HCR may not agree to make additional advances pursuant to the facility. Failure to receive further funding from HCR may result in our having insufficient financing for our existing business plan. Our financing facility with HCR also contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in HCR taking possession and disposing of any collateral.
- Our products may not achieve market acceptance.
- Our product candidates are based on 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 health epidemics, including the COVID-19 pandemic.
- 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.
- 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.

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 prospectus, and you should not consider any such information as part of this prospectus. This prospectus and all of our filings under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including copies of annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, are available free of charge through our website on the date we file those materials with, or furnish them to, the SEC. Such filings are also available to the public on the internet at the SEC's website at www.sec.gov.

THE OFFERING

Selling Stockholders	Accredited investors who purchased shares of our Common Stock in the December 2023 Private Placement and the January 2024 Private Placement.
Common stock offered by the Selling Stockholders	Up to 7,322,197 shares of Common Stock.
Use of proceeds	We will not receive any proceeds from the sale or other disposition of the shares of Common Stock offered hereby.
Risk factors	Investing in our Common Stock involves a high degree of risk. See "Risk Factors" beginning on page 19 of this prospectus, and any other risk factors described in the documents incorporated by reference herein, for a discussion of factors that you should carefully consider before deciding to invest in our Common Stock.
Nasdaq Capital Market symbol	LQDA

When we refer to the Selling Stockholders in this prospectus, we are referring to the entities and individuals named in this prospectus as the Selling Stockholders and, as applicable, any pledgee, assignee, permitted transferee or other successor-in-interest selling shares received after the date of this prospectus from the Selling Stockholders as a pledge, assignment or other transfer that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

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 included in and incorporated by reference into this prospectus such as the information contained under the heading "Special 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.

Risks Related to our Financial Position and Need for Additional Capital

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

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and the ability to secure additional capital to fund operations. We expect to incur significant expenses and may incur significant operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. In addition, if we obtain marketing approval for any of our product candidates, we would incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. If we have not received full FDA approval for both PAH and PH-ILD and begun product sales of YUTREPIA or are unable to access additional capital by the date of issuance of our second quarter 2024 financial statements, there could be substantial doubt about our ability to continue as a going concern as of that date. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. The future viability of our company may depend on our ability to raise additional capital to finance our future operations. We may seek additional funding through public or private financings, debt financing or collaboration. Our inability to obtain funding, when needed, would have a negative impact on our financial condition and ability to pursue our business strategies.

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

We have incurred net losses of $40.9 million during the three months ended March 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 March 31, 2024, we had an accumulated deficit of $470.0 million.

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

We may need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA and/or L606 or for which there may be a greater likelihood of success.

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

If we need additional financing and 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 need additional financing and fail to obtain additional financing on terms that are acceptable to us, we may forgo or delay the pursuit of opportunities presented by other potential product candidates or indications that may later prove to have greater commercial potential than the product candidates and indications that we have chosen to pursue.

Our financing facility with HCR requires mutual agreement of both HCR and us in order to draw down on our financing facility, 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 financing facility with HCR contains restrictions that limit our flexibility in operating our business. Under the terms of the RIFA, HCR has agreed to pay us an aggregate investment amount of up to $100.0 million (the "Investment Amount"). Under the terms of the RIFA, $32.5 million of the Investment Amount was funded in January 2023 at the initial closing, $10.0 million of the Investment Amount was funded in July 2023 in connection with our entry into a license agreement with Pharmosa, $25.0 million of the Investment Amount was funded in January 2024. The third tranche of $10.0 million and the fourth tranche of $22.5 million of the Investment Amount will be funded fifteen business days after the mutual agreement of HCR and us to fund such amount. In the event we and HCR do not mutually agree to the funding of the third and/or fourth tranche of the Investment Amount, we will be unable to draw the full amount of the Investment Amount. In addition, under the terms of the RIFA, we may not, among other actions, without the prior written consent of HCR, (a) pay any dividends or make any other distribution or payment or redeem, retire or purchase any capital stock, except in certain prescribed circumstances, (b) create, incur, assume, or be liable with respect to any indebtedness except certain permitted indebtedness, or make or permit any payment on any indebtedness, except under certain limited circumstances, or (c) make any sale, transfer, out-license, lease or other disposition of any property or any economic interest, other than certain limited exceptions. Additionally, we are required (i) during the period from January 1, 2024 through December 31, 2024, to maintain at all times a minimum cash balance of $7.5 million, and (ii) during all periods after December 31, 2024, to maintain at all times a minimum cash balance of $15.0 million. Our obligations under the RIFA are collateralized by all of our assets and property, subject to limited exceptions.

If we breach certain of our covenants in the RIFA and are unable to cure such breach within the prescribed period or are not granted waivers in relation to such breach, it may constitute an event of default under the RIFA, giving HCR the right to require us to repay the then outstanding obligations immediately,

and HCR could, among other things, foreclose on the collateral granted to them to collateralize such indebtedness, which includes our intellectual property, if we are unable to pay the outstanding debt immediately.

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

We are using the net proceeds of our financing facility with HCR, the January 2024 Private Placement, our December 2023 public equity offering, the December 2023 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.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change", generally defined as a greater than 50.0% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. With the January 2024 Private Placement, our December 2023 public equity offering, the 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 "ownership changes" within the meaning of Section 382 of the Code have occurred, and if we earn net taxable income, our ability to use our net operating loss carryforwards and research and development tax credits generated since inception to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

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. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions could materially affect our tax obligations.

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. As another example, in August 2022, the Inflation Reduction Act

of 2022 was enacted, and, among other things, included a new 15% alternative minimum tax on the adjusted financial statement income of certain large corporations for tax years beginning after December 31, 2022. 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.

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

Sandoz holds the FDA approval, or the ANDA, for and controls 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;
- the requirement by third-party payors to use generic treprostinil for parenteral administration in place of Remodulin;
- the availability of third-party coverage and adequate reimbursement for Treprostinil Injection;
- the prevalence and severity of any side effects;
- any restrictions on the use of Treprostinil Injection together with other medications;
- our and Sandoz's ability to maintain relationships with the specialty pharmacies; and
- the services provided by specialty pharmacies related to use of Treprostinil Injection.

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

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

In order for Treprostinil Injection to be administered to patients, patients must use certain other medical equipment, including pumps, cartridges and infusion sets. We do not manufacture or control such medical equipment, which is manufactured by third parties and owned and dispensed by specialty pharmacies,

hospitals or other third parties. Our ability to serve patients is dependent upon the ability of specialty pharmacies to maintain sufficient inventory of such medical equipment to provide to patients. If manufacturers cease to manufacture or support medical equipment or if specialty pharmacies are unable to obtain or maintain sufficient inventories of such medical equipment, our sales may be adversely impacted.

We have worked with Chengdu to develop the RG Cartridge, which received FDA 510(k) clearance in March 2021. The ability of patients to administer Treprostinil Injection through subcutaneous injection is dependent on the continued availability of the RG Cartridge. If the RG Cartridge experiences any quality problems, recalls or other adverse events, our ability to provide Treprostinil Injection to patients who receive treprostinil through subcutaneous injection will be limited.

