

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

AMENDMENT NO. 1
TO

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

LIQUIDIA CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

85-1710962
(I.R.S. Employer
Identification No.)

**419 Davis Drive, Suite 100
Morrisville, North Carolina 27560
Telephone: (919) 328-4400**

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

**Roger Jeffs
Chief Executive Officer
Liquidia Corporation
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date 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, or a smaller reporting 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

Non-accelerated filer

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 THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

EXPLANATORY NOTE

This Pre-Effective Amendment No. 1 to the Registration Statement on Form S-3 (File No. 333-276244) initially filed by Liquidia Corporation (the “**Company**”) on December 22, 2023 (the “**Registration Statement**”) is being filed for the purposes of deleting references to selling stockholders included in the prospectus that forms a part of the Registration Statement, updating the last reported sale price of the Company’s common stock and the date thereof included on the front cover of the prospectus that forms a part of the Registration Statement, correcting the page number of the “Plan of Distribution” section cross-referenced on the front cover of the prospectus that forms a part of the Registration Statement, revising the table of contents of the prospectus that forms a part of the Registration Statement, and updating the dates included on the front and back covers of the prospectus that forms a part of the Registration Statement. This Amendment No. 1 is not intended to amend or delete any part of the Registration Statement except as specifically noted herein.

SUBJECT TO COMPLETION, DATED DECEMBER 28, 2023

PROSPECTUS



\$200,000,000**Common Stock, Preferred Stock,
Debt Securities, Warrants and Units**

We may offer from time to time in one or more offerings up to an aggregate of \$200,000,000 of the common stock, preferred stock, debt securities, warrants or units described in this prospectus, separately or together in one or more combinations. The preferred stock, debt securities, and warrants may be convertible into or exercisable or exchangeable for common stock or preferred stock or other securities, as identified in the applicable prospectus supplement.

This prospectus provides a general description of the securities we may offer. This prospectus will allow us to offer for sale securities over time. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may add, update or change information contained in 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. This prospectus may not be used to sell the securities unless accompanied by a prospectus supplement.

We may offer and sell the securities through underwriters, dealers or agents, or directly to purchasers, or through a combination of these methods. See "Plan of Distribution" beginning on page 60 of this prospectus.

Our common stock is listed on The Nasdaq Capital Market under the symbol "LQDA." On December 27, 2023, the last reported sale price of our common stock was \$12.19 per share.

Investing in our securities involves risk. See "Risk Factors" beginning on page 4 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

The information in this prospectus is not complete and may be changed without notice. We may not sell these securities until the registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This prospectus is neither an offer to sell nor a solicitation of an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the U.S. Securities and Exchange Commission, or the SEC, using a “shelf” registration process under the Securities Act of 1933, as amended, or the Securities Act. Under this shelf registration process, we may offer and sell, from time to time, any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$200,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell the securities, we will, to the extent required by law, provide a prospectus supplement that will contain specific information about the terms of the offering. We may also authorize one or more free writing prospectuses to 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.

We have not 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 we have authorized for use in connection with a specific offering. You must not rely upon any other information or representation.

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 by us to consummate sales of our 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, 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 ℠ 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.

ABOUT LIQUIDIA CORPORATION

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” and “our business” refer to Liquidia Corporation, a Delaware corporation, and its subsidiaries.

Overview

We are a biopharmaceutical company focused on the development, manufacture and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension, or PH. We operate through our wholly owned operating subsidiaries, Liquidia Technologies, Inc. and Liquidia PAH, LLC, or Liquidia PAH, formerly known as RareGen, LLC, or RareGen.

We currently generate revenue pursuant to a promotion agreement between Liquidia PAH and Sandoz Inc., or Sandoz, dated as of August 1, 2018, as amended, or the Promotion Agreement, sharing profit derived from the sale of Sandoz’s substitutable generic treprostinil injection, or 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 pulmonary arterial hypertension, or PAH, in the United States, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient base to expand from for the launch of YUTREPIA (treprostinil) inhalation powder, or YUTREPIA, upon final approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.

We conduct research, development and manufacturing of novel products by applying our subject matter expertise in cardiopulmonary disease 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. YUTREPIA is an inhaled dry powder formulation of treprostinil designed with PRINT to improve the therapeutic profile of treprostinil by enhancing deep lung delivery while using a convenient, low resistance dry-powder inhaler, or DPI, and by achieving higher dose levels than the labeled doses of current inhaled therapies. The United States Food and Drug Administration, or the FDA, tentatively approved our New Drug Application, or NDA, for YUTREPIA for the treatment of PAH in November 2021. The FDA also confirmed that the clinical data in the NDA would support our pursuit of an amendment to our NDA to treat patients with pulmonary hypertension associated with interstitial lung disease, or PH-ILD, upon the expiration of regulatory exclusivity in March 2024. We filed an amendment to our NDA to add PH-ILD to the label on July 24, 2023. The FDA accepted the amendment to our NDA and has set a Prescription Drug User Fee Act, or PDUFA, goal date of January 24, 2024.

We are also currently developing L606, an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, which we licensed from Pharmosa Biopharm Inc., or 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.

We will continue to investigate projects that include new indications, formulations, and delivery devices for our existing products and product candidates and evaluating potential new products to treat PH and other conditions. We conduct research, development, and manufacturing of novel products by applying

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. We have development experience in inhaled therapies, vaccines, biologics, and ophthalmic implants, among others.

RISK FACTORS

Investing in any securities offered pursuant to this prospectus, the applicable prospectus supplement and any related free writing prospectus involves a high degree of risk. You should carefully consider the risks described under “Risk Factors” in the applicable prospectus supplement, any related free writing prospectus and in our most recent Annual Report on Form 10-K, or any updates in our Quarterly Reports on Form 10-Q, together with all of the other information appearing in or incorporated by reference into this prospectus, the applicable prospectus supplement and any related free writing prospectus, before deciding whether to purchase any of the securities being offered. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

Our business is subject to a number of risks and uncertainties. The following is a summary of the principal risk factors described in this section:

- We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company will depend on our ability to raise additional capital to finance our future operations.
- We have a history of losses and our future profitability remains uncertain. Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.
- We are primarily dependent on the success of our product candidates, YUTREPIA and L606, and these product candidates may fail to receive final marketing approval (in a timely manner or at all) 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 and a separate lawsuit against us that we and a former United Therapeutics employee, who later joined us as an employee, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. Final judgment was entered by Judge Andrews of the U.S. District Court for the District of Delaware in one of the lawsuits finding that one of the three asserted United Therapeutics’ patents is both valid and infringed and ordering that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the infringed patent, which will be in 2027. The Patent Trial and Appeal Board, or the PTAB, found that this same patent was unpatentable, and on December 20, 2023, the United States Court of Appeals for the Federal Circuit affirmed this decision by the PTAB. However, although the PTAB’s decision has now been affirmed on appeal, Judge Andrews may need to lift the injunction in his order before we are able to obtain final FDA approval for YUTREPIA, and there are no assurances whether and when Judge Andrews would do so. Nevertheless, as a result of this decision by the United States Court of Appeals for the Federal Circuit, we will immediately seek to set aside the injunction issued by Judge Andrews and pursue final regulatory approval of YUTREPIA by the FDA. 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 or 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 no obligation to service or maintain CADD-MS 3 infusion pumps

after January 1, 2025. Should components of the CADD-MS 3 pump become unavailable, Smiths Medical's ability to service and maintain such pumps may terminate earlier than anticipated. For instance, during 2022 we became aware of a potential shortage of a critical component of the CADD-MS 3 infusion pump that may cause the number of CADD-MS 3 infusion pumps available for the administration of Treprostinil Injection to be depleted prior to January 1, 2025. In the event the specialty pharmacies are unable to access sufficient quantities of operable pumps or in the event we are unable to identify or develop a new pump prior to the current pumps becoming unavailable, the commercial success of Treprostinil Injection may be adversely affected.

- Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration and the medical devices used for administration of Treprostinil Injection, including the Smiths Medical infusion pumps, any future pumps that we develop, and the RG Cartridge, by patients, health care providers and by third-party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection.
- We expect that we will need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA 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.
- 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.

Prospective investors should carefully consider the risks described in this section, together with all of the other information in this Registration Statement on Form S-3. These risks may not be the only risks we face but are risks we believe may be material at this time. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations or financial results. If any of the events or circumstances described in this section occur, our business, financial condition or results of operations and the trading price of our securities could decline. Investors and prospective investors should consider these risks, the information contained under the heading “Cautionary Note Regarding Forward-Looking Statements” and the risks described elsewhere in this Registration Statement on Form S-3 before deciding whether to invest in our securities. 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 will 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. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. The future viability of our company will depend on our ability to 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. Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.

We have incurred net losses of \$51.1 million during the nine months ended September 30, 2023, and \$41.0 million and \$34.6 million during the years ended December 31, 2022 and 2021, respectively. We also had negative operating cash flows for each of these periods. As of September 30, 2023, we had an accumulated deficit of \$401.6 million.

Since our incorporation, we have invested heavily in the development of our product candidates and technologies, as well as in recruiting management and scientific personnel. To date, we have not

commenced the commercialization of our product candidates and all of our revenue has been derived from up-front fees and milestone payments made to us in connection with licensing and collaboration arrangements we have entered into and the Promotion Agreement, under which we share in the profit derived from the sale of Trepstinil Injection in the United States. These up-front fees and milestone payments have been, and combined with revenue generated from Trepstinil 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. These factors raise substantial doubt about our ability to continue as a going concern and to satisfy our estimated liquidity needs for one year from the issuance of the condensed consolidated financial statements dated as of September 30, 2023.

There is substantial doubt regarding our ability to continue as a going concern absent obtaining adequate new financing.

In our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 as filed with the SEC on November 7, 2023, we disclosed that we had concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least 12 months from the date of the filing of such Form 10-Q as our cash and cash equivalents at September 30, 2023 were not sufficient to fund our planned operations and remain in compliance with our financial covenants. In addition, until such time, if ever, we can generate substantial revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. There can be no assurances that we will be able to secure such additional financing if at all, or on terms that are satisfactory to us, and that it will be sufficient to meet our needs. In the event we are not successful in obtaining sufficient funding, even if we are successful in this offering, this could force us to delay, limit, or reduce our product development, commercialization efforts or other operations, and could result in a default on the Revenue Interest Financing Agreement, or RIFA, with HCR.

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

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

Our financing facility with 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 with HCR, HCR has agreed to pay us an aggregate investment amount of up to \$100.0 million, or the Investment Amount. Under the terms of the RIFA, \$32.5 million of the Investment Amount was funded at the initial closing, an additional \$10.0 million of the Investment Amount was funded in connection with our entry into a license agreement with Pharmosa, and additional tranches of \$35.0 million and \$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, our April 2022 public equity offering and prior public and private equity offerings to support the development and commercialization of YUTREPIA, including the potential commercial launch of YUTREPIA in the event of final FDA approval, the commercialization of Trepstinil Injection, the development and servicing of pumps for the administration of Trepstinil Injection, the development of L606, one or more strategic transactions, preclinical pipeline activities, the development and commercialization of any products acquired or developed and for general corporate purposes. Our management has broad discretion in the application of such proceeds and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our equity. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, diminish cash flows available to service our obligations to HCR, cause the value of our equity to decline and delay the development of our product candidates. Pending their use, we may invest such proceeds in short-term, investment-grade, interest-bearing securities, which may not yield favorable returns.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50.0% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. With our April 2022 public equity offering, 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.

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

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

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

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

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

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

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

Sandoz holds the FDA approval, 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. Our role is one of a specialized service provider to Sandoz. As a result, we are dependent on Sandoz to manufacture and supply Treprostinil Injection, and dependent on Sandoz for the continued FDA compliance of Treprostinil Injection. We do not have control over Sandoz's compliance with laws and regulations applicable to drug manufacturers and ANDA holders (for example, applicable current good manufacturing practices, 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, including as a result of the ongoing COVID-19 pandemic. Our share of net profits under the Promotion Agreement is reduced by certain manufacturing costs and other write-offs related to Sandoz's inability to sell Treprostinil Injection, including in the event that Treprostinil Injection expires prior to sale. Currently, Treprostinil Injection expires 24 months after the date of manufacture.

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

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

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

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

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer Treprostinil Injection for sale at competitive prices (generic drug prices, after initial generic entry, have been observed to decline with the entrance of additional generic competition);
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning;

- the willingness of the target patient population to try new treatments, including the generic version of a brand, and of physicians to prescribe such treatments;
- our ability to hire and retain sales and marketing personnel and their ability to support Sandoz under the Promotion Agreement;
- the strength of Sandoz’s manufacturing and distribution support;
- the requirement by third-party payors to use generic trestatinil for parenteral administration in place of Remodulin;
- the availability of third-party coverage and adequate reimbursement for Trestatinil Injection;
- the prevalence and severity of any side effects;
- any restrictions on the use of Trestatinil 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 Trestatinil 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 Trestatinil Injection.

