Filed Pursuant to Rule 424(b)(3)
File No. 333-259265

PROSPECTUS

8,626,037 Shares of Common Stock

This prospectus relates to the resale or other disposition by the selling stockholders identified in this prospectus (the "Selling Stockholders"), from time to time, of up to 8,626,037 shares of our common stock, par value $0.001 per share (the “Common Stock”).

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

The selling stockholders or their pledgees, assignees, permitted transferees or other successors-in-interest may offer and sell or otherwise dispose of the shares of common stock described in this prospectus from time to time through public or private transactions at fixed prices, at prevailing market prices, at prices related to prevailing market prices, at varying prices determined at time of sale, or at privately negotiated prices. The selling stockholders will bear all commissions and discounts, if any, attributable to the sales of shares. We will bear all costs, expenses and fees in connection with the registration of the shares. See “Plan of Distribution” beginning on page 52 for more information about how the selling stockholders may sell or dispose of their shares of Common Stock.

Our common stock is traded on the Nasdaq Capital Market under the symbol “LQDA.” On September 21, 2021, the last reported sale of our Common Stock was $2.60 per share.

Investing in our securities involves risk. See “Risk Factors” beginning on page 13 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 September 22, 2021

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You should rely only on the information provided in this prospectus (as supplemented and amended) as well as the information incorporated by reference. Neither we nor the selling stockholders have authorized anyone to provide you with different information. Neither we nor the selling stockholders are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus (as supplemented and amended) or any documents incorporated by reference is accurate as of any date other than the date of the applicable document

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the U.S. Securities and Exchange Commission, referred to herein as the SEC, using a "shelf" registration process. Under a shelf registration process, certain selling stockholders may from time to time sell the shares of common stock described in this prospectus in one or more offerings.

This prospectus provides you with a general description of the securities we may offer. Each time 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, RareGen, the RareGen logo, and PRINT, or Particle Replication In Non-wetting Templates, which are protected under applicable intellectual property laws and are the property of our company. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

PROSPECTUS SUMMARY

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

About Liquidia Corporation

Overview

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

We generate revenue pursuant to a Promotion Agreement between our subsidiary, Liquidia PAH, and Sandoz Inc. ("Sandoz"), sharing profit derived from the sale of the first-to-file fully substitutable generic treprostinil injection ("Treprostinil Injection") in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. We employ a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of pulmonary arterial hypertension (PAH), as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient launch of our product candidate, LIQ861, upon approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.

We conduct research, development and manufacturing of novel products by applying our 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 implants, among others.

We are currently developing one product candidate for which we hold worldwide commercial rights: LIQ861 to treat PAH. LIQ861 is an inhaled dry powder formulation of treprostinil designed to improve the therapeutic profile of treprostinil by enhancing deep lung delivery and achieving higher dose levels than current inhaled therapies while using a convenient, easy-to-use dry-powder inhaler (DPI). We submitted the New Drug Application (NDA) for LIQ861 in January 2020. In November 2020, the Company received a Complete Response Letter ("CRL") issued by the Food and Drug Administration ("FDA") with respect to the NDA for LIQ861. In May 2021, the Company resubmitted the NDA for LIQ861 in response to the CRL. In June of 2021, the FDA accepted the Company's resubmitted NDA for LIQ861 for review and established a PDUFA goal date of November 7, 2021. In July 2021, the Company received notices from the FDA that, due to restrictions on travel related to COVID-19, the FDA may be unable to conduct the pre-approval inspections ("PAIs") for LIQ861 prior to the PDUFA goal date. Subsequent to those notices, the FDA scheduled the PAI for the Company's Morrisville, North Carolina facility, which was completed in August 2021. In addition to the completed inspection of our Morrisville site, the FDA has notified us that a PAI will also be required for the third-party provider of encapsulation and packaging services for LIQ861. At this time, we have not been notified of when this additional PAI may be completed.

Our Products and Candidates for PH

PH is divided into five groups based on the criteria of the World Health Organization (WHO) as defined at the 5th World Symposium on Pulmonary Hypertension in Nice, France. WHO Group I is comprised of individuals with PAH.

PAH is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death, with an estimated prevalence in the United States of approximately 30,000 patients. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression and improve quality of life. Drugs targeting the prostacyclin pathway are central to PAH therapy. Prostacyclin analogs, like treprostinil, have been developed for continuous infusion, either intravenously or subcutaneously, inhalation using a nebulizer and oral administration in the form of tablets. The maximal efficacy benefit of any one drug in the prostacyclin pathway is partially limited by its specific safety profile.

Delivering prostacyclin analogs locally to the lungs by inhalation has been effective and causes fewer systemic side effects. Inhalation of prostacyclin analogs supplements the endogenous production of prostacyclin where it is normally synthesized, near the targeted pulmonary arteries. As a result, inhalation of prostacyclin analogs helps avoid side effects related to off-target tissues and takes advantage of binding key prostacyclin receptors that are preferentially expressed in the lung. The only inhaled prostacyclin analogs approved by the FDA are Tyvaso® (treprostinil) and Ventavis® (iloprost), which both require nebulizers.

Parenteral delivery of prostacyclin analogs is considered the most effective treatment for PAH; however, the inconvenience of external pumps and side-effect profiles have limited their use to the most severely ill patients. Remodulin® (treprostinil) can be administered subcutaneously or intravenously. United Therapeutics reported that its class of treprostinil-based products generated net revenue of $1.48 billion in 2020, of which Tyvaso® contributed $483.3 million from predominately U.S. net sales and Remodulin® contributed $516.7 million with $64.3 million in net revenue coming from non-U.S. sales.

Prior to 2021, prostacyclin based therapies had only been approved for WHO Group I patients; however, prostacyclin analogs may have utility in the treatment of PH in other categories. In April 2021, United Therapeutics announced that the FDA approved Tyvaso® for a sub-population of patients in WHO Group III with Interstitial Lung Disease (ILD), which they estimate to be 30,000 patients. If Tyvaso® is approved for any additional indications, the market for inhaled treprostinil products may increase with an increased addressable patient population.

LIQ861, Treprostinil Powder for Inhalation to Treat PAH

Our lead product candidate, LIQ861, is an inhaled dry powder formulation of treprostinil designed using our PRINT technology to enhance deep lung delivery using a convenient DPI, the RS00 Model 8 DPI. This device and its variants have been used in at least eight marketed products globally since 2001, including Novartis's Foradil Aerolizer® for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

We believe LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of inhaled treprostinil in treating PAH by safely delivering higher doses into the lungs. If approved, we believe LIQ861 will have the potential to increase the number of patients using the inhaled route of administration for PAH by providing the benefits of inhaled prostacyclin therapy earlier in a patient's disease progression as well as delaying the burden of starting continuously infused agents.

We are developing LIQ861 under the 505(b)(2) regulatory pathway using the nebulized form of treprostinil, Tyvaso®, as the reference listed drug. This regulatory pathway allows us to rely in part on the FDA's previous findings of efficacy and safety of Tyvaso® and the active ingredient treprostinil.

We submitted an NDA to the FDA for LIQ861 in January 2020, which was accepted for review in April 2020 and provided a Prescription Drug User Fee Act (PDUFA) goal date of November 24, 2020. On November 25, 2020, we announced the FDA issued a CRL for our NDA for LIQ861. The CRL identified the need for additional information and clarification on chemistry, manufacturing and controls (CMC) data pertaining to the drug product and device biocompatibility. The FDA also reconfirmed the need to conduct on-site PAIs of two U.S. manufacturing facilities before our NDA can be approved. The FDA noted it had been unable to conduct these inspections during the initial review cycle due to COVID-19 related travel restrictions. The CRL did not cite the need to conduct further clinical studies, nor did the FDA indicate that additional studies related to toxicology or clinical pharmacology would be necessary. In May 2021, the Company resubmitted the NDA for LIQ861 in response to the CRL. In June of 2021, the FDA accepted the Company's resubmitted NDA for LIQ861 for review and established a PDUFA goal date of November 7, 2021. In July 2021, the Company received notices from the FDA that, due to restrictions on travel related to COVID-19, the FDA may be unable to conduct the PAIs for LIQ861 prior to the PDUFA goal date. Subsequent to those notices, the FDA scheduled the PAI for the Company's Morrisville, North Carolina facility, which was completed in August 2021. In addition to the completed inspection of our Morrisville site, the FDA has notified us that a PAI will also be required for the third-party provider of encapsulation and packaging services for LIQ861. At this time, we have not been notified of when this additional PAI may be completed.

FDA approval and launch of LIQ861 are directly impacted by resolution of the CRL and the pending Hatch-Waxman litigation commenced by United Therapeutics on June 4, 2020. As a result, the FDA may not issue a final approval for the LIQ861 NDA until the expiration of a 30-month regulatory stay in October 2022 or earlier judgment unfavorable to United Therapeutics by the court. When the FDA is precluded from approving a 505(b)(2) application due to a 30-month stay, it is generally possible that the FDA could issue "tentative approval" of an NDA if all requirements for approval have been met. The FDA's tentative approval can be subject to change based on new information that may come to FDA's attention between such time as the tentative and final approval. A new drug product may not be marketed until the date of final approval.

Our NDA submission was based in part upon the results of our pivotal, open-label Phase 3 clinical trial, Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, for LIQ861 ("INSPIRE"). The primary objective of the INSPIRE study was to evaluate the long-term safety of LIQ861 with a primary endpoint to assess safety and tolerability through Month 2. The study enrolled patients who have either (a) been under stable treatment with Tyvaso® (nebulizer-delivered treprostinil) for at least three months and transitioned to LIQ861 under the protocol ("Transition patients"), or (b) patients who had been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and then had their treatment regimen supplemented with LIQ861 under the protocol ("Add-On patients"). Transition patients started at a dose comparable to their prior nebulized treprostinil dose and were titrated to higher doses as warranted by their clinical disease. Add-On patients started on a dose of 26.5 mcg of LIQ861, with most (>80%) titrating to a 79.5 mcg dose or higher within the first two months of treatment. Of the 121 patients enrolled in the study, 55 were Transition patients and 66 were Add-On patients.

LIQ861 was observed to be well-tolerated and treatment-emergent adverse events (TEAEs) were mostly mild to moderate in nature at Month 2 up to doses of 159 mcg of LIQ861, the highest dose studied at Month 2. Of the 121 PAH patients, 113, or 93%, completed their two-month visit. The most common reported TEAEs (reported in ≥ four percent) were cough (42%), headache (26%), throat irritation (16%), dizziness (11%), diarrhea (9%), chest discomfort (8%), nausea (7%), dyspnea (5%), flushing (5%) and oropharyngeal pain (4%). Durability of therapy with LIQ861 appeared to be favorable, with 96% of Transition patients and 91% of Add-On patients remaining on study drug at the Month 2 timepoint.