In addition, to administer Treprostinil Injection through subcutaneous injection, patients currently must use the CADD-MS 3 infusion pump manufactured by Smiths Medical. Smiths Medical no longer manufactures the CADD-MS 3 infusion pump and has indicated that they will no longer support the CADD-MS 3 infusion pump after November 2024. Moreover, in the event components of the CADD-MS 3 infusion pump become unavailable prior to November 2024, Smiths Medical may be unable to service pumps that require a replacement of such components. For instance, there is a shortage of a critical component of the CADD-MS 3 infusion pump that has caused the number of CADD-MS 3 infusion pumps available for the administration of Treprostinil Injection to be limited. Due to this limitation in the availability of pumps, specialty pharmacies are not currently placing new patients on subcutaneous Treprostinil Injection therapy in order to preserve the available pumps for those patients already receiving subcutaneous administration of Treprostinil Injection. Until we are able to obtain a pump to replace the CADD-MS 3, 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 an agreement with Sandoz and Mainbridge to develop a new pump that can be used to administer Treprostinil Injection in the future. Such pumps will require FDA 510(k) clearance before they can be sold. There is no guarantee that we or our partners will receive FDA 510(k) clearance for any such pumps or, even if they do receive FDA 510(k) clearance for any such pumps, that they will do so in a timely manner. If we are unable to identify, develop and obtain any required FDA clearance for new pumps for the subcutaneous and intravenous administration of Treprostinil Injection prior to the unavailability of the CADD-MS 3, 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 banking institutions that may exceed the Federal Deposit Insurance Corporation, or the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank, where we previously held all of our cash and cash equivalents, on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole, and we were able to move substantially all of our cash and cash equivalents to another financial institution. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

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

United Therapeutics has initiated lawsuits against us in which it claims that YUTREPIA is infringing 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. Two of these patents are U.S. Patent No. 9,604,901 (the "'901 Patent"), entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", and U.S. Patent No. 9,593,066 (the "'066 Patent"), entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", both of which are owned by United Therapeutics. A notice of the paragraph IV certification was required to be provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. In June 2020, United Therapeutics, as the holder of such patents, asserted a patent challenge directed to the '901 Patent and the '066 Patent by filing a complaint against us in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA) (the"Original Hatch-Waxman Litigation").

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

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

Trial proceedings in the Original Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Original Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the '066 Patent were invalid, that the remaining asserted claims of the '066 Patent were not infringed by us, and that all of the asserted claims of the '793 Patent were both valid and infringed by us, based on the arguments we presented in the Original Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Original Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent, which will be in 2027. Both we and United Therapeutics appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. On July 24, 2023, the United States Court of Appeals for the Federal Circuit affirmed Judge Andrews' decision with respect to both the '066 Patent and the '793 Patent.

In March 2020, we filed a petition for *inter partes* review with the Patent Trial and Appeal Board, or the PTAB, of the USPTO with respect to the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the inter partes review of the '901 patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the '901 Patent to the United States Court of Appeals for the Federal Circuit. On June 27, 2024, the United States Court of Appeals for the Federal Circuit affirmed the PTAB's decision with respect to the '901 patent.

In January 2021, we filed a petition with the PTAB for *inter partes* review of the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. In July 2022, the PTAB ruled in our favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with

respect to the PTAB's decision in the inter partes review of the '793 Patent. The rehearing request was denied in February 2023. In April 2023, United Therapeutics appealed the decision of the PTAB with respect to the '793 Patent to the United States Court of Appeals for the Federal Circuit. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in inter partes review proceedings. In January 2024, United Therapeutics filed a request for rehearing of the decision by the United States Court of Appeals for the Federal Circuit. The request for rehearing was denied on March 12, 2024. On June 10, 2024, United Therapeutics filed a petition for a writ of certiorari to seek an appeal with the United States Supreme Court. The petition remains pending.

As a result of this decision by the United States Court of Appeals for the Federal Circuit with respect to the invalidity of the '793 Patent, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch-Waxman Litigation. The motion was granted in March 2024, and the injunction on final approval by the FDA of YUTREPIA was set aside. United Therapeutics has appealed Judge Andrews' decision to set aside the injunction to the Federal Circuit. Briefing in the appeal remains ongoing, and the Federal Circuit has stated that it will schedule oral argument for September 2024.

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 second 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"), again asserting infringement by the Company of the '793 Patent. In November 2023, the U.S. Patent and Trademark Office (the USPTO) issued U.S. Patent No. 11,826,327, or the '327 Patent, entitled "Treatment for Interstitial Lung Disease", 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, we 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 the PTAB's finding 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 us from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. Briefing on the motion for preliminary injunction is ongoing, and the motion remains pending. Judge Andrews denied the motion for a preliminary injunction in May 2024. Discovery in the case remains ongoing.

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 "FDA Litigation"). In March 2024, United Therapeutics filed a motion for a temporary restraining order in the 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. Briefing on the motions to dismiss has been completed. 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, 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 appeals or requests for rehearing, we may be unable to commercialize YUTREPIA until the expiration of United Therapeutics' patents, which could materially harm our business. Also, if United Therapeutics is successful in obtaining a preliminary injunction or temporary restraining order in the New Hatch-Waxman Litigation or the 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 Robert Roscigno ("Dr. Roscigno"), a former United Therapeutics employee, who later joined us as an employee many years after terminating his employment with United Therapeutics, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2024, Dr. Roscigno filed a motion to dismiss all claims. The motion has been briefed and oral argument was held in May 2024. The motion and remains pending.

In May 2024, United Therapeutics filed a second complaint in the Superior Court in Durham County, North Carolina, against Dr. Roscigno, 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 Dr. Roscigno 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 Dr. Roscigno 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 Dr. Roscigno while employed by the company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information.

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

If, after the appeals process has been completed, we are found to infringe, misappropriate or otherwise violate any United Therapeutics' intellectual property rights, we could be required to obtain a license from United Therapeutics to continue developing and marketing YUTREPIA. However, we may not be able to obtain any required license on commercially reasonable terms or at all. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or to have misappropriated a trade secret of United Therapeutics. In addition, we may be forced to redesign YUTREPIA to avoid infringement.