In order for Trestatinil 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 Trestatinil Injection through subcutaneous injection is dependent on the continued availability of the RG Cartridge. Our ability to sell the Trestatinil Injection for subcutaneous administration is dependent on market acceptance of the RG Cartridge by patients, health care providers and by third-party payors. If the RG Cartridge does not achieve an adequate level of acceptance or if the RG Cartridge experiences any quality problems, recalls or other adverse events, our ability to provide Trestatinil Injection to patients who receive Trestatinil through subcutaneous injection will be limited. The degree of market acceptance of the RG Cartridge will depend on a number of factors, including:

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

In addition, to administer Trestatinil Injection through subcutaneous injection, patients currently must use the CADD-MS 3 infusion pump manufactured by Smiths Medical. Smiths Medical no longer manufactures the CADD-MS 3 infusion pump and, under our Settlement Agreement with Smiths Medical, they are no longer obligated to support the CADD-MS 3 infusion pump after January 1, 2025. Moreover, in the event components of the CADD-MS 3 infusion pump become unavailable prior to January 1, 2025, Smiths Medical may be unable to service pumps that require a replacement of such components. For instance, during 2022 we became aware of a shortage of a critical component of the CADD-MS 3 infusion pump that has caused the number of CADD-MS 3 infusion pumps available for the administration of Trestatinil

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. If we are unable to identify a solution to this shortage, the number of patients that can receive subcutaneous administration of Treprostinil Injection will continue to be constrained, which would continue to adversely affect sales of Treprostinil Injection.

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 applicable route of administration.

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

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

Our cash is held in non-interest-bearing and interest-bearing accounts 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, which may result in our company being further delayed in its efforts to commercialize YUTREPIA.

We are developing YUTREPIA under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. Accordingly, under the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act, we were required to, in the NDA for YUTREPIA, certify that patents listed in the Orange Book for Tyvaso are invalid, unenforceable or will not be infringed by the manufacture, use or sale of YUTREPIA. Two of these patents are U.S. Patent No. 9,604,901, or the '901 Patent, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin[®]", and U.S. Patent No. 9,593,066, or 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), or the Hatch-Waxman Litigation.

In July 2020, the U.S. Patent and Trademark Office, or the USPTO, issued U.S. Patent No. 10,716,793, or the '793 Patent, entitled "Treprostinil Administration by Inhalation," to United

Therapeutics. In July 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the '793 Patent by the practice of YUTREPIA.

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

Trial proceedings in the Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the '066 Patent were invalid, that the remaining asserted claims of the '066 Patent were not infringed by us, and that all of the asserted claims of the '793 Patent were both valid and infringed by us, based on the arguments we presented in the Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent, which will be in 2027. Both we and United Therapeutics 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 two petitions for *inter partes* review with the Patent Trial and Appeal Board, or the PTAB, of the USPTO. One petition was for *inter partes* review of the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid, and a second petition was for *inter partes* review of the '066 Patent, seeking a determination that the claims in the '066 Patent are invalid. In October 2020, the PTAB instituted an *inter partes* review of the '901 Patent and concurrently denied institution on the '066 Patent, stating that the '066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '901 patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the '901 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending, and oral argument has been scheduled for February 2024.

In January 2021, we filed a petition with the PTAB for *inter partes* review of the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. In August 2021, the PTAB instituted an *inter partes* review of the '793 Patent, finding that we had demonstrated a reasonable likelihood that we would prevail with respect to showing that at least one challenged claim of the '793 Patent is unpatentable as obvious over the combination of certain prior art cited by us in our petition to the PTAB. In July 2022, the PTAB ruled in our favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '793 Patent. The rehearing request was denied in February 2023. 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, and oral argument was held on December 4, 2023. On December 20, 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, we will immediately seek to set aside the injunction issued by Judge Andrews in the Hatch-Waxman Litigation and pursue final regulatory approval of YUTREPIA by the FDA.

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 a second complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware (Case No. 1:23-cv-00975-RGA), or the New Hatch-Waxman Litigation, again asserting infringement by the

Company of the ‘793 Patent. Although we do not believe United Therapeutics is entitled to a new 30-month stay 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. However, on December 20, 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. Such ruling by the United States Court of Appeals for the Federal Circuit has precedential effect in the New Hatch-Waxman Litigation, and, as a result of such ruling, we will seek to dismiss all claims related to the ‘793 patent in the New Hatch-Waxman lawsuit filed by United Therapeutics in connection with the amendment to our NDA to add PH-ILD as an indication for YUTREPIA.

On November 28, 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.

As a result of this litigation and the order by Judge Andrews in the Hatch-Waxman Litigation, we may be subject to significant delay and incur substantial additional costs in litigation before we are able to commercialize YUTREPIA, if at all. In addition, if United Therapeutics is successful in any appeals of the December 20, 2023 decision by the United States Court of Appeals for the Federal Circuit, we may be unable to commercialize YUTREPIA until the expiration of United Therapeutics’ patents, which could materially harm our business.

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 legal proceedings, including the New Hatch-Waxman Litigation.

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

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 tadalafil products, than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies. We may also face competition as a result of advances in the commercial applicability of new technologies and greater availability of capital for investment in such technologies. Our competitors may also invest heavily in the discovery and development of novel drug products that could make our product candidates less competitive or may file FDA citizen petitions which may delay the approval process for our product candidates. Furthermore, our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. Our competitors may also succeed in asserting existing patents or developing new patents, including patents that may issue from patent applications that are currently being pursued by United Therapeutics, to which we do not have a license in an attempt to prevent us from marketing our products. These competitors may also compete with us in recruiting and retaining qualified sales personnel.

Any new drug product that competes with a prior approved drug product must demonstrate advantages in safety, efficacy, tolerability or convenience in order to overcome price competition and to be commercially successful. Our products, if and when approved, are expected to face competition from drug products that are already on the market, as well as those in our competitors' development pipelines. We expect that our lead program, YUTREPIA, an inhaled tadalafil therapy for the treatment of PAH and PH-ILD, and L606, a nebulized, liposomal formulation of tadalafil for treatment of PAH and PH-ILD, will face competition from the following inhaled tadalafil therapies that are either currently marketed or in clinical development:

- Tyvaso, marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009. In April 2021, United Therapeutics announced that Tyvaso was approved by FDA to include treatment of patients with PH-ILD. 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.
- Ventavis[®], marketed by Actelion, a division of Johnson & Johnson, has been approved for the treatment of PAH in the United States since 2004.
- Tyvaso DPI, licensed from MannKind by United Therapeutics, is a dry-powder formulation of tadalafil that was approved for the treatment of PAH and PH-ILD in the United States in May 2022. There is a possibility that the FDA could grant three years of market exclusivity to Tyvaso DPI as an inhaled dry-powder formulation of tadalafil that could delay the final approval of YUTREPIA until said exclusivity expires.
- Tadalafil Palmitate Inhalation Powder, or TPIP, is a dry-powder formulation of a tadalafil prodrug being developed by Insmid. Insmid 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. Insmid initiated Phase 2 trials studying patients diagnosed with PAH and PH-ILD in May 2021 and December 2022, respectively. If the TPIP clinical program is successful in demonstrating less frequent dosing with similar efficacy and safety to YUTREPIA and Tyvaso DPI, then TPIP has the potential to be viewed as a more attractive option and may take market share rapidly.

