As filed with the Securities and Exchange Commission on December 16, 2020

Registration Statement No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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

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

Delaware	**85-1710962**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

419 Davis Drive, Suite 100
Morrisville, North Carolina 27560
Telephone: (919) 328-4400
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Damian deGoa
Chief Executive Officer
Liquidia Corporation
419 Davis Drive, Suite 100
Morrisville, North Carolina 27560
Telephone: (919) 328-4400
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Andrew P. Gilbert, Esq.
DLA Piper LLP (US)
51 John F. Kennedy Parkway, Suite 120
Short Hills, New Jersey 07078
Telephone: (973) 520-2550

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐		Accelerated Filer ☒
Non-accelerated filer ☐	(Do not check if a smaller reporting company)	Smaller reporting company ☒

Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☒

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be Registered (1)(2)	Proposed Maximum Offering Price Per Unit (3)(4)	Proposed maximum aggregate offering price (3)(4)	Amount of registration fee (4)(5)
Secondary Offering				
Common Stock, par value $0.0001 per share	16,039,533	$2.93	$46,995,831.69	$5,127.25
Primary Offering				
Common Stock, par value $0.0001 per share				
Preferred Stock, par value $0.0001 per share				
Debt Securities				
Warrants				
Units				
Total (Primary Offering)			$200,000,000	$6,670(6)
Total (Primary and Secondary)			$246,995,831.69	$11,797.25

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, the securities being registered hereunder shall be deemed to cover additional shares of common stock and preferred stock that may be offered or issued to prevent dilution resulting from stock splits, stock dividends, anti-dilution provision or similar transactions.

(2) With regard to the securities included in the primary offering made hereby, an indeterminate number of the securities of each identified class is being registered as may from time to time be offered hereunder at indeterminate prices, along with an indeterminate number of securities that may be issued upon exercise, settlement, exchange or conversion of securities offered or sold hereunder as shall have an aggregate initial offering price not to exceed $200,000,000. Any securities registered hereunder may be sold separately or as units with the other securities registered hereunder. The proposed maximum offering price per unit will be determined, from time to time, by the registrant in connection with the issuance by the registrant of the securities registered hereunder. With respect to the secondary offering, there is being registered hereunder 16,039,533 shares of Common Stock registered for resale by the selling stockholders named in this registration statement, including 5,550,000 shares of Common Stock issued pursuant to the Agreement and Plan of Merger, dated as of June 29, 2020, among Liquidia Technologies, Inc., a Delaware corporation and a predecessor-by-merger to the registrant ("Liquidia Technologies"), RareGen, LLC, the registrant, Gemini Merger Sub I, Inc., Gemini Merger Sub II, LLC, and PBM RG Holdings, LLC (the "Merger Agreement"), up to 616,666 shares of Common Stock that may be issued as Holdback Shares pursuant to the Merger Agreement, up to 2,708,333 shares of Common Stock that may be issued as Net Sales Earnout Shares pursuant to the Merger Agreement, and 7,164,534 shares of Common Stock registered for resale by the selling stockholders, sold in a private placement that closed in December 2019.

(3) With regard to the securities included in the primary offering made hereby, the proposed maximum offering price per security will be determined from time to time by the registrant in connection with, and at the time of, the issuance of the securities and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act of 1933, as amended.

(4) With regard to the securities included in the secondary offering made hereby, the offering price and registration fee are estimated pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low prices reported for the shares of common stock as reported on The Nasdaq Capital Market on December 11, 2020.

(5) With regard to the securities included in the primary offering made hereby, the registration fee is calculated pursuant to Rule 457(o) under the Securities Act, based on the proposed maximum aggregate offering price.

(6) Pursuant to Rule 457(p) under the Securities Act, the amount of the registration fee payable hereunder has been partially offset by previously paid filling fees as follows: Liquidia Technologies filed a Registration Statement on Form S-3 (File No. 333-233438) filed under the Securities Act with the Securities and Exchange Commission on August 23, 2019 (the "2019 S-3") and paid a filing fee of $24,240. The offering contemplated by the 2019 S-3 was terminated pursuant to a Post-Effective Amendment No. 1 to the 2019 S-3 filed by Liquidia Technologies on November 18, 2020; upon completion of the offering there was $125,000,000 of unsold shares of Liquidia Technologies common stock registered thereunder for which a filing fee of $15,150 had been paid that may be used as an offset against future filings.

EXPLANATORY NOTE

This registration statements contains two prospectuses:

- a base prospectus which covers the offering, issuance and sale of by us of up to $200,000,000 in the aggregate of the securities identified above from time to time in one or more offering;

- a resale prospectus that covers the resale by the selling stockholders of up to 16,039,533 shares of our common stock.

The base prospectus immediately follows this explanatory note. The specific terms of any securities to be offered pursuant to the base prospectus other than the shares sold by the selling stockholders identified in this registration statement will be specified in a prospectus supplement to the base prospectus. The specific terms of the securities to be issued and sold by the selling stockholders are specified in the resale prospectus that immediately follows the base prospectus.

The information in this preliminary prospectus is not complete and may be changed or supplemented. No securities described in this preliminary prospectus can be sold until the registration statement that we filed to cover the securities has become effective under the rules of the Securities and Exchange Commission. This preliminary prospectus is not an offer to sell the securities, nor is it a solicitation of an offer to buy the securities in any state where an offer or sale of the securities is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 16, 2020

PROSPECTUS

$200,000,000

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

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

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

We may offer and sell the securities through underwriters, dealers or agents, or directly to purchasers, or through a combination of these methods. See "Plan of Distribution" beginning on page 78 of this prospectus.