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

We face significant competition from industry players worldwide, including large multi-national pharmaceutical companies, other emerging or smaller pharmaceutical companies, as well as universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as a larger research and development staff and more experience in manufacturing and marketing, than we do. As a result, these companies may obtain marketing approval for their product candidates more quickly than we are able to and/or be more successful in commercializing their products, including generic treprostinil products, than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies. We may also face competition as a result of advances in the commercial applicability of new technologies and greater availability of capital for investment in such technologies. Our competitors may also invest heavily in the discovery and development of novel drug products that could make our product candidates less competitive or may file FDA citizen petitions or other correspondence with the FDA 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.
- Treprostinil Palmitil Inhalation Powder (TPIP), is a dry-powder formulation of a treprostinil prodrug being developed by Insmed. Insmed announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once-daily dosing. Insmed initiated Phase 2 trials studying patients diagnosed with PAH and PH-ILD in May 2021 and December 2022, respectively. In May 2024, Insmed reported positive topline safety and tolerability data as well as certain exploratory efficacy endpoints from the Phase 2 PH-ILD. Based on these Phase 2 results, Insmed is pursuing discussions with global regulatory authorities on the design of a Phase 3 study in PH-ILD to initiate in 2025. 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 the specialty pharmacies, Teva Pharmaceutical Industries Ltd. launched a generic treprostinil for parenteral administration in October 2019 that is sold primarily through a specialty pharmacy and to hospitals, Par Pharmaceutical, Inc. launched a generic treprostinil for parenteral administration after receiving approval in September 2019 that is sold primarily to hospitals, Dr. Reddy's Laboratories Inc. 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 include the following:

- ***IP-agonists***, such as selexipag, marketed by Actelion, and ralinepeg, licensed from Arena Pharmaceuticals, Inc. by United Therapeutics, which is currently in clinical development.
- ***Endothelin receptor antagonists***, such as bosentan and macitentan, both marketed by Actelion, and ambrisentan, marketed by Gilead. Generic versions of bosentan and ambrisentan are currently available.
- ***PDE-5 inhibitors***, such as tadalafil, marketed by United Therapeutics, and sildenafil, marketed by Pfizer Inc. Generic versions of both tadalafil and sildenafil are currently available.
- ***Soluble guanylate cyclase (sGC) stimulator,*** such as riociguat marketed by Bayer.
- ***Activin signaling inhibitor,*** 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 potential 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 Merck & Co. Inc., Gossamer Bio, Inc. and Aerovate Therapeutics, Inc., 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). In the event United Therapeutics sought and was able to obtain one or more regulatory exclusivities with respect to Tyvaso DPI, it could 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 on 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 detail 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.

Our products may not achieve market acceptance.

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

- the timing of our receipt of marketing approvals, the terms of such approvals and the countries in which such approvals are obtained;
- the safety, efficacy, reliability and ease of administration of our drug products;
- the prevalence and severity of undesirable side effects and adverse events;
- the extent of the limitations or warnings required by the FDA or comparable regulatory authorities in other countries to be contained in the labeling of our drug products;
- the clinical indications for which our drug products are approved;
- the availability and perceived advantages of alternative therapies;
- any publicity related to our drug products or those of our competitors;
- the quality and price of competing drug products;
- our ability to obtain third-party payor coverage and sufficient reimbursement;
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage; and
- the selling efforts and commitment of our commercialization collaborators.

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

We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or 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, we have recently significantly increased the size of our sales force in anticipation of a potential launch of YUTREPIA. 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 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. In addition, our collaborators or licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. To the extent that they are uninsured or uninsurable, claims or losses that may be suffered by us, our collaborators or our licensees may have a material and adverse effect on our financial condition and results of operations.

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

We are primarily dependent on the success of our product candidate, YUTREPIA, for which we received tentative approval from the FDA, 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 in November 2021. However, our receipt of tentative approval does not mean that we will receive final approval of our NDA for YUTREPIA in a timely manner or at all or that we will receive approval for other indications, such as PH-ILD. Expectations related to final FDA approval and projected product launch timelines are impacted by ongoing litigation following lawsuits filed by United Therapeutics. Judge Andrews issued an order in the Original Hatch-Waxman Litigation enjoining the FDA from issuing a final approval for the YUTREPIA NDA until the expiration of the '793 Patent in 2027. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in inter partes review proceedings. As a result, Judge Andrews set aside his injunction. However, United Therapeutics has appealed Judge Andrews' decision to set aside the injunction. 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 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 February 2024, United Therapeutics also commenced the 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 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 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. For instance, United Therapeutics recently filed a citizen petition related to the supplier of the active pharmaceutical ingredient for YUTREPIA in an attempt to prevent or delay the approval of YUTREPIA. It is possible that the issues raised in the citizen petition could lead to further information requests from the FDA or otherwise delay FDA's review of the NDA for YUTREPIA. In addition, the FDA has not yet issued any approval for YUTREPIA for the treatment of PH-ILD, which remains under review. 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 "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 uncertainties can be presented by their ability to exercise judgment and discretion during the review process. During the course of review prior to final approval, the FDA may request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC) or other data and information or conduct additional inspections. If any additional issues were identified in such information requests or inspections, 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, if a competing product comprised of an inhaled dry-powder formulation of treprostinil, such as Tyvaso DPI, is granted 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.

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, they may not achieve a sufficient level of market acceptance, or we may not be able to effectively build our marketing and sales capabilities or scale our manufacturing operations to meet commercial demand. The successful commercialization of YUTREPIA 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, 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 conduct the required studies and trials may vary substantially according to the type, complexity, novelty and intended use of the product candidate. A single clinical trial may take up to several years to complete. Moreover, our preclinical studies and clinical trials may be delayed or halted due to various factors, including, among others:

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

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

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

Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We cannot provide any assurance or certainty regarding when we might receive regulatory approval for our products, including YUTREPIA 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 an independent IRB may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. Although clinical data is an essential part of NDA filings, NDAs must also contain a range of additional data including CMC data to meet FDA standards for approval. In the event we do not ultimately receive final regulatory approval for YUTREPIA 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, or that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable regulatory authorities in other countries that our product candidate is safe and effective for its proposed indication, or that its clinical and other benefits outweigh its safety risks;
- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval.

Even if we obtain marketing approval, the FDA or comparable regulatory authorities in other countries may approve our product candidates for fewer or more limited indications than those for which we requested approval or may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates. Likewise, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or other studies or the conduct of an expensive 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, among others:

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

- other environmental factors such as the ongoing COVID-19 pandemic or other natural or unforeseen disasters.

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

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

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 recently 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, 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. In August 2022, prior to the expiration of the 30-month stay, the Court found that the asserted claims of one of the patents, the '793 Patent, were both valid and infringed by the Company and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in inter partes review proceedings. As a result of this decision by the United States Court of Appeals for the Federal Circuit with respect to the invalidity of the '793 Patent, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch-Waxman Litigation. The motion was granted in March 2024, and the injunction on final approval by the FDA of YUTREPIA was set aside. However, United Therapeutics has appealed Judge Andrews' decision to set aside the injunction to the Federal Circuit.

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. In addition, United Therapeutics recently filed a citizen petition related to the supplier of the active pharmaceutical ingredient for YUTREPIA in an attempt to prevent or delay the approval of YUTREPIA. Even if the FDA ultimately denies the petition and prevails in such litigation, the FDA may substantially delay approval while it considers and responds to the petition or correspondence and 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' requests.

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 FDA-approved 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.