In addition to these other inhaled tadalafil therapies, we expect that YUTREPIA and L606 will also face competition from other tadalafil-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 Tadalafil 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.

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., Aerovate Therapeutics, Inc., Aerami Therapeutics Inc., Tenax Therapeutics, Inc. and Sumitovant Biopharma Ltd, among others. For example, Merck & Co's injectable sotatercept is an investigational, potential first-in-class molecule that targets the proliferation of cells in the pulmonary arterial wall and is being reviewed by the FDA for approval in 2024. If approved, it is possible that it may be used prior to prostacyclin therapies, which may have an adverse effect on the market potential for YUTREPIA and/or L606.

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 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.

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

The ability of competitors to utilize other regulatory incentive programs could also expedite their FDA review and approval timeline, which could result in their products reaching the market before our product candidate, and which could create further potential implications on exclusivity as noted above. For example, when a Priority Review Voucher 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 and could delay any drug launch. 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;
- our ability to appropriately market, detail and distribute products in light of any healthcare provider facility closures, quarantine, travel restrictions and other governmental restrictions caused by COVID-19;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- any distribution and use restrictions imposed by the FDA or to which we agree;

- liability for sales and marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- our ability to maintain a healthcare compliance program including effective mechanisms for compliance monitoring; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

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

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

Our business is exposed to the risk of product liability and other liability risks that are inherent in the development, manufacture, clinical testing and marketing of pharmaceutical products. These risks exist even if a product is approved for commercial sale by the FDA or comparable regulatory authorities in other countries and manufactured in licensed facilities. Our current product 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 in November 2021 for the treatment of PAH, and this product candidate may fail to receive final marketing approval (in a timely manner or at all) or may not be commercialized successfully.

We do not have any products approved for marketing in any jurisdiction and we have never generated any revenue from sales of our own products. Our ability to generate revenue from sales of our

own products and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We expect that a substantial portion of our efforts and expenditure over the next few years will be devoted to our product candidate, YUTREPIA, a proprietary inhaled dry powder formulation of treprostinil for the treatment of 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 Hatch-Waxman Litigation following a lawsuit filed by United Therapeutics in June 2020. As a result of Judge Andrews' order in the Hatch-Waxman Litigation, the FDA may not issue a final approval for the YUTREPIA NDA until 2027 unless the PTAB's decision with respect to the '793 Patent is affirmed on appeal. On December 20, 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. Although the PTAB's decision has now been affirmed on appeal, Judge Andrews may need to lift the injunction in his order before we are able to obtain final FDA approval for YUTREPIA, and there are no assurances whether and when Judge Andrews would do so. Nevertheless, as a result of this decision by the United States Court of Appeals for the Federal Circuit, we will immediately seek to set aside the injunction issued by Judge Andrews in the Hatch-Waxman Litigation and pursue final regulatory approval of YUTREPIA by the FDA. 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 we do not believe United Therapeutics is entitled to a new 30-month stay 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. However, on December 20, 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. Such ruling by the United States Court of Appeals for the Federal Circuit has precedential effect in the New Hatch-Waxman Litigation, and, as a result of such ruling, we will seek to dismiss all claims related to the '793 patent in the New Hatch-Waxman lawsuit filed by United Therapeutics in connection with the amendment to our NDA to add PH-ILD as an indication 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. In addition, the FDA has not yet issued any approval for YUTREPIA for the treatment of PH-ILD, which remains under review. The FDA has set a PDUFA goal date of January 24, 2024, with respect to our amendment to add PH-ILD to the label for YUTREPIA. 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 “—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, or CMC, or other data and information, and the development and information may be time-consuming and expensive. Status as a combination product, as is the case for YUTREPIA 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 treprostnil, such as Tyvaso DPI, is granted three years of market exclusivity, that could delay the final approval of YUTREPIA until said exclusivity expires. Moreover, the applicable requirements for approval may differ from country to country.

If we successfully obtain marketing approval for YUTREPIA and/or L606, we cannot assure you that it 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, or 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 institutional review board 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 with the FDA to contest approval of our NDA, which may delay or even prevent the FDA from approving any NDA that we submit under the 505(b)(2) regulatory pathway. If an FDA decision or action relative to our product candidate, or the FDA's interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for our product candidates. Even if we are able to utilize the 505(b)(2) regulatory pathway, a drug approved via this pathway may be subject to the same post-approval limitations, conditions and requirements as any other drug.

In addition, we may face Hatch-Waxman litigation in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the approval of our product candidates. The pharmaceutical industry is highly competitive, and 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505(b)(2) NDA. If the previously approved drugs referenced in an applicant's 505(b)(2) NDA are protected by patent(s) listed in the Orange Book, the 505(b)(2) applicant is required to make a claim after filing its NDA 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. As a result of the Court's order, the FDA may not issue a final approval for the YUTREPIA NDA until the expiration of the '793 Patent unless the PTAB's decision invalidating the '793 Patent is affirmed on appeal. On December 20, 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, we will immediately seek to set aside the injunction issued by Judge Andrews in the Hatch-Waxman Litigation and pursue final regulatory approval of YUTREPIA by the FDA.

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 we do not believe United Therapeutics is entitled to a new 30-month stay 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. However, on December 20, 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. Such ruling by the United States Court of Appeals for the Federal Circuit has precedential effect in the New Hatch-Waxman Litigation, and, as a result of such ruling, we will seek to dismiss all claims related to the '793 patent in the New Hatch-Waxman lawsuit filed by United Therapeutics in connection with the amendment to our NDA to add PH-ILD as an indication for YUTREPIA.

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 with the FDA seeking to delay approval of, or impose additional approval

requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product.

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

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

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

A key element of our long-term strategy is to continually develop a pipeline of product candidates by developing 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, or 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, we are relying upon Mainbridge for the development of new pumps for the subcutaneous administration of Treprostinil Injection. In the event of any failure of Mainbridge to successfully develop such a pump, sales of Treprostinil Injection may be adversely affected.

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.