Our common stock is listed on the Nasdaq Capital Market under the symbol "LQDA." On December 15, 2020, the last reported sale price of our common stock was $2.92 per share.

Investing in our securities involves risk. See "Risk Factors" beginning on page 11 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 , 2020

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ABOUT THIS PROSPECTUS

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

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

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained in, or incorporated by reference into, this prospectus and the applicable prospectus supplement, and any free writing prospectus we have authorized for use in connection with a specific offering. You must not rely upon any other information or representation.

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

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

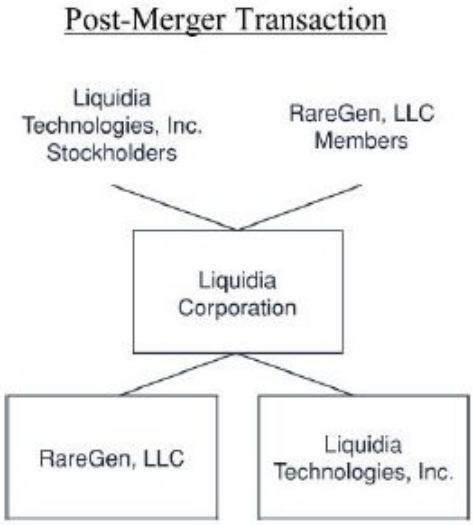
This prospectus includes our trademarks, trade names and service marks, such as Liquidia, the Liquidia logo, RareGen, the RareGen logo, and PRINT, or Particle Replication In Non-wetting Templates, which are protected under applicable intellectual property laws and are the property of our company. This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

ABOUT LIQUIDIA CORPORATION

This summary highlights selected information contained elsewhere in this prospectus or incorporated by reference into this prospectus. This summary does not contain all the information that you should consider before investing in our securities. You should carefully read this entire prospectus, the applicable prospectus supplement and any related free writing prospectus, including each of the documents incorporated herein or therein by reference, before making an investment decision. Unless the context otherwise requires, references in this prospectus to "Liquidia," "we," "us," "our," "our company" and "our business" refer to Liquidia Corporation, a Delaware corporation, and its subsidiaries (except for periods prior to November 18, 2020, which refer to Liquidia Technologies, Inc.).

Closing of RareGen Merger

On November 18, 2020, or the Closing Date, Liquidia Corporation 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, or the Merger Agreement, by and among Liquidia Corporation, Liquidia Technologies, Inc., a Delaware corporation, or Liquidia Technologies, RareGen, LLC, a Delaware limited liability company, or RareGen, Gemini Merger Sub I, Inc., a Delaware corporation, or Liquidia Merger Sub, Gemini Merger Sub II, LLC, a Delaware limited liability company, or RareGen Merger Sub, and PBM RG Holdings, LLC, a Delaware limited liability company, as Members' Representative. Pursuant to the Merger Agreement, Liquidia Merger Sub, a wholly owned subsidiary of Liquidia Corporation, merged with and into Liquidia Technologies, or the Liquidia Technologies Merger, and RareGen Merger Sub, a 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. The organization of Liquidia Corporation, Liquidia Technologies, and RareGen following the Merger Transaction is illustrated below:



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, or 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, or 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.

Overview

We are a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing our proprietary PRINT® technology to transform the lives of patients. PRINT is a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. Our primary objective has been to pursue marketing approval of LIQ861 and to commercialize such product if approved by the U.S. Food and Drug Administration, or the FDA.

Pursuant to its Promotion Agreement with Sandoz Inc., or Sandoz, as described below, RareGen owns the exclusive rights to conduct any and all promotional and non-promotional activities to encourage the appropriate use of the first-to-file fully substitutable generic treprostinil injection for the treatment of patients with PAH in the United States. To that end, RareGen has a small, targeted sales force focused on PAH which it employs to conduct such marketing activities.

Product Pipeline

We are currently focused on the development of two product candidates for which we hold worldwide commercial rights: LIQ861 for the treatment of pulmonary arterial hypertension, or PAH, and LIQ865 for the treatment of local post-operative pain.

The following table summarizes our clinical-stage product candidates being developed using PRINT technology:

Program	Indication	Formulation	Phase 1	Phase 2	Phase 3	NDA	Worldwide Rights
LIQ861	PAH	treprostinil, inhalation powder					LIQUIDIA
LIQ865	Local, post-surgical pain	bupivacaine, sustained-release					LIQUIDIA

LIQ861

Our lead product candidate, treprostinil, is a potential treatment for patients with PAH. Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function, which is deficient in patients with PAH. We believe that LIQ861 has the potential to improve the therapeutic profile of existing formulations of treprostinil by enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies. We are developing LIQ861 under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug, which allows us to rely in part on the FDA's previous findings of efficacy and safety of Tyvaso and the active ingredient treprostinil, which has been approved in four different products administered through the oral, inhaled and continuous infusion (parenteral) routes.