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

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

Risks Related to Our Dependence on Third Parties

We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA and single suppliers for the active ingredient, 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 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 also rely upon Chengdu for the manufacture and supply of RG Cartridges for the subcutaneous administration of Treprostinil Injection and upon Smiths Medical for ongoing servicing and support of the CADD-MS 3, CADD Legacy and CADD-Solis infusion pumps. In the event of any disruption to our supply of RG Cartridges or any disruption in the availability of parts or servicing for the CADD-MS 3, CADD Legacy and CADD-Solis infusion pumps, sales of Treprostinil Injection may be adversely affected.

In addition, Smiths Medical has indicated that they will no longer support the CADD MS-3 after November 2024. We are relying upon Mainbridge for the development of new pumps for the subcutaneous administration of Treprostinil Injection to replace the CADD MS-3. At present, we anticipate that the new pump under development will not receive FDA clearance prior to the date on which Smiths Medical ceases to support the CADD MS-3 pump. If we are unable to identify options to maintain the availability of the existing CADD MS-3 pumps until the new pumps are cleared by the FDA, sales of Treprostinil Injection may be adversely affected.

For L606, we rely upon single sources of supply for the active pharmaceutical ingredient, manufacture of bulk drug product and packaging. Some of these suppliers are located in Taiwan. Although we are working to establish a secondary supply chain outside of Taiwan, if hostilities were to break out between Taiwan and China, we may be unable to secure a supply of L606. Also, we are currently evaluating 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 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 June 2020, United Therapeutics asserted a patent challenge directed to the Orange Book listed patents for Tyvaso by filing a complaint against us in the U.S. District Court for the District of Delaware, thereby triggering an automatic 30-month regulatory stay on final approval of the NDA for YUTREPIA. As a result of United Therapeutics' patent challenge, the FDA was prohibited from approving the NDA for YUTREPIA until the expiration of the 30-month stay. In August 2022, prior to the expiration of the 30-month stay, the Court found that the asserted claims of one of the patents, the '793 Patent, were both valid and infringed by the Company and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent. However, in December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in inter partes review proceedings. As a result of this decision by the United States Court of Appeals for the Federal Circuit with respect to the invalidity of the '793 Patent, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch-Waxman Litigation. The motion was granted in March 2024, and the injunction on final approval by the FDA of YUTREPIA was set aside. United Therapeutics has appealed Judge Andrews' decision to set aside the injunction to the Federal Circuit.

In addition, 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 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 matters covered by our pending patent applications without us being aware of such applications, and our patent applications may not have priority over patent applications of others. In addition, we cannot assure you that our pending patent applications will result in patents being obtained. Once published, all patent applications and publications throughout the world, including our own, become prior art to our new patent applications and may prevent patents from being obtained or interfere with the scope of patent protection that might be obtained. The standards that patent offices in different jurisdictions use to grant patents are not always applied predictably or uniformly and may change from time to time.

Even if we have been or are able to obtain patent protection for our product candidates or PRINT technology, if the scope of such patent protection is not sufficiently broad, we may not be able to rely on such patent protection to prevent third parties from developing or commercializing product candidates or technology that may copy our product candidates or technology. The enforceability of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Accordingly, we cannot assure you that third parties will not successfully challenge the validity, enforceability or scope of our patents. A successful challenge to our patents may lead to generic versions of our drug products being launched before the expiry of our patents or otherwise limit our ability to stop others from using or commercializing similar or identical products and technology. A successful challenge to our patents may also reduce the duration of the patent protection of our drug products or technology. In addition, we cannot assure you that we will be able to detect unauthorized use or take appropriate, adequate and timely actions to enforce our intellectual property rights. If we are unable to adequately protect our intellectual property, our business, competitive position and prospects may be materially and adversely affected.

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

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

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 Dr. Roscigno 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.

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 payments, royalty, insurance and other obligations on us, and if we fail to comply with these obligations, our licensors may have the right to terminate these license agreements. Termination of these license agreements or the reduction or elimination of our licensed rights or the exclusivity of our licensed rights may have an adverse impact on, among others, our ability to develop and commercialize our product candidates. We cannot assure you that we will be able to negotiate new or reinstated licenses on commercially acceptable terms, or at all.

In addition, we license certain patent rights for our PRINT technology from UNC under the UNC License. Under the UNC License, UNC has the right to terminate our license if we materially breach the agreement and fail to cure such breach within the stipulated time. In the event that UNC terminates our license and we have a product that relies on that license, 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 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 temperature at which our blister packs are sealed to reduce the risk of the product being exposed to moisture. 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 payers, 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 operations are concentrated in Morrisville, North Carolina and interruptions affecting us or our suppliers due to natural disasters or other unforeseen events could materially and adversely affect our operations.

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

In addition, for L606, we rely upon single sources of supply for the active pharmaceutical ingredient and manufacture of bulk drug that are located in Taiwan. Although we are working to establish a secondary supply chain outside of Taiwan, if hostilities were to break out between Taiwan and China, we may be unable to secure a supply of L606, which could limit our ability to continue development of L606 and materially and adversely affect our business, financial condition and results of operations.

Risks Related to our Employees

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

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

Risks Related to our Common Stock

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

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

As of June 14, 2024, 76,413,836 shares of our Common stock were outstanding, of which 59,227,819 shares of Common Stock, or 86.9% of our outstanding shares as of June 14, 2024, 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. Following the registration of the shares of Common Stock being offered by this prospectus, the resale of 10,003,485 shares held by our stockholders as of June 14, 2024 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 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 to pursuant to the Promotion Agreement;
- the market acceptance of the RG Cartridge for the subcutaneous administration of Treprostinil Injection;
- whether Mainbridge is able to complete the development of a new pump for the subcutaneous administration of Treprostinil Injection and obtain FDA clearance on a timely basis or at all;
- our cash resources;
- the approvals or success of competitive products or technologies;
- potential approvals of any product candidate we may develop, including YUTREPIA 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 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 39.1% of our capital stock as of June 14, 2024. 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.

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 of December 31, 2023, we are no longer an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012. 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. 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 RIFA with HCR preclude us, and the terms of any future debt or financing agreement may preclude us, from paying dividends. As a result, capital appreciation, if any, of our equity securities will likely be your sole source of gain for the foreseeable future.

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

In connection with the accounting for our RareGen acquisition, we have recorded significant amounts of contract acquisition costs, intangible assets, and goodwill. Under GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill has been impaired. Contract acquisition costs and amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. The valuation of goodwill depends on a variety of factors, the success of 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.

General Risk Factors

General Risks Related to the Commercialization of our Product Candidates

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

Our business and operations could be adversely affected by health epidemics in regions where we have offices, manufacturing facilities, concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of clinical trial sites, contract manufacturers or suppliers and contract research organizations upon whom we rely.

The extent to which health epidemics, including the COVID-19 pandemic, impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this prospectus, such as the severity and duration of future outbreaks (including from the spread of COVID-19 variants or mutant strains), the duration and effect of business disruptions and the short-term effects, the administration, availability and efficacy of vaccination programs and the ultimate effectiveness of travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat any such health epidemic. These impacts could adversely affect our business, financial condition, results of operations and growth prospects.