Our NDA submission also include results from pharmacokinetic (PK) studies in healthy volunteers indicating that the 79.5 mcg dose of LIQ861 provides comparable PK with nine breaths of Tyvaso, the maximum recommended label dose of Tyvaso.

Clinical results from LIQ861 have been presented at various international scientific meetings such as the American Thoracic Society (ATS), International Society of Heart Lung Transplantation (ISHLT), Pulmonary Vascular Research Institute (PVRI) and American College of Chest Physicians (ACCP) in 2019 and 2020.

We continued to treat patients who chose to remain on LIQ861 beyond the Month 2 timepoint of the primary endpoint. At the completion of the INSPIRE study, the patient with the longest duration of treatment had been on LIQ861 therapy for 18 months and the highest dosing reached in the INSPIRE study was 212 mcg of treprostinil given four times per day.

To provide for continuity of treatment, patients from INSPIRE were provided the opportunity to continue receiving treatment in an extension study, which is currently ongoing (LTI-302). Currently, more than 75 patients have now received therapy with LIQ861 for more than two years. We have also observed that more than 75 percent of patients who have been enrolled in the INSPIRE and extension studies have received LIQ861 doses of 100 mcg or more.

In addition to the studies submitted in the NDA for FDA review, we conducted a clinical study, known as LTI-201, at certain investigational sites in France and Germany to characterize the hemodynamic dose-response relationship to LIQ861. In December 2020, we decided to terminate the study earlier than planned due to challenges related to the COVID-19 pandemic. French sites were closed in the second quarter of 2020 and will not re-open for enrollment. German sites stopped enrolling patients in the second quarter of 2020, but remained open until the second quarter of 2021 in order to transition patients from LIQ861 to currently approved therapies. We are considering conducting other clinical trials to generate additional data on LIQ861, including a clinical trial in pediatric patients.

Treprostinil Injection, a Generic Version of Remodulin®

Remodulin® is treprostinil administered through continuous intravenous and subcutaneous infusion, as approved by the FDA in 2002 and 2004, and marketed by United Therapeutics. Patients must use external pumps manufactured by third parties to deliver Remodulin®. Smiths Medical ASD, Inc. ("Smiths Medical") manufactures the pumps used by most patients in the United States to administer Remodulin®, including the CADD-MS® 3 (MS-3) pump used to deliver subcutaneous Remodulin®, and the CADD-Legacy® pump to deliver intravenous Remodulin®. It is estimated that 3,000 patients are treated annually with branded Remodulin® which generated approximately $452 million in U.S. revenue in 2020 (and approximately $516.7 million in total, including approximately $64.3 million of non-U.S. sales), split between the two routes of administration.

There are serious side effects associated with Remodulin®. For example, when infused subcutaneously, Remodulin® causes varying degrees of infusion site pain and reaction, such as redness and swelling, in most patients. Patients who cannot tolerate the infusion site pain related to the use of subcutaneous Remodulin® may instead use intravenous Remodulin®. Intravenous Remodulin® is delivered continuously through a surgically implanted central venous catheter, similar to Flolan®, Veletri® and generic epoprostenol. Patients who receive therapy through implanted venous catheters have a risk of developing blood stream infections and a serious systemic infection known as sepsis. Other common side effects associated with both subcutaneous and intravenous Remodulin® include headache, diarrhea, nausea, jaw pain, vasodilation and edema.

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

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

Sandoz's Treprostinil Injection, as well as competing generics approved by FDA from Teva Pharmaceuticals Industries Ltd ("Teva"), Par Pharmaceutical, Inc ("Par Pharmaceutical"), Dr. Reddy's Laboratories Inc. ("Dr. Reddy's"), and Alembic Pharmaceuticals, Ltd ("Alembic"), were initially used for intravenous administration only. In April 2019, Liquidia PAH and Sandoz alleged in outstanding litigation that Smiths Medical and United Therapeutics blocked access to cartridges necessary for administering the generic treprostinil through the CADD MS-3 pump manufactured by Smiths Medical for use in the administration of subcutaneous infusions of generic treprostinil. On November 6, 2020, Sandoz, Liquidia PAH and Smiths Medical entered into a binding settlement term sheet in order to resolve the outstanding litigation solely with respect to disputes between Smiths Medical, Liquidia PAH and Sandoz. On April 12, 2021, Liquidia PAH and Sandoz entered into a Long Form Settlement Agreement (the "Settlement Agreement") with Smiths Medical to further detail the terms of the settlement among such parties as reflected in the term sheet. Pursuant to the term sheet and Settlement Agreement, Smiths Medical has paid $4.25 million to Sandoz and former RareGen members. In addition, pursuant to the term sheet and Settlement Agreement, Smiths Medical disclosed and made available to Sandoz and Liquidia PAH certain specifications and other information related to the cartridge that Smiths Medical developed and manufactures for use with the CADD-MS 3 infusion pump.

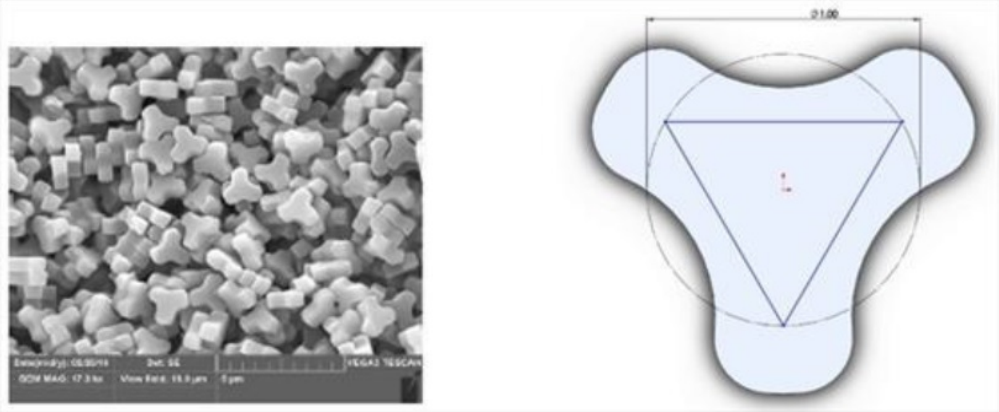
In May 2021, Liquidia PAH's manufacturing partner, Chengdu Shifeng Medical Technologies LTD ("Chengdu") began selling the RG 3ml Medication Cartridge, which may be used with the CADD-MS 3 infusion pump to supply medications to PAH patients, at which time Sandoz's Treprostinil Injection became available for use through both intravenous and subcutaneous administration.

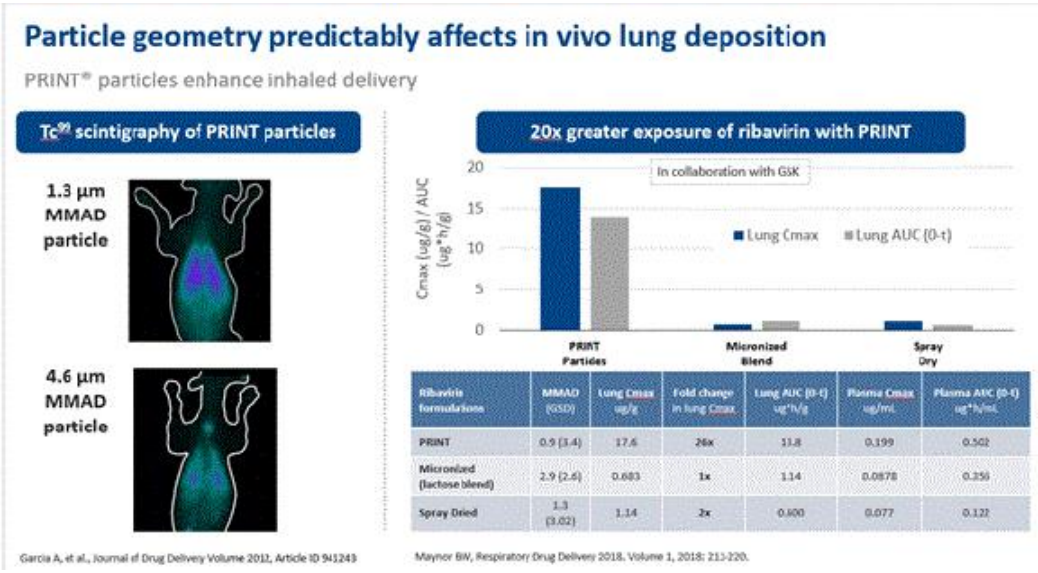
Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Sandoz's purpose is to pioneer novel approaches to help people around the world access high-quality medicine. Sandoz's broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2019 sales of $9.7 billion. Sandoz's headquarters are in Holzkirchen, in Germany's Greater Munich area.

Our PRINT Technology

LIQ861 is being developed using our proprietary PRINT particle engineering technology, which allows us to engineer and manufacture highly uniform drug particles with precise control over the size, three-dimensional geometric shape and chemical composition of the particles. By controlling these physical and chemical parameters of particles, PRINT enables us to engineer desirable pharmacological benefits into product candidates, including prolonged duration of drug release, increased drug loading, more convenient routes of administration, the ability to create novel combination products, enhanced storage and stability and the potential to reduce adverse side effects. Our manufacturing equipment and materials used in the production of our drug particles are proprietary and protected by our patent portfolio and trade secret know-how.

An example of the precise particle engineering enabled by PRINT technology is demonstrated in LIQ861. Each particle is designed to enhance delivery and deep-lung penetration with a precise size and highly uniform shape inspired by a naturally occurring pollen. LIQ861 PRINT particles have a one micrometer trefoil-shape measured by an inscribed one micrometer circle as shown in the figure below. In vitro studies suggest that the uniformity of size and shape allow our inhaled particles to target delivery into the lungs with less deposition in the upper airways. The figures below depict LIQ861, with the figure on the left showing size and shape consistency among particles and the figure on the right showing their trefoil shape:





Ribavirin formulations	MMAD (GSD)	Lung Cmax ug/g	Fold change in lung Cmax	Lung AUC (0-t) ug*h/g	Plasma Cmax ug/mL	Plasma AUC (0-t) ug*h/mL
PRINT	0.9 (1.4)	17.6	26x	11.8	0.199	0.502
Micronized (lactose blend)	2.9 (2.6)	0.683	1x	1.14	0.0878	0.259
Spray Dried	1.3 (3.02)	1.14	2x	0.600	0.077	0.122

Development, Regulatory and Commercial Strategy

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

We intend to focus our commercial efforts initially on the U.S. market in the treatment of PAH. We have started to build a commercial presence with the acquisition and merger of Liquidia PAH (formerly RareGen) in November 2020. We employ a small, targeted sales force for Treprostinil Injection calling on physicians involved in the treatment of PAH in the US, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient launch of LIQ861 if and when we obtain approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients. As we have success increasing the utilization of Treprostinil Injection and advancing LIQ861 to FDA approval, we will increase our efforts to pursue the highly concentrated target market of PAH centers of excellence and high prescribers of PAH therapies. Our physician call points within these sites of care will include cardiologists, pulmonologists and their supporting staff. We believe that we can effectively commercialize LIQ861, if approved, with an expanded specialty field team. We also expect to further develop our internal resources and functional areas to support other types of communication. For example, we may utilize medical science liaisons and reimbursement specialists to support the proper conveying of scientific and medical information, and healthcare economic information regarding, and utilization of, LIQ861.