In January 2020, we submitted an NDA to the FDA for LIQ861, and in April 2020, the FDA accepted the NDA for review and provided a Prescription Drug User Fee Act, or PDUFA, goal date of November 24, 2020. On November 25, 2020, we announced the FDA issued a complete response letter, or CRL, for our NDA for LIQ861. The CRL identified the need for additional information and clarification on chemistry, manufacturing and controls, or CMC, data pertaining to the drug product and device biocompatibility. We do not believe that the items raised in the CRL will be a barrier to the ultimate approval of 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. We believe that we can address the items raised in the CRL (through a resubmission) without delaying the otherwise projected launch timing of LIQ861 in the second half of 2022, subject to FDA approval.

Under the Hatch-Waxman Act, as a result of the Hatch-Waxman Litigation commenced by United Therapeutics on June 4, 2020, 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 precluded from approving 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 requirements for approval 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.

Our NDA submission was based in part upon the results of our open-label Phase 3 clinical trial, INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, for LIQ861, the initiation of which we announced in January 2018. The primary objective of the INSPIRE study was to evaluate the long-term safety and tolerability of LIQ861. The study was designed to evaluate patients who have either been under stable treatment with Tyvaso (nebulizer-delivered treprostinil) for at least three months and were transitioned to LIQ861 under the protocol, or Transition patients, or 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, or Add-On patients.

In August 2019, we completed the pivotal INSPIRE trial. 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. Consistent with preliminary data presented in the second quarter of 2019, LIQ861 was observed to be well-tolerated and treatment-emergent adverse events, or 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. 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.

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%).

Analysis of the exploratory endpoints from the INSPIRE study indicates that LIQ861 may provide functional and quality-of-life benefits to PAH patients in New York Heart Association, or NYHA, functional classes II and III. More than 70% of patients were able to titrate to a LIQ861 dose greater than or equal to 79.5 mcg, the LIQ861 dose-level comparable to 54 mcg of nebulized treprostinil, the maximum recommended dose in the Tyvaso® package insert. More than 95% of all patients who completed two months of treatment maintained (75.9%) or improved (20.5%) their NYHA functional class. We observed improvements in median six-minute-walk-distance (+10.1 meter increase). Quality-of-life as measured by the MLHFQ showed an improved total score (>5-point reduction), as well as improvements in both emotional and physical dimensions. We observed a greater percentage of subjects who met two or three PAH low-risk criteria at month 2 compared to baseline. We did not see clinically meaningful changes in N-terminal pro b-type natriuretic peptide (NT-proBNP). The majority of Transition patients preferred the LIQ861 dry-powder inhaler to the Tyvaso® Inhalation System.

In September 2019, we reported results from pharmacokinetic (PK) studies indicating that the 79.5 mcg dose of LIQ861 correlates with nine breaths of Tyvaso, the maximum recommended label dose of Tyvaso. To accurately characterize the pharmacokinetics of LIQ861, we conducted two PK studies in healthy volunteers. In the first of these studies, we observed unexpected variability in PK levels. Post-hoc analysis showed that plasma levels of treprostinil were tightly correlated to the LIQ861 dose delivered. Based upon additional non-clinical and clinical work, we believe the unexpected variability seen in this healthy volunteer study was due to an administration technique unique to the conduct of the study in the Phase 1 setting. In August 2019, we completed a second PK study in healthy volunteers in which the proper administration technique was followed. This study demonstrated significantly reduced variability, and we believe we have established comparative bioavailability to the reference listed drug.

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

We 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 70 patients have now received therapy with LIQ861 for more than two years. We have also observed that more than 70 percent of patients who have been enrolled in the INSPIRE and extension studies have received LIQ861 doses of 100 mcg or more.

Prior to submission of the NDA in January 2020, the FDA visited our manufacturing site in June 2019 as a qualifying participant in the Emerging Technology Program sponsored by the Center for Drug Evaluation and Research (CDER). The program supports innovation by providing a forum for sponsors to engage the FDA early in development and ensures consistency, continuity, and predictability in review and inspection. The program has allowed us to discuss PRINT® technology with Emerging Technology Team members, including personnel who may be involved in the prior approval inspection (PAI) and review of the Chemistry Manufacturing Controls section of the NDA to support LIQ861.

The FDA communicated in August 2020 that inspections of two sites involved in the manufacturing of LIQ861, both of which are located in the United States, would be required before the FDA can approve the NDA for LIQ861. The FDA also informed us that because of restrictions on travel due to the COVID-19 pandemic, the FDA may be unable to conduct inspections of those two sites prior to the PDUFA date of November 24, 2020. In the CRL, the FDA reconfirmed the need to conduct on-site PAIs of two U.S. manufacturing facilities before our NDA can be approved, and noted it had been unable to conduct these inspections during the initial review cycle due to COVID-19 related travel restrictions.

In addition to the studies submitted in the NDA for FDA review, we are conducting a clinical study at certain investigational sites in France and Germany to characterize the hemodynamic dose-response relationship to LIQ861 (LTI-201). After pausing enrollment due to the COVID-19 pandemic in the second quarter of 2020, we resumed enrollment in September 2020 at sites in Germany as allowed by local regulatory authorities. French sites will remain closed and not reopen due to the COVID-19 pandemic.

We are considering conducting other clinical trials to generate additional data on LIQ861, including a clinical trial in pediatric patients. We will continue to conduct development work in support of potential approval and commercialization of LIQ861, including label and patient-use assessments.

LIQ865

LIQ865 is our proprietary injectable, sustained-release formulation of bupivacaine, a non-opioid pain medication. We have engineered the size and composition of the LIQ865 PRINT particles to release bupivacaine over three to five days through a single administration for the management of local post-operative pain after a surgical procedure. We completed a Phase 1a clinical trial of LIQ865 in Denmark in 2017 and a Phase 1b clinical trial in the United States in 2018.