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

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

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

Collaboration and licensing arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish collaboration or other alternative arrangements should we so choose to enter into such arrangements. In addition, the terms of any collaboration or other arrangements that we may enter into may not be favorable to us or may restrict our ability to enter into further collaboration or other arrangements with third parties. For example, collaboration agreements may contain exclusivity arrangements which limit our ability to work with other pharmaceutical companies to expand the applications for our PRINT technology, as is the case in our collaboration agreement with GSK, 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. As a result of the Court's order, the FDA may not issue a final approval for the YUTREPIA NDA until the expiration of the '793 Patent unless the PTAB's decision invalidating the '793 Patent is affirmed on appeal. Accordingly, we may be subject to significant delay and incur substantial costs in litigation before we are able to commercialize YUTREPIA, if at all. However, on December 20, 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, we will immediately seek to set aside the injunction issued by Judge Andrews in the Hatch-Waxman Litigation and pursue final regulatory approval of YUTREPIA by the FDA.

In addition, in connection with an amendment to our NDA filed on July 24, 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 a new Hatch-Waxman suit for patent infringement, which may trigger a new 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. Although we do not believe United Therapeutics is entitled to a new 30-month stay 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. However, on December 20, 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. Such ruling by the United States Court of Appeals for the Federal Circuit has precedential effect in the New Hatch-Waxman Litigation, and, as a result of such ruling, we will seek to dismiss all claims related to the '793 patent in the New Hatch-Waxman lawsuit filed by United Therapeutics in connection with the amendment to our NDA to add PH-ILD as an indication for YUTREPIA. 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.

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

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

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

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

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

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

clinical testing and regulatory review of new product candidates, any patents protecting our product candidates may expire before or shortly after such product candidates might become approved for commercialization.

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

In addition, we, our collaborators or our licensees may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. As a result, we may miss potential opportunities to seek patent protection or strengthen our patent position.

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

In addition to patent protection, we rely on trade secret protection to protect certain aspects of our intellectual property. 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.

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 November 1, 2023, 64,905,495 shares of our common stock were outstanding, of which 55,024,148 shares of common stock, or 84.8% of our outstanding shares as of November 1, 2023, are freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, or Rule 144. The resale of the remaining 9,881,347 shares held by our stockholders as of November 1, 2023 is currently prohibited or otherwise restricted as a result of securities law provisions. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

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

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

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

- results of any clinical trials of any product candidate we may develop, 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 success of Chengdu’s launch of the RG Cartridge and the market acceptance of the RG Cartridge for the subcutaneous administration of Treprostinil Injection;
- whether Mainbridge is able to complete the development of a new pump for the subcutaneous administration of Treprostinil Injection and obtain FDA clearance on a timely basis or at all;
- our cash resources;

- the approvals or success of competitive products or technologies;
- potential approvals of any product candidate we may develop, including YUTREPIA and L606, for marketing by the FDA or equivalent foreign regulatory authorities or any failure to obtain such approvals;
- our involvement in significant lawsuits, such as stockholder or patent litigation, including *inter partes* review proceedings and Hatch-Waxman litigation with originator companies or others which may hold patents, including the ongoing litigation in connection with the patents that United Therapeutics has asserted against us;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize any product candidate we may develop, including YUTREPIA 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 37.3% of our capital stock as of November 1, 2023. Accordingly, our executive officers, directors and principal stockholders have significant influence in determining the composition of our board of directors, or 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, or 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 control over financial reporting. See Item 4. Controls and Procedures for additional information.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.235 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement (which is December 31, 2023), (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

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

- permit the Board to issue up to 10 million shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our Board;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- create a staggered board of directors such that all members of our Board are not elected at one time;
- allow for the issuance of authorized but unissued shares of our capital stock without any further vote or action by our stockholders; and
- establish advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon at stockholders' meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the 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 the Company's business, including our ability to obtain regulatory approval for YUTREPIA, global market and economic conditions, earnings growth and expected cash flows. Impairments may be caused by factors outside the Company's control, such as actions by the FDA, increasing competitive pricing pressures, and various other factors. Significant and unanticipated changes or our inability to obtain or maintain regulatory approvals for our product candidates, including the NDA for YUTREPIA, could require a non-cash charge for impairment in a future period, which may significantly affect the Company's results of operations in the period of such charge.

General Risk Factors

General Risks Related to the Commercialization of our Product Candidates

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

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

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

The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain

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

In addition, to the extent the 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, ongoing military conflicts between Russia and Ukraine and Israel and Hamas, and periods of high inflation. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine and the Middle East, geopolitical tensions, or high inflation.

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

Although, to date, our business has not been materially impacted by the ongoing military conflict between Russian and Ukraine or Israel and Hamas, geopolitical tensions, or high inflation, such matters may affect our business and it is impossible to predict the extent to which our operations will be impacted in

the short and long term, or the ways in which such matters may impact our business. We anticipate that increases in compensation to our employees and costs paid to vendors may similarly be greater than in past periods due to inflation. The extent and duration of the conflicts in Ukraine and the Middle East, geopolitical tensions, changes in inflation rates 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 (ANDAs). In support of an ANDA, a generic manufacturer is generally required to show that its product has the same active pharmaceutical ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug. Generic drug products may be significantly less expensive to bring to market than the reference listed drug, and companies that produce generic drug products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug product, a significant percentage of the sales of any reference listed drug may be lost to the generic drug product.

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

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

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

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

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

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

General Risks Related to Healthcare Regulation

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

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

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

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

- The federal Anti-Kickback Statute, 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.

- 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 new 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 (first due in 2023); 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 CROs to monitor and manage data for our preclinical studies and clinical trials. However, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable regulatory standards and our reliance on CROs does not relieve us of our regulatory responsibilities.

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

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

General Risks Related to Legal Compliance Matters

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

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

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

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

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

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

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

General Risks Related to our Intellectual Property

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

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

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

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

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

affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

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

General Risks Related to the Manufacturing of our Product Candidates

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

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

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

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

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 4 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 4 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 of and our ability to commercially launch YUTREPIA, including the potential impact of regulatory review, approval, and exclusivity developments which may occur for competitors;
- 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, including any related appeals, or any future litigation with United Therapeutics or any other third party;
- the timing and our business partners’ ability to obtain and maintain regulatory clearance for the infusion pump that we are developing with Sandoz and 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;
- our ability to continue operations as a going concern without obtaining additional funding;
- our expectations regarding the size of the patient populations for, market acceptance and opportunity for those drug products that we commercialize in collaboration with third parties, including Sandoz’s first-to-file fully substitutable generic treprostinil injection;
- the availability and market acceptance of medical devices and components of medical devices used to administer our drug products and drug products that we commercialize with third parties, including Smiths Medical’s CADD-MS 3 infusion pump, the RG 3ml Medication Cartridge

that we developed in collaboration with Chengdu Shifeng Medical Technologies LTD. used for the subcutaneous administration of Sandoz's generic trestatinil injection, Smiths Medical's CADD Legacy and CADD-Solis infusion pumps used for the intravenous administration of Sandoz's generic trestatinil injection, the infusion pump that we are developing with Sandoz and Mainbridge for the subcutaneous administration of Sandoz's generic trestatinil injection, Plastiap's RS00 Model 8 dry powder inhaler, which we plan to use for the administration of YUTREPIA and any devices used for the administration of L606;