Manufacturing and Supply

We operate from a 45,000 square foot facility in Morrisville, North Carolina in which we design, formulate and manufacture engineered drug particles using PRINT particle fabrication lines as well as supportive activity including research and development, analytical development, quality control and production of mold templates that enable our production processes. Our three operational PRINT particle fabrication lines are located within class ISO7 clean rooms that operate under applicable ISO and current good manufacturing practices (cGMP) air quality and environmental requirements. Our current operational fabrication lines are scaled and capable of producing the necessary materials to support our clinical trials and, if approved, commercial demand for our products. We utilize contract manufacturers to finish production and package our drug product for clinical and commercial use.

We depend on third-party suppliers for clinical supplies, including active pharmaceutical ingredients which are used in our product candidates. For example, we currently rely on a sole supplier, LGM Pharma, LLC, for treprostinil, the active pharmaceutical ingredient of LIQ861, and we currently rely on a sole supplier, Plastiape S.p.A ("Plastiape"), for RS00 Model 8 DPI, the DPI used to administer LIQ861. We also rely on a sole supplier, Xcelience LLC (now a Lonza Group Ltd company), for encapsulation and packaging services. If and when we receive marketing approval for our product candidates, we may, from time to time, rely on third-party CMOs to manufacture, package and distribute some or all of our approved drug products on a commercial scale.

Supply of Treprostinil Injection is managed directly by our partner Sandoz, who retains the ANDA, manages inventory and records gross revenue on product sales. Sandoz is either the manufacturer or contracted party for the entire supply chain. We collaborate with Sandoz on a regular basis to plan appropriate inventory production and management based on the demand for Treprostinil Injection and observations in the field. Additionally, we engaged Carelife USA Inc. to develop a medication cartridge for use with CADD-MS 3 infusion pumps and enable subcutaneous administration of Treprostinil Injection. In May 2021, Carelife USA Inc.'s affiliate, Chengdu, began selling the RG 3ml Medication Cartridge, which may be used with the CADD-MS 3 infusion pump to supply medications to PAH patients.

Summary of Private Placement

Private Placement and Common Stock Purchase Agreement

On April 12, 2021, we entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with a fund and account managed by Caligan Partners LP ("Caligan") and certain other accredited investors, including Roger Jeffs, a director of Liquidia, and PD Joint Holdings, LLC Series 2016-A, of which Paul Manning, a director of Liquidia, is a manager (the "Purchasers"), for the sale by the Company in a private placement (the "Private Placement") of an aggregate of 8,626,037 shares (the "Private Placement Shares") of the Company's common stock, par value $0.001 per share ("Common Stock"), at a purchase price of $2.52 per Private Placement Share.

The aggregate gross proceeds for the sale of the Private Placement Shares were approximately $21.7 million, before deducting offering expenses. The closing of the Private Placement occurred on April 13, 2021.

We intend to use the net proceeds from the Private Placement to strengthen our commercial capability for the introduction of LIQ861 and the subcutaneous administration of Treprostinil Injection, for growth initiatives, and for general corporate purposes.

Registration Rights Agreement

In connection with the Private Placement, on April 12, 2021, we entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers. Pursuant to the Registration Rights Agreement, the Company agreed to file a shelf registration statement (the "Registration Statement") with the SEC within 180 days following the date of entry into the Registration Rights Agreement (the "Filing Deadline") to register the Private Placement Shares for resale and use its best efforts to cause the Registration Statement to be declared effective by the SEC or otherwise become effective under the Securities Act as soon as practicable after the filing thereof, but in no event later than that date that is the earlier of (i) 60 days after the Filing Deadline provided, that the Effectiveness Deadline shall be extended to 90 days after the Filing Deadline if such Registration Statement is reviewed by the SEC and (ii) five (5) business days after the date the Company receives written notification from the SEC that the Registration Statement will not be reviewed (the "Effectiveness Deadline"). The Company also agreed, among other things, to indemnify the selling holders under the registration statements from certain liabilities and to pay all fees and expenses incident to the Company's performance of or compliance with the Registration Rights Agreement.

Legal Proceedings

LIQ861-Related Litigation

On June 4, 2020, United Therapeutics Corporation, a Delaware corporation ("United Therapeutics"), filed a complaint for patent infringement against us in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-UNA) (the "Hatch-Waxman Litigation") asserting infringement by us of U.S. Patent Nos. 9,604,901, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®" (the "'901 Patent") and 9,593,066, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®" (the "'066 Patent") relating to United Therapeutics' Tyvaso, a nebulized treprostinil solution for the treatment of pulmonary arterial hypertension (PAH). On July 16, 2020, we filed an answer to United Therapeutics' complaint and also included defenses and counterclaims of invalidity, non-infringement, and Orange Book de-listing of the '901 Patent and '066 Patent. United Therapeutics seeks a judgment that the asserted patents are infringed and an injunction of FDA final approval and subsequent commercial launch of LIQ861 product until after the latest to expire asserted patent. United Therapeutics' complaint is in response to our New Drug Application (the "LIQ861 NDA"), filed with the U.S. Food and Drug Administration (FDA) requesting approval to market LIQ861, a dry powder inhalation of treprostinil for the treatment of PAH. The LIQ861 NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving the LIQ861 NDA for up to 30 months, absent an earlier judgment unfavorable to United Therapeutics by the court. Although we believe our LIQ861 dry powder inhaler for the treatment of PAH is highly differentiated from Tyvaso, since we are seeking approval of the LIQ861 NDA under the 505(b)(2) regulatory pathway, the LIQ861 NDA is subject to the provisions of the Hatch-Waxman Act.

On July 21, 2020, the U.S. Patent and Trademark Office (the "USPTO"), issued U.S. Patent No. 10,716,793 (the "'793 Patent") entitled "Treprostinil Administration by Inhalation", to United Therapeutics. On July 22, 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the '793 Patent by the practice of LIQ861. The infringement allegation of the '793 Patent is separate from the 30-month regulatory stay on final approval of the NDA for LIQ861, which is only associated with the infringement allegations of the '901 Patent and the '066 Patent. United Therapeutics' motion to dismiss the Company's invalidity defenses and counterclaims concerning the '793 Patent was denied by the U.S. District Court for the District of Delaware on November 3, 2020.

On July 30, 2020, Judge Andrews, presiding over the Hatch-Waxman Litigation, conducted a scheduling conference and set a claim construction hearing, which was held in June 2021, and a date for trial, which is to begin in March 2022. Following the claim construction hearing, the Court issued an order that two of the terms under consideration would be given their plain and ordinary meaning and ruling in our favor regarding a third term. Two of the terms that were under consideration at the claim construction hearing remain under consideration by the Court.

On June 4, 2021, United Therapeutics filed a motion seeking leave to amend its complaint in the Hatch-Waxman Litigation. United Therapeutics alleges that we and a former United Therapeutics employee who later joined us as an employee conspired to misappropriate certain trade secrets of United Therapeutics. We disagree with United Therapeutics' allegations, deny any liability for misappropriation of any trade secrets and intend to vigorously defend against these new allegations.

On March 30, 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (the PTAB) of USPTO. One petition was for *inter partes* review of the '901 Patent and sought a determination that the claims in the '901 Patent are invalid, and a second petition was for *inter partes* review of the '066 Patent and sought a determination that the claims in the '066 Patent are invalid. Both the '901 Patent and '066 Patent are owned by United Therapeutics and both patents are related to U.S. Patent No. 8,497,393 which was granted to United Therapeutics and subsequently invalidated by the USPTO in an *inter partes* review instituted in 2016 by SteadyMed Ltd. On October 13, 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. On March 1, 2021, PTAB denied a request from United Therapeutics for a rehearing regarding PTAB's decision to institute an *inter partes* review of the '901 patent. The PTAB held a hearing with respect to the *inter partes* review of the '901 patent on June 23, 2021. A final written decision determining the validity of the challenged claims of the '901 Patent is expected within 12 months from institution.

On January 7, 2021, we filed a petition for *inter partes* review with the PTAB, relating to the '793 patent, which is also owned by United Therapeutics, 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. A final written decision determining the validity of the challenged claims of the '793 patent is expected within 12 months from institution.

Liquidia PAH-Related Litigation

On April 16, 2019, Sandoz and Liquidia PAH (then known as RareGen) filed a complaint against United Therapeutics and Smiths Medical in the District Court of New Jersey (Case No. No. 3:19-cv-10170) (the "UTC/Smiths Medical Litigation"), alleging that United Therapeutics and Smiths Medical violated the Sherman Antitrust Act of 1890, state law antitrust statutes and unfair competition statutes by engaging in anticompetitive acts regarding the drug treprostinil for the treatment of PAH. On March 20, 2020, Sandoz and Liquidia PAH filed a first amended complaint adding a claim that United Therapeutics breached a settlement agreement that was entered into in 2015, in which United Therapeutics agreed to not interfere with Sandoz's efforts to launch its generic treprostinil, by taking calculated steps to restrict and interfere with the launch of Sandoz's competing generic product. United Therapeutics developed treprostinil under the brand name Remodulin and Smiths Medical manufactured a pump and cartridges that are used to inject treprostinil into patients continuously throughout the day. Sandoz and Liquidia PAH allege that United Therapeutics and Smiths Medical entered into anticompetitive agreements whereby United Therapeutics and Smiths Medical placed restrictions on the cartridges such that they can only be used with United Therapeutics' branded Remodulin product and requiring Smiths Medical to enter into agreements with specialty pharmacies to sell the cartridges only for use with Remodulin.