We initiated Phase 2-enabling toxicology studies in 2019 to assess LIQ865 in multiple non-clinical tissue models. Results from a study to assess incision tensile strength after healing were acceptable and not statistically different from controls. A nonclinical study to examine soft tissue healing was also completed, and the results were acceptable and comparable to vehicle-treated, saline-treated, and Marcaine-treated sites. We believe this data supports progression to Phase 2 hernia repair studies.

In a toxicology study to assess bone fracture healing, we observed dose-dependent delayed healing at the two LIQ865 doses studied; however, there were no adverse effects noted on surrounding soft tissues. We have completed an additional non-Good Laboratory Practice (GLP) study to investigate bone fracture healing using the same animal model with lower doses of LIQ865. This additional non-GLP study has established a no adverse effect level, or NOAEL, on bone healing and provides evidence that LIQ865 could proceed into a GLP toxicology study to support Phase 2 clinical activities.

Considering our focus in advancing our lead asset, LIQ861, we will seek to advance LIQ865 through a strategic collaboration with an external partner. We believe LIQ865, if successfully developed and approved, has the potential to provide significantly longer local post-operative pain relief compared to currently marketed formulations of bupivacaine.

Other Potential Applications of PRINT

We believe that our PRINT technology can be applied to a wide range of therapeutic areas, molecule types and routes of administration. We are currently focused on developing product candidates that we believe are eligible to be approved under the 505(b)(2) regulatory pathway, which can be capital efficient and potentially enable a shorter time to approval, as it allows us to rely in part on existing knowledge of the safety and efficacy of the relevant reference listed drugs to support our applications for approval in the United States. If any of our product candidates are approved, we intend to conduct initial commercial manufacturing of drug product using in-house capabilities, and to outsource packaging and distribution to third parties. Where appropriate, we may also transition the commercial manufacture of our drug product to third parties. In addition to developing our two product candidates, we have provided specific field-limited licenses to our PRINT technology to pharmaceutical companies seeking to develop their own potential drugs and biological therapies.

RareGen's Business

Overview

Pursuant to its Promotion Agreement with Sandoz, as described below, RareGen owns the exclusive rights to conduct any and all promotional and non-promotional activities to encourage the appropriate use of the first-to-file fully substitutable generic treprostinil injection for the treatment of patients with PAH in the United States. To that end, RareGen has a small, targeted sales force focused on PAH which it employs to conduct such marketing activities.

Treprostinil, Remodulin® and the Generic Version of Remodulin®

Treprostinil/Remodulin® Generally

Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function that is deficient in patients with PAH. Treprostinil can be administered as a continuous infusion through the use of an infusion pump or continuous intravenous infusion through the use of a central venous catheter. PAH is a rare disease, with an estimated prevalence in the United States of approximately 30,000 patients. Of such patients, approximately 3,000 patients are on Remodulin®. Remodulin® is treprostinil administered through subcutaneous or intravenous infusion and is marketed by United Therapeutics. Because parenteral agents are considered to offer the greatest efficacy, but also carry the most significant side effects related to infusion site pain, risk of infection, and significant limitations on quality of life, they are usually reserved for patients later in the course of the disease.

Treprostinil is currently sold mainly through specialty pharmacies, such as Accredo and CVS, and hospitals through traditional distributors. Treprostinil generally has a two-year shelf life, although Remodulin® has a four-year shelf life.

Remodulin® was approved by the FDA for subcutaneous and intravenous administration in 2002 and 2004, respectively, and has been sold commercially in the United States since 2002. United Therapeutics sells Remodulin® to specialty pharmaceutical distributors in the United States and to pharmaceutical distributors internationally. Remodulin® is indicated to treat patients with PAH, to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with functional class II-IV (moderate to severe) symptoms. Outside of the United States, Remodulin® is marketed and sold for the treatment of PAH throughout most of Europe, and various countries throughout Asia, the Middle East and South America.

Remodulin® has many qualities that make it an appealing alternative to other parenteral therapies for the treatment of PAH. Remodulin® is stable at room temperature, so it does not need to be cooled during infusion and patients do not need to use cooling packs or refrigeration to keep it stable. Treprostinil is highly soluble under certain circumstances and highly potent in concentrated solutions. This allows therapeutic concentrations of Remodulin® to be delivered at very low flow rates via miniaturized infusion pumps for both subcutaneous and intravenous infusion. Remodulin® can be continuously infused for up to 48 hours before refilling the external infusion pump. This profile contrasts favorably with non-treprostinil based, continuously infused prostacyclin therapies that are presently available — Flolan®, Veletri® and generic epoprostenol. Flolan® and generic epoprostenol are not stable at room temperature (and therefore require refrigeration or the use of cooling packs), but Veletri® may be stable at room temperature depending on its concentration. Flolan®, generic epoprostenol, and Veletri® have shorter half-lives than Remodulin, requiring mixing prior to pump refills. None of these other parenteral products may be administered via subcutaneous infusion, and therefore may only be delivered intravenously.

Patients must use external pumps manufactured by third parties to deliver Remodulin®. 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®.

There are serious side effects associated with Remodulin®. For example, when infused subcutaneously, Remodulin® causes varying degrees of infusion site pain and reaction (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.