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

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

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

The global economy has been, and may continue to be, negatively impacted by Russia's invasion of Ukraine. As a result of Russia's invasion of Ukraine, the U.S., the European Union, the United Kingdom, and other G7 countries, among other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia's ability to import various goods. Russian military actions and the resulting sanctions could continue to adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

In addition, on October 7, 2023, Hamas militants and members of other terrorist organizations infiltrated Israel's southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Thereafter, Hamas launched extensive rocket attacks on Israeli population and industrial centers located along the Israeli border with the Gaza Strip. Shortly following the attack, Israel's security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza

Strip. The Israeli government subsequently called for the evacuation of over one million residents of the northern part of the Gaza Strip and initiated ground operations in the Gaza Strip. It is possible that other terrorist and/or regional organizations will join the hostilities as well, including Hezbollah in Lebanon, and Palestinian military organizations in the West Bank, resulting in a widening of the conflict. The intensity and duration of Israel's current war against Hamas is difficult to predict as are such war's economic implications on the global economy.

Furthermore, because of current geopolitical tensions, the Biden administration has recently signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, signed on September 12, 2022, will likely impact the pharmaceutical industry to encourage U.S. domestic manufacturing of pharmaceutical products. Moreover, there have been Congressional legislative proposals, such as the recent bill titled the Biosecure Act, to discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products. Any additional executive orders or legislative action regarding or potential sanctions on China could materially impact our current manufacturing partners.

Although our business has not been materially impacted by these geopolitical tensions to date, such matters may affect our business 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 the military action, sanctions 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.

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

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

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

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

We are subject to risks related to information technology systems, including cyber-security risks; successful cyber-attacks or technological malfunctions can result in, among other things, financial losses, the inability to process transactions, the unauthorized release of confidential information and reputational risk, all of which would negatively impact our business, financial condition or results of operations.

Our use of technology is critical to our continued operations. We are susceptible to operational, financial and information security risks resulting from cyber-attacks or technological malfunctions. Successful cyber-attacks or technological malfunctions affecting us, our CMOS or our business partners can

result in, among other things, financial losses, the inability to process transactions, the unauthorized release of confidential or proprietary information and reputational risk. 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.

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

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

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

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

General Risks Related to Healthcare Regulation

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

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

In addition, we may be subject to transparency laws and patient privacy regulation by both the federal government and the states in which we conduct our business. 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, or AKS, prohibits, among other things, persons and entities including pharmaceutical manufacturers from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for or the purchase, lease, or order of, or the arranging for an item or service for

which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs.

- The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act, or the FCA prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Claims resulting from a violation of the federal AKS constitute a false or fraudulent claim for purposes of the FCA. Promotion that is deemed to be "off label" can be the basis of FCA exposure.
- Federal law includes provisions (established under the Health Insurance Portability and Accountability Act of 1996) addressing healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Violations of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs.
- Privacy and data security laws may apply to our business. Under 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.
- 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, or the CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Payments and transfers of value made to certain other providers such as nurse practitioners and physician assistants will also need to be reported under the Sunshine Act.
- For both investigational and commercialized products, interactions with or communications directed to healthcare professionals, 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.

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

Recently enacted and future legislation 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, as amended by the Health Care and Education Affordability Reconciliation Act, or 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;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, required sequestration that included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will increase in future years of the sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years.

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. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is capped at 100% of the average manufacturer price for a covered outpatient drug. 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, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; 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). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. In response to the executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation

Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. 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.

General Risks Related to Our Dependence on Third Parties

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

We currently rely on, and plan to continue to rely on, third-party contract research organizations, 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.

General Risks Related to Legal Compliance Matters

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

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, drug supply chain security surveillance and tracking, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and comparable requirements outside of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we may receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product

may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. We will also be required to report certain adverse reactions and production problems, if any, to the FDA or other regulatory agencies and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA or other regulatory agency approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a clinical study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

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

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to environmental, social and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result

in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While we strive to improve our ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations.

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 disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. 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, and business interruption caused by such natural 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.

General Risks Related to our Intellectual Property

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

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, we may engage in litigation to, among others, enforce or defend our intellectual property rights, determine the validity or scope of our intellectual property rights and those of third parties, and protect our trade secrets. Such actions may be time-consuming and costly and may divert our management's attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome.

In addition, in an infringement proceeding, a court may decide that a patent owned by, or licensed to, us is invalid or unenforceable, or may refuse to stop the other party from using the technology in question on the ground that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted

narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information may be compromised by disclosure.

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

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

General Risks Related to the Manufacturing of our Product Candidates

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

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

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

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

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our Common Stock sold pursuant to this prospectus by the Selling Stockholders. The Selling Stockholders will receive all of the proceeds from sales of our Common Stock sold pursuant to this prospectus.

We have agreed to pay all costs, expenses and fees relating to the registration of the shares of our Common Stock covered by this prospectus. The Selling Stockholders will pay any brokerage commissions and/or similar charges incurred in connection with the sale or other disposition by them of the shares covered hereby.

SELLING STOCKHOLDERS

The shares of Common Stock being offered by the Selling Stockholders are shares of Common Stock previously issued to Legend and Dr. Jeffs pursuant to the January 2024 Private Placement and December 2023 Private Placement, respectively. For additional information regarding the issuances and terms of these securities, see "Prospectus Summary—Summary of Private Placements" above. We are registering the shares of Common Stock in order to permit the Selling Stockholders, or their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part, to offer the shares for resale from time to time.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the Selling Stockholders as of June 14, 2024. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our Common Stock. Generally, a person "beneficially owns" shares of our Common Stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days. The second column lists the number of shares of Common Stock beneficially owned by each Selling Stockholder. The third column lists the number of shares of Common Stock being offered by the Selling Stockholders pursuant to this prospectus. The fourth and fifth columns list the number of shares of Common Stock and percentage of our outstanding Common Stock to be held by the Selling Stockholders assuming the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Number of Shares of Common Stock Owned After Offering(1)	Percentage of Class Following the Offering(1)
Legend Aggregator, LP	7,182,532(2)	7,182,532	—	—
Roger Jeffs	3,928,086(3)	139,665	3,788,421	5.0%

(1) Represents the number of shares of Common Stock that will be beneficially owned by the Selling Stockholder after completion of this offering based on the assumptions that (i) all of the shares of Common Stock registered for resale by the registration statement of which this prospectus is a part will be sold and (ii) no other shares of Common Stock will be acquired or sold by the Selling Stockholder before completion of this offering. However, the Selling Stockholder may sell all, part or none of their shares of Common Stock offered pursuant to this prospectus and may sell all, part or none of their Common Stock pursuant to one or more exemptions from the registration provisions of the Securities Act. Applicable percentage ownership following the offering is based on 76,413,836 shares of Common Stock outstanding as of June 14, 2024.