On January 29, 2020, the court denied Liquidia PAH's and Sandoz's motion for a preliminary injunction and United Therapeutics' and Smiths Medicals' motion to dismiss. On November 6, 2020, Sandoz and Liquidia PAH entered into a binding term sheet (the "Term Sheet") with Smiths Medical in order to resolve the outstanding UTC/Smiths Medical Litigation solely with respect to disputes between Smiths Medical, Liquidia PAH and Sandoz. On April 12, 2021, Liquidia PAH and Sandoz entered into a Long Form Settlement Agreement (the "Settlement Agreement") with Smiths Medical to further detail the terms of the settlement among such parties as reflected in the Term Sheet. Pursuant to the Term Sheet and the Settlement Agreement, the former RareGen members and Sandoz received a payment of $4.25 million that was evenly split between the parties. In addition, pursuant to the Term Sheet and Settlement Agreement, Smiths Medical disclosed and made available to Sandoz and Liquidia PAH certain specifications and other information related to the cartridge that Smiths Medical developed and manufactures for use with the CADD-MS 3 Infusion pump (the "CADD-MS 3 Cartridge"). Pursuant to the Settlement Agreement, Smiths Medical also granted Liquidia PAH and Sandoz a non-exclusive, royalty-free license in the United States to Smiths Medical's patents and copyrights associated with the CADD-MS 3 Cartridge and certain other information for use of the CADD-MS 3 pump and the CADD-MS 3 Cartridges. Smiths also agreed in the Settlement Agreement to provide information and assistance in support of Liquidia PAH's efforts to receive FDA clearance for the RG Cartridge and to continue to service certain CADD-MS 3 pumps that are available for use with the Treprostinil Injection through January 1, 2025. Liquidia PAH and Sandoz agreed, among other things, to indemnify Smiths from certain liabilities related to the RG Cartridge.

Recent Developments

Effective as of August 26, 2021, we and our two wholly owned subsidiaries, Liquidia Technologies and Liquidia PAH, entered into a Loan Modification Agreement (the "Loan Modification Agreement") with Silicon Valley Bank, a California corporation, as lender ("SVB"). The Loan Modification Agreement amended the terms of the Loan and Security Agreement, dated February 26, 2021, with SVB (the "Loan Agreement") to modify the cumulative "Cash Burn" (as defined in the Loan Agreement) requirements for the periods ending September 30, 2021, December 31, 2021 and March 31, 2022 and for each calendar quarter thereafter to $56.1 million, $61.1 million and $65.6 million, respectively; provided, however, that the above amounts shall be increased by an amount equal to 75% of the aggregate net cash proceeds received by us from the sale of our equity securities on or after June 30, 2021 but on or prior to the last day of such calendar quarter; provided, further, that upon the Funding Date of the Term C Loan Advance (as such terms are defined in the Loan Agreement), the Cash Burn covenant shall no longer apply.

Corporate Information

Merger with RareGen, LLC (now Liquidia PAH, LLC)

On November 18, 2020 (the "Closing Date"), we completed the previously announced acquisition contemplated by the Agreement and Plan of Merger, dated as of June 29, 2020, as amended by a Limited Waiver and Modification to the Merger Agreement, dated as of August 3, 2020 (the "Merger Agreement") by and among Liquidia Corporation, Liquidia Technologies, RareGen (now Liquidia PAH), Gemini Merger Sub I, Inc. ("Liquidia Merger Sub"), Gemini Merger Sub II, LLC ("RareGen Merger Sub"), and PBM RG Holdings, LLC, as Members' Representative. Pursuant to the Merger Agreement, Liquidia Merger Sub, a then-wholly owned subsidiary of Liquidia Corporation, merged with and into Liquidia Technologies (the "Liquidia Technologies Merger") and RareGen Merger Sub, a then-wholly owned subsidiary of Liquidia Corporation, merged with and into RareGen (the "RareGen Merger" and, together with the Liquidia Technologies Merger, the "Merger Transaction"). Upon consummation of the Merger Transaction, the separate corporate existences of Liquidia Merger Sub and RareGen Merger Sub ceased and Liquidia Technologies and RareGen continued as wholly owned subsidiaries of Liquidia Corporation.

Following the Merger Transaction, Liquidia Corporation is the successor issuer to Liquidia Technologies pursuant to Rule 12g-3(a) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Pursuant to Rule 12g-3(a) under the Exchange Act, shares of Liquidia Corporation common stock, $0.001 par value per share ("Liquidia Corporation Common Stock"), are deemed to be registered under Section 12(b) of the Exchange Act, and Liquidia Corporation is subject to the informational requirements of the Exchange Act, and the rules and regulations promulgated thereunder. The Liquidia Corporation Common Stock is now listed on Nasdaq under the symbol "LQDA" following the removal from listing of Liquidia Technologies Common Stock by the Nasdaq Stock Market LLC.

On February 24, 2021, upon the filing of a Certificate of Amendment to its Certificate of Formation with the Secretary of State of Delaware, RareGen changed its name to Liquidia PAH.

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

THE OFFERING

Selling stockholders	Accredited investors who purchased shares of our common stock in a private placement in April 2021 pursuant to the Purchase Agreement.
Common stock offered by the selling stockholders	Up to 8,626,037 shares of Common Stock.
Use of proceeds	We will not receive any proceeds from the sale or other disposition of the shares of Common Stock offered hereby.
Risk factors	Investing in our Common Stock involves a high degree of risk. See “Risk Factors” beginning on page 13 of this prospectus, and any other risk factors described in the documents incorporated by reference herein, for a discussion of factors that you should carefully consider before deciding to invest in our common stock.
Nasdaq Capital Market symbol	LQDA

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

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 lead pipeline product candidate, LIQ861. 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 13 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 13 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. Our results may be affected by our ability to manage our financial resources, difficulties or delays in developing manufacturing processes for our product candidates, preclinical and toxicology testing and regulatory developments. Delays in clinical programs, whether caused by competitive developments, adverse events, patient enrollment rates, regulatory issues or other factors, could adversely affect our financial position and prospects. Prior clinical trial program designs and results are not necessarily indicative of future clinical trial designs or results. If our product candidates do not meet safety or efficacy endpoints in clinical evaluations, they will not receive regulatory approval and we will not be able to market them. The FDA may not approve an NDA for LIQ861, our data, our results, or permit us to proceed. We may not be able to enter into any strategic partnership agreements. Operating expenses and cash flow projections involve a high degree of uncertainty, including variances in future spending rates due to changes in corporate priorities, the timing and outcomes of clinical trials, competitive developments and the impact on expenditures and available capital from licensing and strategic collaboration opportunities. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our drug development or discovery research programs and delay or abandon potential commercialization efforts. We may not ever have any products that generate significant revenue. 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.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information included in and incorporated by reference into this prospectus such as the information contained under the heading "Special Note Regarding Forward-Looking Statements" before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. We may update these risk factors in our periodic and other filings with the SEC.

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

- We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company is dependent on our ability to raise additional capital to finance our future operations.
- We have a history of losses and our future profitability remains uncertain.
- We are primarily dependent on the success of our product candidate, LIQ861, for which we recently resubmitted an NDA with the FDA in response to a CRL received from the FDA in November 2020, and this product candidate may fail to receive marketing approval (in a timely manner or at all) or may not be commercialized successfully.
- United Therapeutics has initiated a lawsuit against us in which it claims that LIQ861 is infringing three of its patents, which may result in our company being delayed in its efforts to commercialize LIQ861.
- Liquidia PAH does not hold the FDA regulatory approval for Injected Treprostinil or the RG Cartridge and is dependent on Sandoz and Chengdu to manufacture and supply Injected Treprostinil and the RG Cartridge, respectively, in compliance with FDA requirements, and is more broadly dependent on Sandoz's and Chengdu's FDA and healthcare compliance relative to Injected Treprostinil and the RG Cartridge, respectively.
- Sales of Injected Treprostinil are dependent on market acceptance of generic treprostinil for parenteral administration and the medical devices used for administration of Injected Treprostinil, including 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 Injected Treprostinil may also be impacted by increasing generic competition which may result in declining prices for Injected Treprostinil.
- 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 LIQ861 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.
- Our credit facility with SVB contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in SVB taking possession and disposing of any collateral.
- Our products may not achieve market acceptance.
- Our product candidates are based on our proprietary, novel technology, PRINT, which has not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

- Our business and operations are likely to be adversely affected by the evolving and ongoing COVID-19 global pandemic.
- We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or enter into agreements with third parties to market and sell our drug products.
- We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of LIQ861.
- 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. The results of our assessment of the effectiveness of internal control over financial reporting ("ICFR") indicate that we had multiple material weaknesses which have not been fully remedied as of June 30, 2021.

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 is dependent on our ability to raise additional capital to finance our future operations.

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the impact of the COVID-19 coronavirus, and the ability to secure additional capital to fund operations. We expect to incur significant expenses and operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and 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 additional 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 is dependent on its ability to raise additional capital to finance our future operations. We will seek additional funding through public or private financings, debt financing or collaboration. The inability to obtain funding, as and when needed, would have a negative impact on our financial condition and ability to pursue our business strategies.

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

We have incurred net losses of $15.7 million during the six months ended June 30, 2021 and $59.8 million and $47.6 million during the years ended December 31, 2020 and 2019, respectively. We also had negative operating cash flows for each of these periods. As of June 30, 2021, we had an accumulated deficit of $290.7 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 pre-acquisition revenue has been derived from up-front fees and milestone payments made to us in connection with licensing and collaboration arrangements we have entered into and the Promotion Agreement, under which we share in the profit derived from the sale of Treprostinil Injection in the United States. These up-front fees and milestone payments have been, and combined with revenue generated from Injected Treprostinil may continue to be, insufficient to match our operating expenses. We expect to continue to devote substantial financial and other resources to the clinical development of our product candidates and, as a result, must generate significant revenue to achieve and maintain profitability or raise additional capital to fund clinical development. We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow.

We 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 LIQ861 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 additional financing on terms that are acceptable 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 credit facility with SVB contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in SVB taking possession and disposing of any collateral.

Our credit facility contains restrictions that limit our flexibility in operating our business. Under the terms of the loan and security agreement dated as of February 26, 2021 (“LSA”) with SVB, pursuant to which SVB extended a $20.5 million term loan facility to us, of which $10.5 million was received on March 1, 2021 in an initial tranche and up to an aggregate of $10.0 million may be received in two equal tranches subject to our satisfaction of certain conditions thereunder, we may not, among other actions, without the prior written consent of SVB, (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 or be liable with respect to any indebtedness except certain permitted indebtedness, or make or permit any payment on any subordinated debt, except under certain limited circumstances, or (c) merge or consolidate with any other person, other than certain limited exceptions. Additionally, on August 26, 2021, we and our two wholly owned subsidiaries, Liquidia Technologies and Liquida PAH, entered into the Loan Modification Agreement with SVB which amended the terms of the LSA to modify the cumulative “Cash Burn” (as defined in the LSA) requirements for the periods ending September 30, 2021, December 31, 2021 and March 31, 2022 and for each calendar quarter thereafter to $56.1 million, $61.1 million and $65.6 million, respectively; provided, however, that the above amounts shall be increased by an amount equal to 75% of the aggregate net cash proceeds received by us from the sale of our equity securities on or after June 30, 2021 but on or prior to the last day of such calendar quarter; provided, further, that upon the Funding Date of the Term C Loan Advance (as such terms are defined in the LSA), the Cash Burn covenant shall no longer apply. Our facility with SVB is collateralized by all of our assets excluding our intellectual property, on which we have granted a negative pledge.