It is estimated that branded sales of Remodulin® recorded approximately $466 million in U.S. revenue in 2019 (and approximately $587 million in total, including approximately $121 million of non-U.S. sales), of which approximately 50% of branded Remodulin® sales derived from intravenous administration and 50% of branded Remodulin® sales derived from subcutaneous administration. The majority of sales made pursuant to the Promotion Agreement are made through specialty pharmacies. In consideration for RareGen conducting certain responsibilities associated with the commercialization of the Product, RareGen receives a portion of the net profits generated from the sales of the Product.

Sandoz

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.

Generic Version of Remodulin®

In 2011, Sandoz filed an ANDA with the FDA to market a generic version of treprostinil for parenteral administration. Sandoz claimed that United Therapeutics' patents for Remodulin® were invalid, unenforceable and/or not infringed by its generic version of treprostinil. United Therapeutics then sued Sandoz for patent infringement and the parties settled that litigation in 2015. Pursuant to that settlement agreement, Sandoz was permitted to market its generic treprostinil alternative in June 2018 and United Therapeutics agreed to not interfere with Sandoz's efforts to launch its generic product. In August 2018, Sandoz partnered with RareGen to jointly market and commercialize its generic version of treprostinil pursuant to a Promotion Agreement, as described below. 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 launched the first-to-file fully substitutable generic treprostinil for parenteral administration in March 2019, followed by Teva Pharmaceuticals in October 2019. Par Pharmaceutical, Inc. launched a generic treprostinil for parenteral administration after receiving approval in September 2019, Dr. Reddy's Laboratories Inc.'s received approval in May 2020 for generic treprostinil for parenteral administration, and Alembic Pharmaceuticals Ltd's has settled with United Therapeutics in order to launch a generic treprostinil for parenteral administration, though it has not yet been approved to date. In March 2020, Teva obtained the rights to sell its generic product to CVS, which rights were previously held by RareGen and Sandoz. Currently, RareGen sells Sandoz's generic product mainly through Accredo. The generic product launched by Sandoz and RareGen is a fully substitutable generic for Remodulin®, with 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. This product is currently used only for intravenous administration.

RareGen and Sandoz allege 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, RareGen 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, RareGen and Sandoz, or the Term Sheet. Pursuant to the Term Sheet, Smiths Medical has paid $4.25 million to Sandoz and RareGen and the parties agree to negotiate in good faith to reduce the Term Sheet to a definitive settlement agreement.

Promotion Agreement

RareGen entered into a Promotion Agreement with Sandoz on August 1, 2018, as amended on May 8, 2020, or the Promotion Agreement, pursuant to which Sandoz engaged RareGen on an exclusive basis to promote the appropriate use of Sandoz's treprostinil, or the Product, for the treatment of PAH in the United States, including its commonwealths, territories, possessions and military bases, or the Territory. Under the Promotion Agreement,
RareGen also works jointly with Sandoz on commercial strategy for the Product and has responsibility for identifying, manufacturing and developing medical devices, including pumps and cartridges, that may be used to administer the Product. Sandoz retains all rights in and to the Product. Sandoz is the holder of the ANDA for the Product. As the ANDA holder, Sandoz maintains responsibility for compliance with FDA regulatory and healthcare laws including any regulatory communications with the FDA or any other regulatory authorities as it pertains to, for example, reporting obligations for the ANDA, maintaining regulatory approvals, inspections, and meeting all submission requirements for the product label and for promotional labeling materials at the time of initial dissemination.

Under the Promotion Agreement, Sandoz retains responsibility for: the specifications, manufacture and supply, distribution and future development of treprostinil; regulatory submission and interactions with the FDA pertaining to treprostinil, including maintaining all necessary regulatory approvals; reporting to the FDA or other regulatory authorities on matters relating to manufacturing, sale or promotion, such as any safety events involving treprostinil; internally reviewing and, as it determines appropriate, approving promotional materials developed by RareGen, and making submissions to the FDA's Office of Prescription Drug Promotion; handling safety activities including adverse event reporting, and initiating and managing any recalls of treprostinil.

RareGen's activities and obligations related to regulatory matters conducted under the Promotion Agreement include: promotional and non-promotional activities, including sales and marketing activities for treprostinil, and engagement of healthcare professionals for advisory boards; developing, with prior written approval from Sandoz, marketing and educational materials consistent with FDA approved labeling and applicable laws; notifying Sandoz of notices from governmental authorities about adverse event reports or regulatory inquiries related to the safety of treprostinil, product complaints or alleged defects, unsolicited requests for off-label medical information; providing certain data and information to Sandoz in order to fulfill its transparency and reporting obligations under the Physician Payment Sunshine Act; complying with applicable laws relevant to the activities conducted under the Promotion Agreement; establishing a compliance program and mechanism for disclosure of any violations of RareGen policies and procedures and submission of an annual report and certification to Sandoz of its compliance activities; and managing, with oversight and participation from Sandoz, negotiations and arrangements for managed care activities.

The Promotion Agreement, unless earlier terminated, initially extends until the eight (8) year anniversary of the first commercial sale of the Product by Sandoz, which occurred on or about March 25, 2019. The Promotion Agreement automatically renews for successive two-year terms unless earlier terminated.