(2) Consists of 7,182,532 shares of Common Stock held by Legend Aggregator, LP. Pursuant to the Schedule 13G filed by Legend Aggregator, LP on January 16, 2024, Legend Aggregator Advisors, LLC is the general partner of Legend Aggregator, LP. Voting and investment power over the shares held by Legend Aggregator, LP is exercised by a three-member management committee of Legend Aggregator Advisors, LLC, and pursuant to the governing documents of Legend Aggregator Advisors, LLC, voting and disposition decisions require the approval of a majority of such persons. The principal business address of Legend Aggregator, LP and Legend Aggregator Advisors, LLC is 2884 Sand Hill Road, Suite 100, Menlo Park, CA 94025.

(3) Consists of (i) 46,595 shares of Common Stock held by Roger A. Jeffs Living Trust UAD 2/29/2000, of which Dr. Jeffs is the trustee, (ii) 406,616 shares of Common Stock held by Dr. Jeffs (which includes 7,169 shares of Common Stock purchased pursuant to the Company's 2020 Employee Stock Purchase Plan), (iii) 1,541,667 shares of Common Stock held by Serendipity BioPharma LLC ("Serendipity") and (iv) 1,933,208 shares of Common Stock underlying outstanding options

and restricted stock units which will have vested within 60 days of June 14, 2024. Dr. Jeffs is a manager of Serendipity and has sole voting and dispositive power over the common units held by Serendipity. The principal business address of Dr. Jeffs is 419 Davis Drive, Suite 100, Morrisville, NC 27560.

PLAN OF DISTRIBUTION

The Selling Stockholders may, from time to time, sell any or all of their respective shares of Common Stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed prices, at prevailing market prices, at prices related to prevailing market prices, at varying prices determined at the time of sale or at privately negotiated prices. The Selling Stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale;
- any other method permitted pursuant to applicable law; and
- an underwritten transaction.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act, if available, or other means not described in this prospectus, rather than under this prospectus.

A Selling Stockholder that is an entity may elect to make a pro rata in-kind distribution of shares of our Common Stock to its members, partners or shareholders pursuant to the registration statement of which this prospectus forms a part by delivering a prospectus. To the extent that such members, partners or stockholders are not affiliates of such Selling Stockholder, such members, partners or shareholders would thereby receive freely tradeable shares of our Common Stock pursuant to the distribution through a registration statement.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The Selling Stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of Common Stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by the Selling Stockholders. The Selling Stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the shares of Common Stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of Common Stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing or amending the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus.

The Selling Stockholders also may transfer the shares of Common Stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of Common Stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act supplementing or amending the list of Selling Stockholders to include the pledgee, transferee or other successors in interest as Selling Stockholders under this prospectus.

In connection with the sale of the shares of Common Stock or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of Common Stock in the course of hedging the positions they assume. The Selling Stockholders may also sell the shares of Common Stock short and deliver these securities to close out their short positions or to return borrowed shares in connection with such short sales, or loan or pledge the shares of Common Stock to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares of Common Stock offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares of Common Stock may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of Common Stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. In the event that any selling stockholder is deemed to be an "underwriter" within the meaning of Section 2(11) of the Securities Act, the Selling Stockholders will be subject to the prospectus delivery requirements of the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of Common Stock. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The Selling Stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of Common Stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of Common Stock by any Selling Stockholder. If we are notified by any Selling Stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of Common Stock, if required, we will file a supplement to this prospectus. If the Selling Stockholders use this prospectus for any sale of the shares of Common Stock, they will be subject to the prospectus delivery requirements of the Securities Act, unless an exemption therefrom is available.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. To the extent required, the securities to be sold, the names of the Selling Stockholders, the respective purchase prices and public offering prices, the names of any agents, dealers or underwriters, any applicable commissions or discounts with respect to a particular offering and the place and time of delivery for the securities with respect to a particular offering will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

The anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of our Common Stock and activities of the Selling Stockholders. Regulation M may limit the timing of purchases and sales of any of the shares by the Selling Stockholders and any other such persons. In addition, Regulation M may restrict the ability of any person engaged in the distribution of the shares of Common Stock to engage in market-making activities with respect to the shares being distributed for a period of up to five business days before the distribution. This may affect the marketability of the shares and the ability of any person or entity to engage in market-making activities with respect to the shares of Common Stock.

There can be no assurance that any Selling Stockholder will sell any or all of the shares of Common Stock we registered on behalf of the Selling Stockholders pursuant to the registration statement of which this prospectus forms a part.

Once sold under the registration statement of which this prospectus forms a part, the shares of Common Stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our certificate of incorporation and our bylaws, which have been publicly filed with the SEC. See "Where You Can Find More Information" and "Incorporation of Certain Information by Reference."

General

The total number of shares of capital stock that we have authorized is 110,000,000, divided into two classes consisting of (i) 100,000,000 shares of Common Stock and (ii) 10,000,000 shares of preferred stock.

Common Stock

The holders of Common Stock are entitled to one vote per share on all matters to be voted upon by the stockholders. The holders of Common Stock are entitled to receive ratably those dividends, if any, that may be declared from time to time by the Board out of funds legally available, subject to preferences that may be applicable to preferred stock, if any, then outstanding. In the event of our liquidation, dissolution or winding up of our company, the holders of common stock will be entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The Common Stock has no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the Common Stock. All outstanding shares of Common Stock are fully paid and non-assessable.

Preferred Stock

The Board is authorized to issue preferred stock in one or more series, to establish the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of these shares and any qualifications, limitations or restrictions thereof. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the holders of Common Stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of Common Stock, including the loss of voting control to others. At present, we have no plans to issue any of the preferred stock.

Warrants

As of March 31, 2024, outstanding warrants consisted of the following:

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
64,624	$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.

Registration Rights

December 2023 Private Placement

The December 2023 Purchase Agreement contained certain registration rights such that, upon the written request of Dr. Jeffs, the Company shall promptly file with the SEC a resale registration statement on Form S-3 or such other appropriate form for an offering to be made on a delayed or continuous basis pursuant to Rule 415 of the Securities Act pursuant to which all of the shares of Common Stock sold at the closing of the December 2023 Private Placement shall be registered for resale.

January 2024 Private Placement

In connection with entering into the January 2024 Purchase Agreement, we entered into the Registration Rights Agreement with Legend dated January 4, 2024, pursuant to which we granted customary registration rights to the Legend obligating us to register for resale under the Securities Act on Form S-3 the January 2024 Private Placement Shares. We are required to prepare and file a registration statement with the SEC within 180 days following the date of the Registration Rights Agreement, and to use best efforts to have the registration statement declared effective within 60 calendar days if there is no review by the SEC, and within 90 calendar days in the event of such review.

Anti-Takeover Effects of Our Charter and Bylaws and Delaware Law

Some provisions of Delaware law and our certificate of incorporation and bylaws could make the following transactions more difficult:

- acquisition of our company by means of a tender offer, a proxy contest or otherwise; and
- removal of our incumbent officers and directors.