If we breach certain of our debt covenants 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 LSA, giving SVB the right to require us to repay the then outstanding debt immediately, and SVB could, among other things, foreclose on the collateral granted to them to collateralize such indebtedness, which excludes our intellectual property, if we are unable to pay the outstanding debt immediately.

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

We are using the net proceeds of our April 2021 private offering and prior public and private equity offerings for ongoing commercial development of LIQ861 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 debt, cause the value of our equity to decline and delay the development of our product candidates. Pending their use, we may invest such proceeds in short-term, investment-grade, interest-bearing securities, which may not yield favorable returns.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change", generally defined as a greater than 50.0% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. With our April 2021 private placement, the closing of the RareGen acquisition in November 2020, our July 2020 equity offering, our December 2019 private placement, issuances under our prior at-the-market facility, our March 2019 follow-on equity offering and our July 2018 initial public offering, as well as other past transactions, we may have already triggered an "ownership change" limitation. We have not completed a formal study to determine if any "ownership changes" within the meaning of IRC Section 382 have occurred. If "ownership changes" within the meaning of Section 382 of the Code have occurred, and if we earn net taxable income, our ability to use our net operating loss carryforwards and research and development tax credits generated since inception to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

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 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 Injected Treprostinil and is dependent on Sandoz to manufacture and supply Injected Treprostinil in compliance with FDA requirements, and is more broadly dependent on Sandoz's FDA and healthcare compliance relative to Injected Treprostinil.

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

Sandoz's ability to consistently manufacture and supply Injected Treprostinil 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 Injected Treprostinil, including in the event that Injected Treprostinil expires prior to sale. Currently, Injected Treprostinil expires 24 months after the date of manufacture.

Sales of Injected Treprostinil 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 Injected Treprostinil may also be impacted by increasing generic competition which may result in declining prices for Injected Treprostinil.

Our ability to sell Injected Treprostinil is dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third-party payors. If Injected Treprostinil 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 its business or financial arrangements and relationships.

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

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

- our ability to hire and retain sales and marketing personnel and their ability to support Sandoz under the Promotion Agreement;
- the strength of Sandoz's manufacturing and distribution support;
- the requirement by third-party payors to use generic treprostinil for parenteral administration in place of Remodulin;
- the availability of third-party coverage and adequate reimbursement for Injected Treprostinil;
- the prevalence and severity of any side effects;
- any restrictions on the use of Injected Treprostinil 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 Injected Treprostinil.

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 Injected Treprostinil.

In order for Injected Treprostinil 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 recently received FDA 510(k) clearance. The ability of patients to administer Injected Treprostinil through subcutaneous injection is dependent on the continued availability of the RG Cartridge. Our ability to sell the Injected Treprostinil 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, our ability to provide Treprostinil Injection to patients who receive Treprostinil through subcutaneous injection will be limited. The degree of market acceptance of the RG Cartridge will depend on a number of factors, including:

- the efficacy, safety 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.

We are also seeking to work with third parties to develop or procure pumps that can be used to administer Injected Treprostinil in the future. Such pumps may require FDA 510(k) clearance before they can be sold. There is no guarantee that we or a third party will receive FDA 510(k) clearance. 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 Injected Treprostinil.

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

United Therapeutics has initiated a lawsuit against us in which it claims that LIQ861 is infringing three of its patents, which may result in our company being delayed in its efforts to commercialize LIQ861.

We are developing LIQ861 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 LIQ861, 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 LIQ861. Two of these patents are U.S. Patent No. 9,604,901 (the "'901 Patent"), entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", and U.S. Patent No. 9,593,066 (the "'066 Patent"), entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", both of which are owned by United Therapeutics. A notice of the paragraph IV certification was required to be provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for LIQ861 refers. On June 4, 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-UNA) (the "Hatch-Waxman Litigation"), thereby triggering an automatic 30-month regulatory stay on final approval of the NDA for LIQ861. As a result of United Therapeutics' patent challenge, the FDA is prohibited from approving the NDA for LIQ861 until the earliest to occur of the expiration of the 30-month stay, which is projected to be in October 2022, expiration of the '901 Patent and '066 Patent, settlement of the lawsuit or a decision in the infringement suit that is favorable to us as the NDA applicant. Accordingly, we may be subject to significant delay and incur substantial costs in litigation before we are able to commercialize LIQ861, if at all.

On July 21, 2020, the U.S. Patent and Trademark Office (the USPTO) issued U.S. Patent No. 10,716,793 (the "'793 Patent"), entitled "Treprostinil Administration by Inhalation", to United Therapeutics. On July 22, 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the '793 Patent by the practice of LIQ861. The infringement allegations of the '793 Patent are separate from the 30-month regulatory stay on final approval of the NDA for LIQ861, which is only associated with the infringement allegations of the '901 Patent and the '066 Patent. United Therapeutics' motion to dismiss our invalidity defenses and counterclaims concerning the '793 Patent was denied by the U.S. District Court for the District of Delaware on November 3, 2020.

On July 30, 2020, Judge Andrews, presiding over the Hatch-Waxman Litigation, conducted a scheduling conference and set a claim construction hearing, which was held in June 2021, and a date for the trial, which is currently scheduled to begin in March 2022. Following the claim construction hearing, the Court issued an order that two of the terms under consideration would be given their plain and ordinary meaning and ruling in our favor regarding a third term. Two of the terms that were under consideration at the claim construction hearing remain under consideration by the Court.

On June 4, 2021, United Therapeutics filed a motion seeking leave to amend its complaint in the Hatch-Waxman Litigation. United Therapeutics alleges that we and a former United Therapeutics employee who later joined us as an employee conspired to misappropriate certain trade secrets of United Therapeutics. We disagree with United Therapeutics' allegations, deny any liability for misappropriation of any trade secrets and intend to vigorously defend against these new allegations.

On March 30, 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (PTAB) of the USPTO. One petition was for *inter partes* review of the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid, and a second petition is for *inter partes* review of the '066 Patent, seeking a determination that the claims in the '066 Patent are invalid. Both the '901 Patent and '066 Patent are owned by United Therapeutics and are related to U.S. Patent No. 8,497,393 which was granted to United Therapeutics and subsequently invalidated by the USPTO in an *inter partes* review instituted in 2016 by SteadyMed Ltd. On October 13, 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. On March 1, 2021, PTAB denied a request from United Therapeutics for a rehearing regarding PTAB's decision to institute an *inter partes* review of the '901 patent. The PTAB held a hearing with respect to the *inter partes* review of the '901 patent on June 23, 2021. A final written decision determining the validity of the challenged claims of the '901 Patent is expected within 12 months from institution.

On January 7, 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. A final written decision determining the validity of the challenged claims of the '793 Patent is expected within 12 months from institution.

If we are found to infringe, misappropriate or otherwise violate a United Therapeutics' intellectual property rights, we could be required to obtain a license from United Therapeutics to continue developing and marketing LIQ861. 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. A finding of infringement or misappropriation could also result in an injunction that prevents us from commercializing LIQ861, which could materially harm our business. In addition, we may be forced to redesign LIQ861 to avoid infringement.

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

We face significant competition from industry players worldwide, including large multi-national pharmaceutical companies, other emerging or smaller pharmaceutical companies, as well as universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as a larger research and development staff, and more experience in manufacturing and marketing, than we do. As a result, these companies may obtain marketing approval for their product candidates more quickly than we are able to and/or be more successful in commercializing their products, including generic treprostinil products, than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies. We may also face competition as a result of advances in the commercial applicability of new technologies and greater availability of capital for investment in such technologies. Our competitors may also invest heavily in the discovery and development of novel drug products that could make our product candidates less competitive or may file FDA citizen petitions which may delay the approval process for our product candidates. Furthermore, our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. Our competitors may also succeed in asserting existing patents or developing new patents 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, LIQ861, an inhaled treprostinil therapy for the treatment of PAH, will face competition from the following inhaled treprostinil therapies that are either currently marketed or in clinical development:

- Tyvaso, marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009. Tyvaso is the reference listed drug in our NDA for LIQ861. Following patent litigation, United Therapeutics and Watson Pharmaceuticals reached a settlement whereby Watson Pharmaceuticals will be permitted to enter the market with a generic version of Tyvaso beginning on January 1, 2026. In April 2021, United Therapeutics announced that Tyvaso was approved by FDA to include WHO group III PH-ILD patients.

- 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 as TreT by United Therapeutics, is currently in development in the United States for the treatment of PAH. Under the license agreement with MannKind, United Therapeutics is responsible for global development, regulatory and commercial activities. MannKind will manufacture clinical supplies and initial commercial supplies of the product while long-term commercial supplies will be manufactured by United Therapeutics. United Therapeutics announced that had submitted an NDA in April 2021 to support FDA approval of Tyvaso DPI for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease. United Therapeutics also announced that it had applied a priority review voucher to the NDA that could provide for an FDA decision by October 2021. The NDA includes results from clinical studies evaluating safety and pharmacokinetics of switching PAH patients from Tyvaso to Tyvaso DPI and data comparing the pharmacokinetics of Tyvaso DPI to Tyvaso in healthy volunteers. United Therapeutics further reported that these are the only clinical studies necessary to support FDA approval and that the indicated population for Tyvaso DPI will mirror that of Tyvaso, which United Therapeutics announced in April 2021 was approved by FDA to include WHO group III PH-ILD patients. If Tyvaso DPI is approved by FDA before LIQ861 is approved, then there is a possibility that the FDA could grant three years of market exclusivity to Tyvaso DPI as an inhaled dry-powder formulation of treprostinil that could delay the final approval of LIQ861 until said exclusivity expires.

- Treprostinil Palmitil Inhalation Powder (TPIP), is a dry-powder formulation of a treprostinil prodrug being developed by Insmed. Insmed announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once-daily dosing. Insmed initiated a Phase 2 trial in May 2021 studying patients diagnosed with PAH and intends to initiate trials to study PH-ILD and IPF. If the TPIP clinical program is successful in demonstrating less frequent dosing with similar efficacy and safety to LIQ861 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 treprostinil therapies, we expect that LIQ861 will also face competition from other treprostinil-based drugs, including Orenitram, which is administered orally, and Remodulin, which is administered parenterally, both of which are marketed by United Therapeutics. Branded pharmaceutical companies such as United Therapeutics continue to defend their products vigorously through, among other actions, life cycle management, marketing agreements with third-party payors, pharmacy benefits managers and generic manufacturers. These actions add increased competition in the generic pharmaceutical industry, including competition for Injected Treprostinil.