- our ability to draw down on our financing facility with HCR and our ability to satisfy the covenants contained in the RIFA;
- 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 patent litigation with United Therapeutics, the litigation arising from United Therapeutics' claim that we and a former employee misappropriated trade secrets from United Therapeutics and any future litigation with United Therapeutics or any other third party;
- the effects on our company or our subsidiaries of future regulatory or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we are subject;
- conduct of and changing circumstances related to third-party relationships on which we rely, including the level of credit worthiness of counterparties;
- the volatility and unpredictability of the stock market and credit market conditions;
- conditions beyond our control, such as natural disasters, global pandemics (including COVID-19), or acts of war or terrorism;
- variations between the stated assumptions on which forward-looking statements are based and our actual experience;
- other legislative, regulatory, economic, business, and/or competitive factors;
- our plans to develop and commercialize our product candidates;
- our planned clinical trials for our product candidates;

- the timing of the availability of data from our clinical trials;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our product candidates and their potential advantages compared to other treatments;
- our commercialization, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates and the sufficiency of our current manufacturing facilities to produce development and commercial quantities of our product candidates;
- our ability to establish and maintain collaborations;
- our estimates regarding the market opportunities for our product candidates;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and
- our expected use of proceeds from prior public offerings and the period over which such proceeds, together with our available cash, will be sufficient to meet our operating needs.

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.

USE OF PROCEEDS

Unless the applicable prospectus supplement states otherwise, we anticipate that the net proceeds from our sale of any securities will be used for general corporate purposes. General corporate purposes may include research and development costs, including the conduct of clinical trials and process development and manufacturing of our product candidates, services or technologies, expansion of our technology infrastructure and capabilities, working capital and capital expenditures. We may temporarily invest the net proceeds in a variety of capital preservation instruments, including investment grade, interest bearing instruments and U.S. government securities, until they are used for their stated purpose. We have not determined the amount of net proceeds to be used specifically for such purposes. As a result, management will retain broad discretion over the allocation of net proceeds.

DESCRIPTION OF THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus summarize the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we so indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material U.S. federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may offer and sell from time to time, in one or more primary offerings, our common stock, preferred stock, debt securities, warrants or units, or any combination of the foregoing.

In this prospectus, we refer to the common stock, preferred stock, debt securities, warrants or units, or any combination of the foregoing securities to be sold by us in a primary offering collectively as “securities.” The total dollar amount of all securities that we may issue under this prospectus will not exceed \$200,000,000.

This prospectus may not be used by us to consummate a sale of securities unless it is accompanied by a prospectus supplement.

DESCRIPTION OF CAPITAL STOCK

The following description of our common stock and preferred stock, together with the additional information we include in the applicable prospectus supplement, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. It may not contain all the information that is important to you. For the complete terms of our common stock and preferred stock, please refer to our certificate of incorporation and bylaws, which are incorporated by reference into the registration statement which includes this prospectus. The DGCL may also affect the terms of these securities.

General

The total number of shares of capital stock that the Company has authorized is 110,000,000, divided into two classes consisting of (i) 100,000,000 shares of common stock, \$0.001 par value per share, and (ii) 10,000,000 shares of preferred stock, par value per share \$0.001.

As of September 30, 2023, there were 64,899,295 shares of common stock issued and outstanding and an additional 9,969,300 shares issuable upon exercise of outstanding options and warrants. Of the 9,969,300 shares of common stock issuable upon exercise of outstanding options and warrants, 8,104,299 shares were issuable to executive officers, directors and principal stockholders of the Company and 1,450,377 shares were issuable to other employees. Furthermore, as of September 30, 2023, 1,730,523 shares of common stock were issuable to executive officers and directors upon the vesting and settlement of outstanding restricted stock units.

As of the date of this prospectus, there were no shares of preferred stock issued and outstanding.

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 our Board out of funds legally available, subject to preferences that may be applicable to preferred stock, if any, then outstanding. In the event of a 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

Our 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 September 30, 2023, we had outstanding warrants to purchase an aggregate of 415,572 shares of our common stock at an exercise price of \$3.83 per share. These warrants expire on December 31, 2026, February 26, 2031 or January 6, 2032, as applicable.

Registration Rights

On December 23, 2019, we entered into a common stock purchase agreement for a private placement whereby, on December 27, 2019 we issued and sold 7,164,534 shares of our common stock at a price of \$3.13 per share for aggregate gross proceeds of approximately \$22.4 million, which we refer to as the 2019 Private Placement. In connection with the 2019 Private Placement, we entered into a registration rights agreement, or the Registration Rights Agreement, with the investors in the 2019 Private Placement, pursuant to which we agreed to file a registration statement with the SEC covering the resale of the shares of common stock sold in the 2019 Private Placement. We agreed to file such registration statement within 60 days following the date of the Registration Rights Agreement. The Registration Rights Agreement includes customary indemnification rights in connection with the registration statement.

Pursuant to a Limited Waiver and Modification to the Merger Agreement, dated as of August 3, 2020, (i) RareGen waived the requirement in the Merger Agreement that the shares issuable to RareGen members in the RareGen acquisition be registered on the related Registration Statement on Form S-4 and (ii) we covenanted and agreed to file with the SEC a resale registration statement as promptly as practicable following the closing of the RareGen acquisition to register for resale the shares of our common stock issuable to RareGen members in the RareGen acquisition and to use reasonable best efforts to cause such resale registration statement to be declared effective by the SEC within 60 days following the closing date of the Merger Transaction.

Additionally, we entered into a Seventh Amended and Restated Investors' Rights Agreement, or the Seventh Amended and Restated IRA, on February 2, 2018 with our then-largest stockholders. Subject to the terms of this agreement, Holders, as defined in the Seventh Amended and Restated IRA, of shares having registration rights, or Registrable Securities, as defined in the Seventh Amended and Restated IRA, can demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing, until the earliest to occur of: (i) five years following the consummation of our initial public offering, or July 30, 2023, (ii) as to any Holder, such earlier time after our initial public offering at which such Holder can sell all Registrable Securities held by such Holder (together with any affiliate of the Holder with whom such Holder must aggregate its sales under Rule 144) in a single three (3)-month period without registration in compliance with Rule 144 of the Securities Act or (iii) after the consummation of a "Liquidation Event," as defined in the Seventh Amended and Restated IRA. All registration rights granted under the IRA terminated on the fifth anniversary of the completion of our initial public offering, or July 30, 2023.