RareGen paid Sandoz an initial payment of $10 million on August 1, 2018 and, upon the successful quality release by Sandoz of 9,000 units of the Product on August 3, 2018, RareGen paid Sandoz an additional $10 million as further consideration for the right to conduct the activities as contemplated in the Promotion Agreement and to receive a portion of the "Net Profits" (as defined below). The portion of Net Profits are allocated to RareGen as follows: (i) for that portion of aggregate Net Profits less than or equal to $500 million, RareGen shall receive between 50-80% of all such Net Profits; and (ii) for that portion of aggregate Net Profits greater than $500 million, RareGen shall receive 75% of all such Net Profits.

"Net Profits" are calculated based on net sales of the Product less (i) certain manufacturing costs incurred by Sandoz or its affiliates or any third party, if applicable, (ii) certain write-offs resulting from or relating to unsold and expired Products or components, (iii) costs associated with patient starter kits and (iv) certain other fees, charges and expenses charged by customers. RareGen also has the right to inspect and audit the records and books of account maintained by Sandoz, or any affiliate, as applicable, with respect to Net Profits and related factors.

RareGen also is required to use good faith efforts to bring to market 3ml cartridges for use in a Smiths Medical CADD-MS® 3 (MS-3) ambulatory infusion pump with treprostinil, or the Cartridges, and to market and make the Cartridges available for use with the Product. Upon termination of the Promotion Agreement, Sandoz may make and market the Cartridges pursuant to a license agreement as negotiated between RareGen and Sandoz in good faith.

The Promotion Agreement required the formation of a joint steering committee, or JSC, which meets quarterly and consists of three representatives from each of RareGen and Sandoz. The purpose and responsibilities of the JSC include: (i) reviewing and approving updates or amendments to the "RareGen Activity Plan and Budget" (as defined in the Promotion Agreement); (ii) planning and implementating RareGen promotional activities; (iii) coordinating and implementing commercialization strategy; (iv) discussing the forecasting, procurement and manufacture of the Product and constituent parts; and (v) discussing status and terms of agreements with customers.

RareGen and Sandoz may terminate the Promotion Agreement for cause upon a number of customary events, such as a material breach of the Promotion Agreement that remains uncured, complete withdrawal of marketing approval of the Product or upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings with respect to the other party. Further, either party may terminate the Promotion Agreement upon written notice to the other party at any time after the initial eight (8) year term in the event Sandoz is then procuring 100% of its supply of Product from a single third party upon (a) expiration of the supply agreement with such third party and (b) Sandoz's failure, after exercise of commercially reasonable efforts, to secure continued supply of the Product from such third party or other third parties within 12 months of the termination of such supply agreement. RareGen and Sandoz also each have a right to terminate the Promotion Agreement on not more than 90 days' written notice in the event that Net Profits in the last calendar year are less than $5 million.

Sandoz may terminate the Promotion Agreement on not more than 90 days' written notice after the conclusion of any full 12-month calendar year in the event that Net Profits in such calendar year are less than or equal to 10% of the net sales in such calendar year; *provided*, *however*, that Sandoz may not terminate the Promotion Agreement in such instance unless and until (i) aggregate amounts received by RareGen under the sharing of Net Profits have reached $32.5 million, or (ii) both (x) Net Profits or the profit margin were adversely affected in such calendar year by any temporary event or circumstance and (z) the JSC makes a determination that such profit margin deficiency is not likely to continue in the subsequent calendar year. Sandoz may also terminate the Promotion Agreement upon a change of control of RareGen.

RareGen may terminate the Promotion Agreement on not more than 90 days' written notice after the conclusion of any full 12-month calendar year in the event that RareGen's share of the Net Profits in such calendar year are less than or equal to RareGen's operating expenses relating to the Product for such calendar year; *provided*, *however*, that RareGen may not terminate the Promotion Agreement in such instance unless and until (i) aggregate amounts received by Sandoz under the share of Net Profits have reached $28.125 million, or (ii) both (x) Net Profits or its operating expenses relating to the Product were adversely affected in such calendar year by a temporary event or circumstance and (z) the JSC makes a determination that RareGen's share of the Net Profits is not likely to continue to be less than its operating expenses relating to the Product in the subsequent calendar year.

Pursuant to the terms of the Promotion Agreement, Sandoz and RareGen also entered into a pharmacovigilance agreement on January 9, 2019, or the Pharmacovigilance Agreement. Under the Promotion Agreement, Sandoz is responsible for all pharmacovigilance activities regarding the Product while RareGen's sole obligations related to pharmacovigilance is to notify Sandoz in the event that it receives safety information regarding the Product or information regarding any safety-related regulatory request or inquiry. The Pharmacovigilance Agreement establishes the procedures and guidelines that RareGen must follow when fulfilling its pharmacovigilance notification responsibilities.

Joint Development Agreement

Pursuant to a Joint Development Agreement, dated May 6, 2019, by and between RareGen and Carelife USA Inc., or Carelife, RareGen has engaged Carelife to perform certain development and manufacturing services, and to furnish finished cartridges when ready for commercial sale. Currently, RareGen is working with Carelife to develop a medication cartridge for use with CADD-MS® 3 (MS-3) ambulatory infusion pumps. Pursuant to the Joint Development Agreement, Carelife or an affiliate of Carelife will manufacture the medication cartridge for use with CADD-MS® 3 ambulatory infusion pumps that is currently under development by RareGen and Carelife. Such manufacturer will then sell cartridges to a distributor who will import the cartridges into the United States and sell them to specialty pharmacies and other customers. It is contemplated that RareGen will only receive a commission or fee on sales of the cartridges to the specialty pharmacies and other customers. The amount of RareGen's fee is to be negotiated. All other amounts received with respect to the manufacture and sale of such cartridges will be paid to the manufacturer, distributor and/or other third parties.