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

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

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

- ***IP-agonists***, such as selexipag, marketed by Actelion, and ralinepeg, licensed from Arena Pharmaceuticals, Inc. by United Therapeutics, which is currently in clinical development;

- ***Endothelin receptor antagonists***, such as bosentan and macitentan, both marketed by Actelion, and ambrisentan, marketed by Gilead. Generic version of bosentan and ambrisentan are currently available.

- ***PDE-5 inhibitors***, such as tadalafil, marketed by United Therapeutics, and sildenafil, marketed by Pfizer Inc. Generic versions of both tadalafil and sildenafil are currently available.

- ***Soluble guanylate cyclase (sGC) stimulator,*** such as riociguat marketed by Bayer.

We are also aware of several other agents in clinical development that are exploring mechanisms of action which, if approved, could impact the standard of care for treating PAH in the United States, including programs from Acceleron Pharma, Inc., Gossamer Bio, Inc., PhaseBio Pharmaceuticals, Inc. and Sumitovant Biopharma Ltd., among others.

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

United Therapeutics has been granted New Clinical Study exclusivity for Tyvaso through March 31, 2024 for the indication of treatment of pulmonary hypertension associated with interstitial lung disease to improve exercise ability. Until the expiration of this exclusivity, we will be unable to receive FDA approval for LIQ861 for the indication of treatment of pulmonary hypertension associated with interstitial lung disease 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 will not limit the indications for which the FDA may approve Tyvaso DPI. Thus, if FDA approves Tyvaso DPI, Tyvaso DPI may have a broader label than the label for LIQ861 even if it is approved. If LIQ861 has a narrower label than other competitive products, it may affect our ability to compete with such products.

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

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

Our products may not achieve market acceptance.

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

- the timing of our receipt of marketing approvals, the terms of such approvals and the countries in which such approvals are obtained;

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

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

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

In order to market and sell any of our drug products, if and when approved, we will be required to build our marketing and sales capabilities with respect to such products. With the acquisition of Liquidia PAH, we acquired a sales force to market generic treprostinil in accordance with the Promotion Agreement. We cannot assure you that we will be successful in doing so 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 LIQ861 in anticipation of potential approval from the FDA, we also continue to evaluate additional drug candidates. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our commercial activities. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which include problems relating to managing manufacturing and supply, reimbursement, marketing problems, and other additional costs.

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

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel over a large geographic area;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;

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

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

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

Our business is exposed to the risk of product liability and other liability risks that are inherent in the development, manufacture, clinical testing and marketing of pharmaceutical products. These risks exist even if a product is approved for commercial sale by the FDA or comparable regulatory authorities in other countries and manufactured in licensed facilities. Our current product candidate, LIQ861, 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, LIQ861, for which we recently resubmitted an NDA with the FDA in response to a CRL received from the FDA in November 2020, and this product candidate may fail to receive 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, LIQ861, a proprietary inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension (PAH). We do not anticipate generating revenue from sales of LIQ861 until 2022 at the earliest, if ever.

LIQ861 is being developed under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. We commenced a Phase 3 clinical trial of LIQ861, which we refer to as INSPIRE, in the first quarter of 2018. We completed the pivotal INSPIRE trial in August 2019. Final enrollment included 121 PAH patients to assess safety and tolerability through Month 2, the primary endpoint of the trial. Of the 121 patients enrolled in the study, 55 were Transition patients and 66 were Add-On patients. Add-On patients started on a dose of 26.5 mcg of LIQ861, with most (>80%) titrating to a 79.5 mcg dose or higher within the first two months of treatment.
In April 2020, we reported final safety and tolerability results from the two-month primary endpoint of the INSPIRE study. Of the 121 PAH patients, 113, or 93%, completed their two-month visit. The most common reported TEAEs (reported in ≥ four percent) were cough (42%), headache (26%), throat irritation (16%), dizziness (11%), diarrhea (9%), chest discomfort (8%), nausea (7%), dyspnea (5%), flushing (5%) and oropharyngeal pain (4%).

We submitted an NDA for LIQ861 to the FDA in January 2020. In April 2020, the FDA accepted the NDA for review and provided a Prescription Drug User Fee Act (PDUFA) goal date of November 24, 2020. On November 25, 2020 we announced that the FDA issued a CRL for our NDA for LIQ861. The CRL did not cite the need to conduct further clinical studies, nor did the FDA indicate that additional studies related to toxicology or clinical pharmacology would be necessary. On May 7, 2021, we resubmitted the NDA for LIQ861 to the FDA. We believe that we have addressed the items raised in the CRL in the resubmitted NDA. In June of 2021, the FDA accepted our resubmitted NDA for LIQ861 for review and established a PDUFA goal date of November 7, 2021. The FDA also reconfirmed the need to conduct on-site pre-approval inspections (PAIs) of two U.S. manufacturing facilities before our NDA can be approved. The FDA noted it had been unable to conduct these inspections during the initial review cycle due to COVID-19 related travel restrictions. In August 2021, the FDA completed an on-site PAI of our Morrisville, North Carolina facility, and no Form 483 Inspectional Observations were issued by the Agency. In July 2021, the FDA notified us that, due to restrictions on travel related to COVID-19, the FDA may be unable to conduct the other PAI prior to the PDUFA goal date.

Expectations related to FDA approval and projected product launch timelines are impacted by ongoing Hatch-Waxman Litigation following a lawsuit filed by United Therapeutics on June 4, 2020. Under the Hatch-Waxman Act, as a result of the Hatch-Waxman Litigation commenced by United Therapeutics, the FDA may not issue a final approval for the LIQ861 NDA for up to 30 months, absent an earlier judgment unfavorable to United Therapeutics by the court. When the FDA is not permitted to issue an approval for a 505(b)(2) application due to a 30-month stay, it is generally possible that the agency could issue “tentative approval” if it determines that all regulatory requirements have been met. However, a drug product that is granted tentative approval 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 drug product would be based on information available to FDA at the time of the tentative approval letter (i.e., information in the application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA’s attention. A new drug product may not be marketed until the date of final approval.

Expectations for LIQ861 also may be impacted by competing products, including Tyvaso® DPI. See “Risk Factors - We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively.”

If we successfully complete the clinical development of LIQ861, we cannot assure you that we will receive marketing approval. The FDA or comparable regulatory authorities in other countries may delay, limit or deny 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, the FDA may request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC) or other data and information, and the development and information may be time-consuming and expensive. Status as a combination product, as is the case for LIQ861, may complicate or delay the FDA review process. Product candidates that the FDA deems to be combination products, such as LIQ861, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process. For example, the CRL for LIQ861 identified the need for additional information and clarification on CMC data pertaining to the drug product and device biocompatibility. Additionally, the FDA could delay approval of LIQ861 even if approvable after completing its review. For example, if a competing product comprised of an inhaled dry-powder formulation of treprostinil is approved by FDA before LIQ861 is approved, then there is a possibility that the FDA could grant three years of market exclusivity to the competitor that could delay the final approval of LIQ861 until said exclusivity expires. Moreover, the applicable requirements for approval may differ from country to country.

If we successfully obtain marketing approval for LIQ861, we cannot assure you that it will be commercialized in a timely manner or successfully, or at all. For example, LIQ861 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 LIQ861 will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such product, even if approved. Any delay or setback we face in the commercialization of LIQ861 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 LIQ861, we have not yet obtained 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, LIQ861 has, to date, been tested only in relatively small study populations and, accordingly, the results from our earlier clinical trials may be less reliable than results achieved in larger clinical trials, if required. Additionally, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary and interim results of a clinical trial do not necessarily predict final results.

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

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

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

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

Clinical trials and data analysis can be expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for LIQ861, or any required clinical studies of LIQ861 do not provide positive results, we may be required to delay or abandon development of such product, 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 LIQ861. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon an NDA filed with the FDA or repeat clinical trials. The commencement and completion of clinical trials for any current or future development product candidate may be delayed by several factors, including:

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

In addition, the FDA or an independent institutional review board (IRB) may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. Although clinical data is an essential part of NDA filings, NDAs must also contain a range of additional data including CMC data to meet FDA standards for approval. In the event we do not ultimately receive regulatory approval for LIQ861, we may be required to terminate development of our only product candidate.

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

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

- the FDA or comparable regulatory authorities may, for a variety of reasons, take the view that the data collected from our preclinical and clinical trials and human factors testing, or data that we otherwise submit or reference to support an application, are not sufficient to support approval of a product candidate;

- the FDA or comparable regulatory authorities in other countries may ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers do not sufficiently demonstrate compliance with cGMP to support approval of a product candidate, or that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval;

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

- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval.

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

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

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

Patient enrollment may be affected by, among others:

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

- the number and nature of competing therapies and clinical trials; and
- other environmental factors such as the ongoing COVID-19 pandemic or other natural or unforeseen disasters.

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

We expect that if we initiate, as we are currently contemplating, a clinical trial of LIQ861 in pediatric patients, we may encounter difficulties enrolling patients in such a trial because of the limited number of pediatric patients with this disease. Furthermore, we are aware of a number of therapies for PAH that are being developed or that are already available on the market, and we expect to face competition from these investigational drugs or approved drugs for potential subjects in our clinical trials, which may delay enrollment in our planned clinical trials.

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

Product candidates that the FDA deems to be combination products, such as LIQ861, 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 LIQ861, which is delivered by a DPI, to be a drug-device combination product. Accordingly, the DPI was evaluated as part of our original NDA filing, and the CRL we received from FDA, as announced November 25, 2020, identified the need for additional information pertaining to device biocompatibility. 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 LIQ861, 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 candidate. 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 plan to pursue this pathway for our current product candidate, LIQ861, and have submitted a 505(b)(2) NDA. Even if the FDA allows us to rely on the 505(b)(2) regulatory pathway, we cannot assure you that such marketing approval will be obtained in a timely manner, or at all.