On December 12, 2023, we entered into a common stock purchase agreement, or the Purchase Agreement, with Roger Jeffs, the Chief Executive Officer of the Company, or the Investor, in connection with the private sale of 139,665 unregistered shares of our common stock, in a private placement at a purchase price of \$7.16 per share for an aggregate investment amount of approximately \$1.0 million, which we refer to as the 2023 Private Placement. The Purchase Agreement contains customary representations and warranties, agreements and obligations, closing conditions and termination provisions. Additionally,

pursuant to the Purchase Agreement, we agreed to promptly file a registration statement with the SEC covering the resale of the shares of common stock sold in the 2023 Private Placement upon written request by the Investor.

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 Officers

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.

DESCRIPTION OF DEBT SECURITIES

We may issue from time to time, in one or more offerings, senior or subordinated debt securities covered by this prospectus. When we offer to sell a particular series of debt securities, we will describe the specific terms of the series in a supplement to this prospectus.

DESCRIPTION OF WARRANTS

We may issue warrants to purchase our debt or equity securities or other rights, including rights to receive payment in cash or securities based on the value, rate or price of one or more specified commodities, currencies, securities or indices, or any combination of the foregoing. Warrants may be issued independently or together with any other securities and may be attached to, or separate from, such securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent. The terms of any warrants to be issued and a description of the material provisions of the applicable warrant agreement will be set forth in the applicable prospectus supplement.

DESCRIPTION OF UNITS

As specified in the applicable prospectus supplement, we may issue units consisting of warrants, debt securities, shares of preferred stock, shares of common stock or any combination of such securities.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee maintain for this purpose as the "holders" of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as "indirect holders" of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the

name of a financial institution that holds them as depository on behalf of other financial institutions that participate in the depository's book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Securities issued in global form will be registered in the name of the depository or its nominee. Consequently, for securities issued in global form, we will recognize only the depository as the holder of the securities, and we will make all payments on the securities to the depository. The depository passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depository and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a book-entry security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depository's book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

Street Name Holders

We may terminate a global security or issue securities in non-global form. In these cases, investors may choose to hold their securities in their own names or in "street name." Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee and of any third parties employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with depository participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of the indenture or for other purposes. In such an event, we would seek approval only from the holders, and not the indirect holders, of the securities. Whether and how the holders contact the indirect holders is up to the holders.

Special Considerations for Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;

- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book entry form, how the depositary's rules and procedures will affect these matters.

Global Securities

A global security is a security held by a depositary that represents one or any other number of individual securities. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depositary. Unless we specify otherwise in the applicable prospectus supplement, DTC will be the depositary for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depositary, its nominee or a successor depositary, unless special termination situations arise. We describe those situations below under “—Special Situations When a Global Security Will Be Terminated.” As a result of these arrangements, the depositary, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depositary or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

As an indirect holder, an investor's rights relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only in the form of a global security, an investor should be aware of the following:

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non global certificates for his or her interest in the securities, except in the special situations we describe below;
- an investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe under “—Legal Holders” above;
- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book entry form;
- an investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- the depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in a global security. We and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its

records of ownership interests in a global security. We and the trustee also do not supervise the depositary in any way;

- the depositary may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book entry system use immediately available funds, and your broker or bank may require you to do so as well; and
- financial institutions that participate in the depositary's book entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities. There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When a Global Security Will Be Terminated

In a few special situations described below, the global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

The global security will terminate when the following special situations occur:

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or
- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods or through underwriters or dealers, through agents and/or directly to one or more purchasers. The securities may be distributed from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Each time that we sell securities covered by this prospectus, we will provide a prospectus supplement or supplements that will describe the method of distribution and set forth the terms and conditions of the offering of such securities, including the offering price of the securities and the proceeds to us, if applicable.

Offers to purchase the securities being offered by this prospectus may be solicited directly. Agents may also be designated to solicit offers to purchase the securities from time to time. Any agent involved in the offer or sale of our securities will be identified in a prospectus supplement.

If a dealer is utilized in the sale of the securities being offered by this prospectus, the securities will be sold to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If an underwriter is utilized in the sale of the securities being offered by this prospectus, an underwriting agreement will be executed with the underwriter at the time of sale and the name of any underwriter will be provided in the prospectus supplement that the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for which they may act as agent. Unless otherwise indicated in a prospectus supplement, an agent will be acting on a best efforts basis and a dealer will purchase securities as a principal, and may then resell the securities at varying prices to be determined by the dealer.

Any compensation paid to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers will be provided in the applicable prospectus supplement. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof and to reimburse those persons for certain expenses.

The securities may or may not be listed on a national securities exchange. To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than were sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

If indicated in the applicable prospectus supplement, underwriters or other persons acting as agents may be authorized to solicit offers by institutions or other suitable purchasers to purchase the securities at the public offering price set forth in the prospectus supplement, pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in the prospectus supplement. These purchasers may include, among others, commercial and savings banks, insurance companies, pension funds, investment companies and educational and charitable institutions. Delayed delivery contracts will be subject to the condition that the purchase of the securities covered by the delayed delivery contracts will not at the time of delivery be prohibited under the laws of any jurisdiction in the United States to which the purchaser is subject. The underwriters and agents will not have any responsibility with respect to the validity or performance of these contracts.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

General Information

Underwriters, dealers and agents that participate in the distribution of our securities may be underwriters as defined in the Securities Act, and any discounts or commissions they receive and any profit they make on the resale of the offered securities may be treated as underwriting discounts and commissions under the Securities Act. Any underwriters or agents will be identified and their compensation described in a prospectus supplement. We may indemnify agents, underwriters, and dealers against certain civil liabilities, including liabilities under the Securities Act, or make contributions to payments they may be required to make relating to those liabilities. Our agents, underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

Each series of securities offered by this prospectus may be a new issue of securities with no established trading market. Any underwriters to whom securities offered by this prospectus are sold by us for public offering and sale may make a market in the securities offered by this prospectus, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. No assurance can be given as to the liquidity of the trading market for any securities offered by this prospectus.

Representatives of the underwriters through whom our securities are sold for public offering and sale may engage in over-allotment, stabilizing transactions, syndicate short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Stabilizing transactions permit bids to purchase the offered securities so long as the stabilizing bids do not exceed a specified maximum.

Syndicate covering transactions involve purchases of the offered securities in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the representative of the underwriters to reclaim a selling concession from a syndicate member when the offered

securities originally sold by such syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Such stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the offered securities to be higher than it would otherwise be in the absence of such transactions. These transactions may be effected on a national securities exchange and, if commenced, may be discontinued at any time.

Underwriters, dealers and agents may be customers of, engage in transactions with or perform services for, us and our subsidiaries in the ordinary course of business.

We will bear all costs, expenses and fees in connection with the registration of the securities as well as the expense of all commissions and discounts, if any, attributable to the sales of any of our securities by us.