These provisions, summarized below, are expected to discourage and prevent coercive takeover practices and inadequate takeover bids. These provisions are designed to encourage persons seeking to acquire control of our company to negotiate first with our Board. They are also intended to provide our management with the flexibility to enhance the likelihood of continuity and stability if our Board determines that a takeover is not in the best interests of our stockholders. These provisions, however, could have the effect of discouraging attempts to acquire us, which could deprive our stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Election and Removal of Directors

Our certificate of incorporation and our bylaws contain provisions that establish specific procedures for appointing and removing members of our Board. Under our certificate of incorporation and bylaws, our Board consists of three classes of directors: Class I, Class II and Class III. A nominee for director shall be elected to our Board if they receive a plurality of the votes cast by the stockholders entitled to vote on such nominee's election. Each director will serve a three-year term and will stand for election upon the third anniversary of the annual meeting at which such director was elected. In addition, our certificate of incorporation and bylaws provide that vacancies and newly created directorships on our Board may be filled only by a majority of the directors then serving on our Board. Under our certificate of incorporation, directors may be removed by the stockholders only by the affirmative vote of the holders of at least a majority of the voting power of all of the then-outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class.

Authorized but Unissued Shares. The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without any further vote or action by our stockholders. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of

authorized but unissued shares of our common stock and our preferred stock could render more difficult or discourage an attempt to obtain control over us by means of a proxy contest, changes in our management, tender offer, merger or otherwise. In particular, the authorization of undesignated preferred stock makes it possible for our Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company.

Stockholder Action; Advance Notification of Stockholder Nominations and Proposals. Our certificate of incorporation and bylaws require that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. In addition, our bylaws provide that candidates for director may be nominated and other business brought before an annual meeting only by the Board or by a stockholder who gives written notice to us no later than 90 days prior to nor earlier than 120 days prior to the first anniversary of the last annual meeting of stockholders. These provisions may have the effect of deterring unsolicited offers to acquire our company or delaying changes in our management, which could depress the market price of our common stock.

Special Stockholder Meetings. Under our certificate of incorporation and bylaws, only the Board, the Chairman of our board or our Chief Executive Officer may call special meetings of stockholders.

Delaware Anti-Takeover Law. We are subject to Section 203 of the DGCL, which is an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date that the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or another transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns 15% or more of the corporation's voting stock. The existence of this provision may have an anti-takeover effect with respect to transactions that are not approved in advance by our Board, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

No Cumulative Voting. Under Delaware law, cumulative voting for the election of directors is not permitted unless a corporation's certificate of incorporation authorizes cumulative voting. Our certificate of incorporation does not provide for cumulative voting in the election of directors. Cumulative voting allows a minority stockholder to vote a portion or all of its shares for one or more candidates for seats on our board. Without cumulative voting, a minority stockholder will not be able to gain as many seats on our board based on the number of shares of our stock the stockholder holds as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board to influence its decision regarding a takeover.

Amendment of Charter Provisions. The amendment of certain of the above provisions in our certificate of incorporation and our bylaws requires approval by holders of at least a majority of our outstanding capital stock entitled to vote generally in the election of directors.

These and other provisions could have the effect of discouraging others from attempting hostile takeovers, and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Limitation of Liability and Indemnification

Our certificate of incorporation provides that no director will be personally liable for monetary damages for breach of any fiduciary duty as a director, except with respect to liability:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

- under Section 174 of the DGCL (governing distributions to stockholders); or
- for any transaction from which the director derived any improper personal benefit.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. The modification or repeal of this provision of our certificate of incorporation will not adversely affect any right or protection of a director existing at the time of such modification or repeal.

Our bylaws also provide that we will, to the fullest extent permitted by law, indemnify our directors and officers against all liabilities and expenses in any suit or proceeding or arising out of their status as an officer or director or their activities in these capacities. We will also indemnify any person who, at our request, is or was serving as a director, officer, employee, agent or trustee of another corporation or of a partnership, limited liability company, joint venture, trust or other enterprise. We may, by action of our Board, provide indemnification to our employees and agents within the same scope and effect as the foregoing indemnification of directors and officers.

Exclusive Forum

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for any (1) derivative action or proceeding brought on behalf of our company, (2) action asserting a claim of breach of a fiduciary duty owed by any director or officer of our company to our company or our company's stockholders, (3) action asserting a claim against our company arising pursuant to any provision of the DGCL or our certificate of incorporation or our bylaws or (4) action asserting a claim against our company governed by the internal affairs doctrine. This provision does not apply to any actions arising under the Securities Act or the Exchange Act. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of our company shall be deemed to have notice of and consented to the forum provisions in our certificate of incorporation. However, the enforceability of similar forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be unenforceable.

Transfer Agent

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. and its address is 150 Royall Street, Canton, MA 02021.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus, which constitutes a part of the registration statement on Form S-3 under the Securities Act with respect to the securities offered hereby, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the securities offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

We are required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. The SEC maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is *www.sec.gov*. We also maintain a website at *www.liquidia.com*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus or any accompanying prospectus supplement.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information that is incorporated by reference is considered to be part of this prospectus, and the information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the termination of the offering of the securities.

(1) our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 13, 2024;

(2) our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, filed with the SEC on May 13, 2024;

(3) the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2023 from our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 29, 2024;

(4) our Current Reports on Form 8-K filed with the SEC on January 5, 2024, January 8, 2024, January 19, 2024, January 23, 2024, January 25, 2024, April 1, 2024, May 14, 2024, May 31, 2024, June 3, 2024 and June 21, 2024; and

(5) our Current Report on Form 8-K12B filed with the SEC on November 18, 2020, including the description of Liquidia Corporation Common Stock contained therein, including any amendments or reports filed for the purpose of updating such description.

Any statement contained in any document incorporated by reference herein will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any additional prospectus supplements modifies or supersedes such statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, a copy of any or all documents that are incorporated by reference into this prospectus, but not delivered with this prospectus, other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the documents that this prospectus incorporates. To request such materials, please contact Jason Adair, at the following address or telephone number: Liquidia Corporation, 419 Davis Drive, Suite 100, Morrisville, NC 27560, (919) 328-4400. A copy of all documents that are incorporated by reference into this prospectus can also be found on our website by accessing www.liquidia.com.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by DLA Piper LLP (US), Short Hills, New Jersey. Additional legal matters may be passed upon for us, the selling stockholders or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2023 have been so incorporated in reliance on the report (which contains an emphasis of matter paragraph related to the Company's requirement for additional capital to fund operations as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth an itemization of the various expenses, all of which we will pay, in connection with the issuance and distribution of the securities being registered. All of the amounts shown are estimated except the SEC Registration Fee.