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

In addition, we may face Hatch-Waxman litigation in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the approval of our product candidates. The pharmaceutical industry is highly competitive, and 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505(b)(2) NDA. If the previously approved drugs referenced in an applicant's 505(b)(2) NDA are protected by patent(s) listed in the Orange Book, the 505(b)(2) applicant is required to make a claim after filing its NDA that each such patent is invalid, unenforceable or will not be infringed. The patent holder may thereafter bring suit for patent infringement, which will trigger a mandatory 30-month delay (or the shorter of dismissal of the lawsuit or expiration of the patent(s)) in approval of the 505(b)(2) NDA application. For example, the LIQ861 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 Hatch-Waxman Litigation commenced by United Therapeutics on June 4, 2020, the FDA is automatically precluded from approving the LIQ861 NDA for up to 30 months, absent an earlier judgment unfavorable to United Therapeutics by the court. It is 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 our product candidates, including LIQ861, do not qualify for the 505(b)(2) regulatory pathway, we would need to reconsider our plans and might not be able to commercialize our product candidates in a cost-efficient manner, or at all. If we were to pursue approval under the 505(b)(1) NDA pathway, we would be subject to more extensive requirements and risks such as conducting additional clinical trials, providing additional data and information or meeting additional standards for marketing approval. As a result, the time and financial resources required to obtain marketing approval for our product candidates would likely increase substantially and further complications and risks associated with our product candidates may arise. Also, new competing products may reach the market faster than ours, which may materially and adversely affect our competitive position, business and prospects.

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

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

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

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

Risks Related to Our Dependence on Third Parties

We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of LIQ861.

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 LIQ861, 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 LIQ861, 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, LIQ861 is administered using the RS00 Model 8 DPI, which is manufactured by Plastiape, which is located in Italy. We purchase our RS00 Model 8 DPI supply pursuant to purchase orders and do not have a long-term contract with Plastiape. In the event of any prolonged disruption to our supply of treprostinil, the encapsulation and packaging services, or the manufacture and supply of RS00 Model 8 DPI or, our ability to develop and commercialize, and the timeline for commercialization of, LIQ861 may be adversely affected.

Additionally, in December 2019, a novel strain of COVID-19 (coronavirus) was reported to have surfaced in Wuhan, China and continues to be a global pandemic as of the date of this prospectus. The full impact of the coronavirus is unknown and continues to rapidly evolve. Both South Korea, the country from which our supplier sources treprostinil, and Italy, the country in which Plastiape is headquartered, have had significant outbreaks of this disease, which, in the case of Italy, led to a lockdown of the entire country. The extent to which the coronavirus impacts our ability to procure sufficient supplies for the development and commercialization of our products and product candidates, or the ability for the FDA to conduct required PAIs to obtain sufficient assurance or verification of compliance with good manufacturing practice required by FDA regulations will depend on the severity, location and duration of the spread of the coronavirus, and the actions undertaken to contain the coronavirus or treat its effects. As announced on November 25, 2020, in the CRL for LIQ861 the FDA noted it had been unable to conduct required inspections during the initial review cycle for the LIQ861 NDA due to COVID-related travel restrictions and, in July 2021, notified us that, due to restrictions on travel related to COVID-19, the FDA may be unable to conduct certain necessary inspections prior to the PDUFA goal date. We cannot predict when COVID-related travel restrictions will change or be lifted.

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

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

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

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

Our collaboration and licensing arrangements may not be successful.

Our collaboration and licensing arrangements, as well as any future collaboration and licensing arrangements that we may enter into, may not be successful. The success of our collaboration and licensing arrangements will depend heavily on the efforts and activities of our collaborators, which are not within our control. We may, in the course of our collaboration and licensing arrangements, be subject to numerous risks, including, but not limited to, the following:

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

Risks Related to our Intellectual Property

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

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

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

Claims for infringement of intellectual property which are brought against us, whether with or without merit, and which are generally uninsurable, could result in time-consuming and costly litigation, diverting our management's attention from our core business and reducing the resources available for our drug product development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being issued. We also may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Uncertainties resulting from the initiation and continuation of litigation or other proceedings could also have a material and adverse effect on our ability to compete in the market. Third parties making claims against us could obtain injunctive or other equitable relief against us, which could prevent us from further developing or commercializing our product candidates.

In particular, under the Hatch-Waxman Act, the owner of patents listed on the Orange Book and referenced by an NDA applicant may bring patent infringement suit against the NDA applicant after receipt of the NDA applicant's notice of paragraph IV certification. On June 4, 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 (Case No. 1:20-cv-00755-UNA), thereby triggering an automatic 30-month regulatory stay on final approval of the NDA for LIQ861. As a result of United Therapeutics' patent challenge, the FDA is prohibited from approving the NDA for LIQ861 until the earliest to occur of the expiration of the 30-month stay, which is currently in October 2022, expiration of the Orange Book listed patents, settlement of the lawsuit or a decision in the infringement suit that is favorable to us as the NDA applicant. Accordingly, we may be subject to significant delay and incur substantial costs in litigation before we are able to commercialize LIQ861, if at all.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We believe that the protection of our trademark, trade name and service mark rights, such as Liquidia, the Liquidia logo and PRINT, 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 goodwill 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 goodwill that has been developed in those trademarks, trade names or service marks.

Risks Related to the Manufacturing of our Product Candidates

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

Our future success depends on the successful development of our novel PRINT technology and products based on it, including LIQ861. To our knowledge, no regulatory authority has granted approval to market or commercialize drugs made using our PRINT technology. While our Morrisville, North Carolina facility was recently subject to a PAI by the FDA, we have not yet received the final report from the FDA related to that inspection. We may never receive approval to market and commercialize any product candidate that uses our PRINT technology.

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. A fire, flood, hurricane, earthquake or other disaster or unforeseen event resulting in significant damage to our facilities 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 or to repair or replace our facility 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 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.

Risk 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 Damian deGoa, 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.

On April 13, 2021, the Company sold 8,626,037 shares of the Company’s common stock in a private placement. The purchasers of such shares of common stock have agreed not to offer, sell, transfer or otherwise dispose of any such shares during the 6-month period following the closing. After the expiration of such 6-month period, such shares will not have a lock-up restriction and may be freely sold in the public market which could cause our stock price to decline.

Upon consummation of the Merger Transaction, we issued to RareGen’s former members an aggregate of 5,550,000 shares of our common stock. Additionally, 616,666 shares of our common stock, which are referred to in the Merger Agreement as “Holdback Shares”, are being withheld to satisfy potential indemnification obligations of former RareGen members. In addition, we may issue up to 2,708,333 shares of our common stock in 2022, which are referred to in the Merger Agreement as “Net Sales Earnout Shares”, if Liquidia PAH achieves at least $32.9 million of 2021 net sales (as calculated by Sandoz net sales), with the number of Net Sales Earnout Shares to be issued to depend upon the actual amount of the 2021 net sales. The shares issued to former RareGen members on the closing date of the Merger Transaction were subject to a six-month lock-up that expired on May 18, 2021. In the event that Holdback Shares are released or Net Sales Earnout Shares are issued, such shares will not have a lock-up restriction and may be freely sold in the public market which could cause our stock price to decline.

As of July 15, 2021, 51,975,049 shares of our common stock were outstanding, of which 40,702,993 shares of common stock, or 78.3% of our outstanding shares as of July 15, 2021, are freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our "affiliates," as that term is defined in Rule 144 under the Securities Act ("Rule 144"). The resale of the remaining 11,272,056 shares held by our stockholders as of July 15, 2021 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 July 15, 2021, the holders of 10,513,974 shares, or 20.2%, of our outstanding shares as of July 15, 2021, 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 LIQ861 or any product candidate we may develop, or those of our competitors;
- the success of Sandoz's generic version of Remodulin to which we have commercial rights to pursuant to the Promotion Agreement;
- the success of Chengdu's launch of the RG Cartridge and the market acceptance of the RG Cartridge for the subcutaneous administration of Treprostinil Injection;
- our cash resources;
- the success of competitive products or technologies;
- potential approvals of any product candidate we may develop for marketing by the FDA or equivalent foreign regulatory authorities or any failure to obtain such approvals;
- our involvement in significant lawsuits, including stockholder or patent litigation, including *inter partes* review proceedings and Hatch-Waxman litigation with originator companies or others which may hold patents, including United Therapeutics;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize any product candidate we may develop;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

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

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned 36.1% of our capital stock as of July 15, 2021. Accordingly, our executive officers, directors and principal stockholders have significant influence in determining the composition of 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 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. The results of our assessment of the effectiveness of internal control over financial reporting (ICFR) indicate that we had multiple material weaknesses which have not been fully remedied as of June 30, 2021.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act) or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

As required by the Sarbanes Oxley Act of 2002 and commencing with the fiscal year ended December 31, 2019, we were required to furnish a report by management on, among other things, the effectiveness of our ICFR. In connection with the assessment of the effectiveness of our ICFR, our management identified material weaknesses that existed as of December 31, 2019 and December 31, 2020 which have not been fully remedied as of June 30, 2021.

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

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

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

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

- permit the Board to issue up to 10 million shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our Board;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- create a staggered board of directors such that all members of our Board are not elected at one time;
- allow for the issuance of authorized but unissued shares of our capital stock without any further vote or action by our stockholders; and
- establish advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon at stockholders' meetings.

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

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

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

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

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

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

We have never declared or paid cash dividends on our equity securities. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our existing LSA with SVB preclude us, and the terms of any future debt 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.

General Risk Factors

General Risks Related to the Commercialization of our Product Candidates

Our business and operations are likely to be adversely affected by the evolving and ongoing COVID-19 global pandemic.

Our business and operations are likely to be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared by the World Health Organization as a global pandemic. 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.

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. Currently, many of our employees are continuing to work remotely, with only essential personnel required to work on site as needed to produce LIQ861 and conduct other activities that cannot be conducted remotely.

Such orders may also impact personnel at third-party contract research organizations that conduct clinical trials or research activities, which could impact our ability to continue or commence such activities, or contract manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

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

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this 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. For example, during the course of the pandemic the FDA has at points delayed both domestic and foreign facility inspections. The agency announced in July 2020 that domestic facility inspections will be conducted but prioritized through a risk-based approach, while foreign facility inspections remain delayed unless the FDA determines they can be conducted based on an assessment of whether it is "mission-critical." More recently, in April 2021, the FDA announced that it may request to conduct "remote interactive evaluation," which in a variety of circumstances is inclusive of PAIs, where it is determined to be appropriate in accordance with the mission needs and any travel limitations. In addition, in July 2021, the FDA notified us that, due to restrictions on travel related to COVID-19, the FDA may be unable to conduct the PAIs for LIQ861 prior to the PDUFA goal date, although subsequent to receipt of such notice, the FDA conducted a PAI of our Morrisville, North Carolina facility. We expect the impact of COVID-19 on the FDA's operations will continue to evolve. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

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

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

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

- the FDA or comparable regulatory authorities may, for a variety of reasons, take the view that the data collected from our preclinical and clinical trials and human factors testing, or data that we otherwise submit or reference to support an application, are not sufficient to support approval of a product candidate;

- the FDA or comparable regulatory authorities in other countries may ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers do not sufficiently demonstrate compliance with current good manufacturing practices (cGMP) to support approval of a product candidate; or that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval;

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

- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval.