Each party is responsible for providing the necessary systems, personnel and materials to perform the tasks assigned to it according to the terms of the Joint Development Agreement. Additionally, RareGen is responsible for (i) costs and expenses related to the production of product molds, and (ii) third party costs and expenses relating to testing of any products manufactured by Carelife in accordance with the Joint Development Agreement. RareGen retains all intellectual property and technology created pursuant to the Joint Development Agreement.

The initial term of the Joint Development Agreement expires on May 6, 2027, and RareGen may terminate at any time upon 30 days' prior written notice.

RISK FACTORS

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

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

- Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.
- We have a history of losses, have not commenced commercial operations to date and our future profitability is uncertain.
- We are primarily dependent on the success of our lead product candidate, LIQ861, for which we filed an NDA with, and recently received a CRL from, the FDA, and to a lesser degree, LIQ865, which is still in clinical development, and these product candidates 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.
- We may not achieve the benefits expected from the acquisition of RareGen, LLC, or RareGen, by way of merger, or the Merger Transaction, pursuant to that certain Agreement and Plan of Merger, dated as of June 29, 2020, by and among our company, Liquidia Technologies, RareGen and certain other parties thereto, or the Merger Agreement, which may harm our business and could result in the loss of key suppliers, licensees, collaborators, business partners and personnel.
- RareGen does not hold the FDA regulatory approval for the Product and is dependent on Sandoz to manufacture and supply the Product in compliance with FDA requirements, and is more broadly dependent on Sandoz's FDA and healthcare compliance relative to the Product.
- RareGen's ability to sell the Product is 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.
- 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 and LIQ865 or for which there may be a greater likelihood of success.
- We face significant competition from large pharmaceutical companies, among others, and our operating results will suffer if we are unable to compete effectively.
- Our credit facility with Pacific Western Bank, or PWB, contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in PWB 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 the subject of FDA manufacturing inspections, 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 or enforce our intellectual property rights, 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 2019 assessment of the effectiveness of internal control over financial reporting, or ICFR, indicate that we have multiple material weaknesses.
- Our stockholders may not realize a benefit from the Merger Transaction commensurate with the ownership dilution they will experience in connection with the Merger Transaction.
- Our internal financial forecasts regarding RareGen may not prove accurate.

Prospective investors should carefully consider the risks described in this section, together with all of the other information in this Registration Statement on Form S-3. These risks may not be the only risks we face but are risks we believe may be material at this time. Additional risks and uncertainties that we do not yet know of, or that we currently think are immaterial, may also impair our business operations or financial results. If any of the events or circumstances described in this section occur, our business, financial condition or results of operations and the trading price of our securities could decline. Investors and prospective investors should consider these risks, the information contained under the heading "Cautionary Note Regarding Forward-Looking Statements" and the risks described elsewhere in this Registration Statement on Form S-3 before deciding whether to invest in our securities. We may update these risk factors in our periodic and other filings with the SEC.

Risks Related to our Financial Position and Need for Additional Capital

Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.

Our consolidated financial statements for the nine months ended September 30, 2020 include a statement that our recurring losses and cash outflows from operations, our accumulated deficit and our debt maturing within twelve months raise substantial doubt about our ability to continue as a going concern. As of September 30, 2020, we had $79.6 million of cash. We believe that our existing cash will enable us to fund our operating expenses and capital expenditure requirements, make payments of interest and principal on our term loan facility with Pacific Western Bank, or PWB, and remain in compliance with the minimum cash covenant of $8.5 million pursuant to this term loan facility, into the first quarter of 2022. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If we are unable to obtain sufficient funding or execute on strategic initiatives to generate sufficient cash, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. Future financial statements may also include statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

We have a history of losses, have not commenced commercial operations to date and our future profitability is uncertain.

We have incurred net losses of $43.7 million during the nine months ended September 30, 2020 and $47.6 million, $53.1 million and $29.2 million during the years ended December 31, 2019, 2018 and 2017, respectively. We also had negative operating cash flows for each of these periods. As of September 30, 2020, we had an accumulated deficit of $258.9 million.

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

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 and LIQ865 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 Pacific Western Bank, or PWB, contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in PWB 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 amended and restated loan and security agreement dated as of October 26, 2018, as amended, or the A&R LSA, with PWB, pursuant to which PWB extended a $16.0 million term loan facility to us, of which $11.0 million was received in October 2018 in an initial tranche and $5.0 million was received in May 2019, we may not, among others, without the prior written consent of PWB, (a) pay any dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock except in certain prescribed circumstances, (b) create, incur, assume, guarantee or be or remain liable with respect to any indebtedness except certain permitted indebtedness or prepay any indebtedness, (c) replace or suffer the departure of our Chief Executive Officer or Chief Financial Officer without delivering written notification to PWB within ten days of such change or (d) suffer a change on our board of directors, or Board, which results in the failure of at least one partner of Canaan Partners or their respective affiliates to serve as a voting member, without having used best efforts to deliver at least 15 days' prior written notification to PWB. Our facility with PWB is collateralized by all of our assets excluding our intellectual property, on which we have granted a negative pledge.