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 CERTAIN 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.

- [Our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 20, 2023](#);
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023, June 30, 2023 and September 30, 2023, filed with the SEC on [May 8, 2023](#), [August 10, 2023](#) and [November 7, 2023](#), respectively;
- the information specifically incorporated by reference into our [Annual Report on Form 10-K for the year ended December 31, 2022](#) from our Definitive Proxy Statement on Schedule 14A, filed with the SEC on [April 28, 2023](#);
- our Current Reports on Form 8-K filed with the SEC on [January 9, 2023](#), [January 30, 2023](#), [February 3, 2023](#), [March 16, 2023](#), [March 22, 2023](#), [April 3, 2023](#), [June 8, 2023](#), [June 16, 2023](#), [June 28, 2023](#), [July 17, 2023](#), [July 24, 2023](#), [July 27, 2023](#), [September 6, 2023](#), [September 25, 2023](#), [December 12, 2023](#), [December 12, 2023](#), [December 14, 2023](#) and [December 20, 2023](#) (provided that any portions of such reports that are deemed furnished and not filed pursuant to instructions to Form 8-K shall not be incorporated by reference into this prospectus); and
- the information included in [Exhibit 4.5](#) to our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 20, 2023, including the description of our common stock set forth 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, our Chief Business Officer, 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.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. You should not assume that information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by DLA Piper LLP (US), Short Hills, New Jersey. Any underwriters will be advised about other issues relating to any offering by their own legal counsel.

EXPERTS

The financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2022 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company's requirement for additional financing to fund future 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.



\$200,000,000

**Common Stock, Preferred Stock,
Debt Securities, Warrants and Units**

PROSPECTUS

, 2023

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth an estimate of the costs and expenses payable by us in connection with the offering described in this registration statement. All of the amounts shown are estimates except the Securities and Exchange Commission registration fee:

Securities and Exchange Commission Registration Fee	\$29,520
Printing	*
Accounting Fees and Expenses	*
Transfer Agent and Registrar Fees	*
Legal Fees and Expenses	*
Miscellaneous	*
Total	<u>\$</u> *

* Estimated expenses not presently known

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 provide, 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.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended, or the Securities Act, against certain liabilities.

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 percent change in the

maximum aggregate offering price set forth in the “Calculation of Registration Fee” table 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 (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the 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 of 1933, 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 of 1933 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 of 1933 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 the 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 that 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 the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer and sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) That, for purposes of determining any liability under the Securities Act:

(i) The information omitted from the form of prospectus filed as part of the Registration Statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the Registration Statement as of the time it was declared effective; and

(ii) Each post-effective amendment that contains a form of prospectus 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.

(7) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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.

(8) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission 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 amendment to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Morrisville, State of North Carolina on December 28, 2023.

LIQUIDIA CORPORATION

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

Roger A. Jeffs, Ph.D.

Chief Executive Officer

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

SIGNATURE	TITLE	DATE
<u>/s/ Roger A. Jeffs, Ph.D.</u> Roger A. Jeffs, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	December 28, 2023
<u>/s/ Michael Kaseta</u> Michael Kaseta	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 28, 2023
<u>*</u> Dr. Stephen Bloch	Chairman of the Board of Directors	December 28, 2023
<u>*</u> Damian deGoa	Director	December 28, 2023
<u>*</u> Dr. Joanna Horobin	Director	December 28, 2023
<u>*</u> David Johnson	Director	December 28, 2023
<u>*</u> Arthur Kirsch	Director	December 28, 2023
<u>*</u> Paul B. Manning	Director	December 28, 2023

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>*</u> Katie Rielly-Gauvin	Director	December 28, 2023
<u>*</u> Raman Singh	Director	December 28, 2023

*By: /s/ Michael Kaseta

Name: Michael Kaseta
Title: Attorney-in-fact

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	Bylaws of Liquidia Corporation (incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
4.1	Form of Specimen Common Stock Certificate of Liquidia Corporation (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-4, filed with the SEC on August 5, 2020).
4.2	Form of Warrant to Purchase Shares of Preferred Stock, issued by Liquidia Technologies, Inc. in January 2017 and February 2017 (incorporated herein by reference to Exhibit 4.4 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018).
4.3	Seventh Amended and Restated Investors' Rights Agreement, dated as of February 2, 2018, by and among the Company, the Investors party thereto and the Common Holders party thereto (incorporated herein by reference to Exhibit 4.5 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018).
4.4	Warrant to Purchase Stock, issued February 26, 2021, by Liquidia Corporation to Silicon Valley Bank (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 3, 2021).
4.5	Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and Silicon Valley Bank (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022).
4.6	Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and SVB Innovation Credit Fund VIII, L.P. (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022).
4.7	Warrant to Purchase Stock, dated as of January 7, 2022, by and between Liquidia Corporation and Innovation Credit Fund VIII-A L.P. (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed with the SEC on January 11, 2022).
4.8	Form of Senior Indenture (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-3 (File No. 333-276244), filed on December 22, 2023).
4.9	Form of Subordinated Indenture (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-3 (File No. 333-276244), filed on December 22, 2023).
4.10	Certificate of Designations of Preferred Stock**
4.11	Form of Preferred Stock Certificate**
4.12	Form of Warrant**
4.13	Form of Unit Certificate**
5.1	Opinion of DLA Piper LLP (US) (incorporated by reference to Exhibit 5.1 to the Company's Registration Statement on Form S-3 (File No. 333-276244), filed on December 22, 2023).
23.1	Consent of PricewaterhouseCoopers LLP, Independent Auditors (incorporated by reference to Exhibit 23.1 to the Company's Registration Statement on Form S-3 (File No. 333-276244), filed on December 22, 2023).
23.2	Consent of DLA Piper LLP (US) (incorporated by reference to Exhibit 23.2 to the Company's Registration Statement on Form S-3 (File No. 333-276244), filed on December 22, 2023).
24.1	Power of Attorney (incorporated by reference to Exhibit 24.1 to the Company's Registration Statement on Form S-3 (File No. 333-276244), filed on December 22, 2023).
25.1	Statement of Eligibility on Form T-1 under the Trust Indenture Act of 1939, as amended, of the Trustee under the Senior Indenture***

Exhibit No.	Description
25.2	Statement of Eligibility on Form T-1 under the Trust Indenture Act of 1939, as amended, of the Trustee under the Subordinated Indenture***
107	Filing Fee Table (incorporated by reference to Exhibit 107 to the Company's Registration Statement on Form S-3 (File No. 333-276244), filed on December 22, 2023).

* Filed herewith.

** 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.

*** To be filed by amendment pursuant to Section 305(b)(2) of the Trust Indenture Act of 1939.