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

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

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

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

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

General Risk 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 Risk Related to Healthcare Regulation

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

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

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

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

- The federal Anti-Kickback Statute (AKS)prohibits, among other things, persons and entities including pharmaceutical manufacturers from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for or the purchase, lease, or order of, or the arranging for an item or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs.

- The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act (FCA) prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Claims resulting from a violation of the federal AKS constitute a false or fraudulent claim for purposes of the federal False Claims Act. Promotion that is deemed to be “off label” can be the basis of FCA exposure.

- Federal law includes provisions (established under the Health Insurance Portability and Accountability Act of 1996) addressing healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Violations of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs.

- Privacy and data security laws may apply to our business. Under the Federal Trade Commission Act (the FTCA) Section 5(a), the FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements, for example the California Consumer Privacy Act (CCPA) went into effect in January 2020 creating data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information.

- The federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under government healthcare programs to annually report to the Centers for Medicare and Medicaid Services (CMS) information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Payments and transfers of value made to certain other providers such as nurse practitioners and physician assistants beginning in 2021 will need to be reported under the Sunshine Act in 2022.

- For both investigational and commercialized products, interactions with or communications directed to healthcare professionals (HCPs), patients or patient- or disease-advocates or advocacy groups, and payors, are subject to heightened scrutiny by the FDA. Relative to nonpromotional communications, for example, there are specific and limited FDA accommodations for nonpromotional, truthful and non-misleading sharing of information regarding products in development and off-label uses including dissemination of peer-reviewed reprints, support of independent continuing medical education (CME), and healthcare economic discussions with payors. In a competitive environment, a company's communications about products in development may also be subject to heightened scrutiny.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases may apply regardless of payor (i.e., even for self-pay scenarios). Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives. Many of these state laws differ from each other in significant ways and may not have the same effect, and may apply more broadly or be stricter than their federal counterparts, thus complicating compliance efforts; and

- Price reporting laws require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursements or discounts on our drug products. Participation in such programs and compliance with their requirements may subject us to increased infrastructure costs and potentially limit our ability to price our drug products.

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

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

General Risk Related to Our Dependence on Third Parties

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

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

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

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

General Risks Related to Legal Compliance Matters

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

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

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

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

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

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 Risk 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 are subject to PAIs by the FDA. A PAI has been conducted for our Morrisville, North Carolina facility with respect to the NDA for LIQ861, for which we are awaiting a final report. In addition to the completed inspection of our Morrisville site, the FDA has notified us that a PAI will also be required for the third-party provider of encapsulation and packaging services for LIQ861. At this time, we have not been notified of when this additional PAI may be completed. If LIQ861 or any of our product candidates receive marketing approval from the FDA, the sites where such products are manufactured will remain subject to periodic inspection even after our product candidates have received marketing approval. Suppliers of components and materials, such as active pharmaceutical ingredients, used to manufacture our drug products are also required to comply with the applicable regulatory standards.

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

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

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our common stock sold pursuant to this prospectus by the selling stockholders. The selling stockholders will receive all of the proceeds from sales of our common stock sold pursuant to this prospectus.

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

SELLING STOCKHOLDERS

The shares of common stock being offered by the selling stockholders are (i) shares of common stock previously issued to the Purchasers pursuant to the Purchase Agreement. For additional information regarding the issuances and terms of these securities, see “Prospectus Summary—Summary of Private Placement” above. We are registering the shares of common stock in order to permit the selling stockholders, or their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part, to offer the shares for resale from time to time.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of common stock by each of the selling stockholders as of August 15, 2021. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our common stock. Generally, a person “beneficially owns” shares of our common stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days. The second column lists the number of shares of common stock beneficially owned by each selling stockholder, based on each selling stockholder's ownership of shares of common stock.

The third column lists the number of shares of common stock being offered by this prospectus by the selling stockholders. In accordance with the terms of the Purchase Agreement and the Registration Rights Agreement with the Purchasers, this prospectus covers the resale of the number of shares of common stock sold in the Private Placement.

The fourth and fifth columns list the number of shares of common stock and percentage of our outstanding common stock to be held by the selling stockholder assuming the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Number of Shares of Common Stock Owned After Offering(1)	Percentage of Class Following the Offering(1)
Caligan Partners LP[2]	8,328,418	8,328,418	—	—
PD Joint Holdings, LLC Series 2016-A[3]	737,646	198,413	539,233	1.04%
Roger Jeffs[4]	1,538,340	99,206	1,439,134	2.77%

* Less than one percent of our outstanding shares of common stock.

(1) Represents the number of shares of common stock that will be beneficially owned by the selling stockholder after completion of this offering based on the assumptions that (i) all of the shares of common stock registered for resale by the registration statement of which this prospectus is a part will be sold and (ii) no other shares of common stock will be acquired or sold by the selling stockholder before completion of this offering. However, the selling stockholders may sell all, part or none of their shares of common stock offered pursuant to this prospectus and may sell all, part or none of their common stock pursuant to one or more exemptions from the registration provisions of the Securities Act. Applicable percentage ownership following the offering is based on 51,975,052 shares of common stock that would be outstanding as of August 15, 2021 assuming all shares registered by this prospectus are sold in the offering.

(2) Consists of (i) 7,167,663 shares of common stock held by Caligan Partners CV IV LP (“Caligan IV”) and (ii) 1,160,755 shares of common stock held in an account managed (the “Managed Account”) by Caligan Partners LP (“Caligan Partners”). Caligan Partners CV IV GP LLC is the sole general partner of Caligan IV and may be deemed to have the sole investment and voting power over the shares held by Caligan IV. Caligan Partners LP is the investment manager of the Managed Account and may be deemed to have the sole investment and voting power over the shares held by the Managed Account. David Johnson is the sole managing member of Caligan Partners and Caligan Partners CV IV GP LLC. Investment, voting and dispositive decisions with respect to the shares held by Caligan IV and the Managed Account are made by Mr. Johnson. Mr. Johnson, a member of our board of directors, is the managing partner of Caligan Partners. The address of Caligan is 590 Madison Ave, 21st Floor, New York, NY 10022.

(3) Paul B. Manning, a member of our board of directors, and Bradford Manning are each managers of Tiger Lily Capital, LLC, the manager of the selling stockholder, and have joint voting and investment power with respect to the shares held by the selling stockholder. The selling stockholder's address is 200 Garrett Street, Suite O, Charlottesville, VA 22902.

(4) Consists of (i) 6,095 shares of common stock held by Roger A. Jeffs 2019 GRAT dtd 05/01/2019, of which Dr. Jeffs is the trustee, (ii) 111,706 shares of common stock held by Dr. Jeffs, (iii) 1,387,500 shares of common stock held by Serendipity BioPharma LLC (“Serendipity”), and (iv) 33,039 shares of common stock underlying outstanding options which are vested or will become vested within the next 60 days. Dr. Jeffs is a manager of Serendipity and has sole voting and dispositive power over the common units held by Serendipity. Dr. Jeffs is a member of our board of directors and Dr. Jeffs’ address is 339 W. Barbee Chapel Road, Unit 343, Chapel Hill, NC 27517.

PLAN OF DISTRIBUTION

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

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

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

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

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

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

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

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

We are required to pay all fees and expenses incident to the registration of the shares of common stock. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

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

The anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of our common stock and activities of the selling stockholders.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock we registered on behalf of the selling stockholders pursuant to the registration statement of which this prospectus forms a part.

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

DESCRIPTION OF CAPITAL STOCK

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

General

The total number of shares of capital stock that we have authorized is 90,000,000, divided into two classes consisting of (i) 80,000,000 shares of common stock and (ii) 10,000,000 shares of preferred stock.

Common Stock

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders. The holders of common stock are entitled to receive ratably those dividends, if any, that may be declared from time to time by our board of directors out of funds legally available, subject to preferences that may be applicable to preferred stock, if any, then outstanding. In the event of our liquidation, dissolution or winding up, 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 of directors 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 us 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 June 30, 2021, the Company’s outstanding warrants consisted of the following:

	Number of warrants	Exercise Price	Expiration Date
SVB Warrant	100,000	$ 3.05	February 26, 2031
SVB Warrant	100,000	N/A[1]	February 26, 2031
Other warrants	106,274	$ 0.02	December 31, 2026

[1] The exercise price for these warrants will be determined as the lower of (i) the average closing price of a share of Common Stock reported on the Nasdaq Capital Market for the ten (10) consecutive trading days immediately prior to the date on which the first Term B Loan Advance or Term C Loan Advance (as such terms are defined that certain Warrant to Purchase Stock issued to SVB, dated February 26, 2021, the “Warrant”), as applicable, if any, is made to the Company, and (ii) the closing price of a share of the Common Stock reported on the Nasdaq Capital Market for the trading day immediately prior to such date, subject to further adjustment from time to time in accordance with the provisions of the Warrant.

Registration Rights

Registration Rights Agreement

In connection with entering into the Purchase Agreement, we entered into the Registration Rights Agreement with the Purchasers dated April 12, 2021, pursuant to which we granted customary registration rights to the Purchasers obligating the Company to register for resale under the Securities Act on Form S-3 the Private Placement Shares.

Purchase Agreement

Included in the Purchase Agreement are provisions which require us to register the resale of the Private Placement Shares. We are required to prepare and file a registration statement with the Commission within 180 days following the date of the Registration Rights Agreement, and to use best efforts to have the registration statement declared effective within 60 calendar days if there is no review by the SEC, and within 90 calendar days in the event of such review.

WHERE YOU CAN FIND MORE INFORMATION

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

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

INCORPORATION OF DOCUMENTS BY REFERENCE

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

(1) our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2021 and June 30, 2021, filed with the SEC on May 13, 2021 and August 10, 2021;

(2) our Annual Report on Form 10-K for the year ended December 31, 2020;

(3) our Current Reports on Form 8-K filed with the SEC on January 8, 2021, January 14, 2021, March 3, 2021, March 26, 2021, March 30, 2021, April 13, 2021, May 10, 2021, May 24, 2021, June 2, 2021, June 21, 2021, August 12, 2021, August 19, 2021 and August 30, 2021; and

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

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

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

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.

EXPERTS

The financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2020 have been so incorporated in reliance on the report (which contains an emphasis of matter paragraph related to the Company's requirement for additional financing to fund future operations and management's plans as described in Note 1 to the consolidated financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

8,626,037 Shares
Liquidia Corporation
Common Stock

Prospectus