SEC Registration Fee	$ 13,153
Printing and Engraving Fees	10,000
Legal Fees and Expenses	50,000
Accounting Fees and Expenses	30,000
Transfer Agent and Registrar Fees	0
Miscellaneous	5,000
Total	$108,153

Item 15. Indemnification of Directors and Officers

Section 102 of the Delaware General Corporation Law, or the DGCL, permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation and bylaws provide indemnification for our directors and officers to the fullest extent permitted by the DGCL. We will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner

he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into separate indemnification agreements with each of our directors and certain officers. Each indemnification agreement provides, among other things, for indemnification to the fullest extent permitted by law and our certificate of incorporation and bylaws against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements provide for the advancement or payment of all expenses to the indemnitee and for the reimbursement to us if it is found that such indemnitee is not entitled to such indemnification under applicable law and our amended and restated certificate of incorporation and amended and restated bylaws.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers. Any underwriting agreement or distribution agreement that the we enter into with any underwriters or agents involved in the offering or sale of any securities registered hereby may require such underwriters or dealers to indemnify us, some or all of our directors and officers and our controlling persons, if any, for specified liabilities, which may include liabilities under the Securities Act.

Item 16. Exhibits

The exhibits to this Registration Statement are listed in the Exhibit Index to this Registration Statement, which Exhibit Index is hereby incorporated by reference.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission, pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Filing Fee Tables," in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, *however*, that paragraphs (i), (ii) and (iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

5) That, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Morrisville, North Carolina on June 27, 2024.

LIQUIDIA CORPORATION

By: /s/ Roger A. Jeffs
Roger A. Jeffs
Chief Executive Officer

POWER OF ATTORNEY

We, the undersigned officers and directors of Liquidia Corporation, hereby severally constitute and appoint Roger A. Jeffs and Michael Kaseta, our true and lawful attorneys, with full power to each of them singly, to sign for us and in our names in the capacities indicated below, the registration statement on Form S-3 filed herewith and any and all subsequent amendments to said registration statement, and generally to do all such things in our names and on our behalf in our capacities as officers and directors to enable Liquidia Corporation to comply with the provisions of the Securities Act, and all requirements of the SEC, hereby ratifying and confirming our signatures as they may be signed by our said attorneys, or any of them, to said registration statement and any and all amendments thereto.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Roger A. Jeffs, Ph.D. Roger A. Jeffs, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	June 27, 2024
/s/ Michael Kaseta Michael Kaseta	Chief Financial Officer and Chief Operating Officer (Principal Financial and Accounting Officer)	June 27, 2024
/s/ Dr. Stephen Bloch Dr. Stephen Bloch	Chairman of the Board of Directors	June 27, 2024
/s/ Damian deGoa Damian deGoa	Director	June 27, 2024
/s/ Katherine Rielly-Gauvin Katherine Rielly-Gauvin	Director	June 27, 2024
/s/ Dr. Joanna Horobin Dr. Joanna Horobin	Director	June 27, 2024
/s/ David Johnson David Johnson	Director	June 27, 2024
/s/ Arthur Kirsch Arthur Kirsch	Director	June 27, 2024

SIGNATURE	TITLE	DATE
/s/ Paul B. Manning Paul B. Manning	Director	June 27, 2024
/s/ Raman Singh Raman Singh	Director	June 27, 2024

EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement.*
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 Corporation 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).
5.1	Opinion of DLA Piper LLP (US).**
10.1	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).
10.2	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).
10.3	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).
23.1	Consent of PricewaterhouseCoopers LLP.**
23.2	Consent of DLA Piper LLP (US) (included in Exhibit 5.1).**
107	Filing Fee Table**

* To be filed by amendment or as an exhibit to a document incorporated by reference or deemed to be incorporated by reference in this registration statement, including a current report on Form 8-K, in connection with the offering of any securities, as appropriate.

** Filed herewith.

Exhibit 5.1

DLA Piper LLP (US)
51 John F. Kennedy Parkway,
Suite 120
Short Hills, New Jersey 07078-2704
www.dlapiper.com
T 973.520.2550
F 973.520.2551
Attorneys Responsible for Short Hills Office:
Emilio Ragosa

June 27, 2024
Liquidia Corporation
419 Davis Drive, Suite 100
Morrisville, North Carolina 27560
RE: Liquidia Corporation, Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to Liquidia Corporation, a Delaware corporation (the "***Company***"), in connection with the registration for resale from time to time by the selling stockholders named in the Registration Statement (as defined below) of an aggregate of 7,322,197 shares of the Company's common stock, par value $0.001 per share (the "***Shares***") held by certain selling stockholders. The Shares are included in a registration statement on Form S-3 under the Securities Act of 1933, as amended (the "***Act***") filed with the Securities and Exchange Commission (the "***SEC***") on June 27, 2024 (the "***Registration Statement***").

In connection with this opinion letter, we have examined the Registration Statement and originals, or copies certified or otherwise identified to our satisfaction, of the Certificate of Incorporation of the Company as filed with the Secretary of State of the State of Delaware, the Bylaws of the Company and the minutes of meetings of the stockholders and the Board of Directors of the Company as provided to us by the Company and such other documents, records and other instruments as we have deemed appropriate for purposes of the opinion set forth herein.

We have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of the documents submitted to us as originals, the conformity with the originals of all documents submitted to us as certified, facsimile or photostatic copies and the authenticity of the originals of all documents submitted to us as copies.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, the issue and sale of the Shares have been duly authorized by all necessary corporate action of the Company, and the Shares are validly issued, fully paid and non-assessable, and have been duly authorized by all necessary corporate action of the Company.

In rendering the foregoing opinion, we have assumed that the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the General Corporation Law of the State of Delaware. We hereby consent to the use of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to us under the caption "Legal Matters" in the prospectus included in the Registration Statement. In giving such consent, we do not hereby admit that we are acting within the category of persons whose consent is required under Section 7 of the Act or the rules or regulations of the SEC thereunder.

Very truly yours,
/s/ DLA Piper LLP (US)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement on Form S-3 of Liquidia Corporation of our report dated March 13, 2024 relating to the financial statements, which appears in Liquidia Corporation's Annual Report on Form 10-K for the year ended December 31, 2023. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ PricewaterhouseCoopers LLP
Raleigh, North Carolina
June 27, 2024

Exhibit 107

Calculation of Filing Fee Tables

Form S-3
(Form Type)

LIQUIDIA CORPORATION
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered[1]	Proposed Maximum Offering Price Per Unit[2]	Maximum Aggregate-Offering Price[2]	Fee Rate	Amount of Registration Fee
Newly Registered Securities								
Fees to Be Paid	Equity	Common Stock	457(c)	7,322,197	$ 12.17	$ 89,111,137.49	$ 0.00014760	$ 13,153
Fees Previously Paid	—	—	—	—	—	—	—	—
Carry Forward Securities								
Carry Forward Securities	—	—	—	—	—	—	—	—
				Total Offering Amounts		$ 12.17	$ 0.00014760	$ 13,153
				Total Fees Previously Paid				—
				Total Fee Offsets				—
				Net Fee Due				$ 13,153

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), this Registration Statement also includes an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) of the Securities Act based upon the average of the high and low prices of the Registrant's common stock as reported on the Nasdaq Capital Market on June 26, 2024.

(3) Represents 7,322,197 shares of common stock held collectively by the selling stockholders.