We have, in the past, breached multiple covenants in our loan and security agreement dated as of January 6, 2016, as amended, with PWB related to cash levels, reporting requirements and required periodic deliverables to PWB, but have obtained waivers from PWB in relation to all such breaches. 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 our facility agreements, giving lenders the right to require us to repay the then outstanding debt immediately, and the lenders 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. A breach of covenants in the A&R LSA and the acceleration of our repayment obligations by PWB could have a material adverse effect on our business, financial condition, results of operations and prospects.

Although we have historically depended on GlaxoSmithKline plc, or GSK, for a significant portion of our revenue, we do not expect to receive any additional revenue from our GSK collaboration.

We are party to a licensing agreement with GSK pursuant to which GSK has exercised an option to exclusively license our PRINT technology for applications in certain inhaled therapies, or an Inhaled Collaboration and Option Agreement, or the GSK ICO Agreement. We previously entered into a separate licensing agreement with GSK relating to the field of vaccines, which lapsed in April 2016. We have historically received a significant portion of our revenue from GSK pursuant to these licensing agreements. We recorded no revenue attributable to our collaboration and licensing agreements with GSK during the nine months ended September 30, 2020. For the year ended December 31, 2019, our revenue attributable to our collaboration and licensing arrangements with GSK, which included a combination of billings for particle formulations, manufacturing, milestone payments and amortization of deferred revenue from up-front fees, accounted for 100% of our total revenue.

During the second quarter of 2019 we concluded that no further research and development services will be provided to GSK under the collaboration agreement and the earnings process related to the license fees previously received under the collaboration agreement has been completed under the proportional performance model. Therefore, the remaining deferred revenue of $8.1 million was recognized as revenue during the second quarter of 2019, and we do not expect to receive any additional revenue from GSK pursuant to our collaboration. Because GSK is no longer actively advancing any programs under our collaboration, we entered into the Third Amendment to the GSK ICO Agreement during the second quarter of 2019, pursuant to which we have the right to develop three products for delivery via inhalation, subject to specified milestone payments and royalties due to GSK. Additionally, under certain circumstances GSK has a right of first negotiation with respect to these programs. Although a large proportion of our revenue has historically been obtained from our collaboration with GSK, we do not expect this collaboration to continue. To that end, in January 2020 we notified GSK of our intent to terminate the collaboration because we believe that GSK's inactivity with respect to the collaboration constitutes a material breach and GSK has rebutted our notice of termination. We are currently attempting to resolve the dispute with GSK pursuant to the terms of the GSK ICO Agreement.

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

We expect to use the net proceeds of our July 2020 public offering and prior public and private equity offerings for ongoing commercial development of LIQ861, for continued development of LIQ865 and for general corporate purposes. We do not expect to use any material proceeds from prior offerings to fund the operations of RareGen. 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, or the Code, if a corporation undergoes an "ownership change", generally defined as a greater than 50.0% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. With our July 2020 equity offering, our December 2019 private placement, issuances under Liquidia Technologies' ATM facility, our March 2019 follow-on equity offering and our July 2018 initial public offering, as well as other past transactions, we believe that we have already triggered an "ownership change" limitation, or will likely trigger an "ownership change" following the consummation of the Merger Transaction. 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.

Liquidia Technologies is a late-stage clinical biopharmaceutical company with no approved products and no historical product revenue, which may make it difficult for you to evaluate our business, financial condition and prospects.

Liquidia Technologies is a late-stage clinical biopharmaceutical company with no history of commercial operations upon which you can evaluate our prospects. Drug product development involves a substantial degree of uncertainty. Our operations to date have been limited to 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 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.

The TCJA could adversely affect our business and financial condition.

In December 2017, the Tax Cuts and Jobs Act of 2017, or the TCJA, was enacted into law. The TCJA includes significant changes to the U.S. corporate income tax system, including a permanent reduction in the corporate income tax rate from 35% to 21%, limitations on the deductibility of interest expense and executive compensation and the transition of U.S. international taxation from a worldwide system to a territorial tax system. For taxpayers with revenue over a certain threshold, the TCJA also limits interest expense deductions to 30% of taxable income before interest, depreciation and amortization from 2018 to 2021 and then taxable income before interest thereafter. The TCJA permits disallowed interest expense to be carried forward indefinitely. We calculated our best estimate of the impact of the TCJA in our income tax provision for the year ended December 31, 2017 in accordance with our understanding of the TCJA and guidance available at the time. The overall impact of the TCJA resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of $14.1 million. We completed our accounting for the TCJA during the third quarter of 2018. No changes to the provisional amounts as of December 31, 2017 were recorded. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Risks Related to the Commercialization of our Product Candidates

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 FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or 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, or the '901 Patent, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", and U.S. Patent No. 9,593,066, or the '066 Patent", entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", both of which are owned by United Therapeutics. A notice of the paragraph IV certification was required to be provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for 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), or 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, 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, or the USPTO, issued U.S. Patent No. 10,716,793, or 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 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. We are required to make a certification with respect to the '793 Patent in our NDA for LIQ861. 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 on May 24, 2021 and set the trial to begin on March 28, 2022.

On March 30, 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board, or the PTAB, of the USPTO. One petition was for *inter partes* review of the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid, and a second petition 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. A final written decision determining the validity of the challenged claims of the '901 Patent is expected within 12 months from institution.

We face significant competition from large pharmaceutical companies, among others, 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 be more successful in commercializing their 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.

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.

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

- TreT, licensed from MannKind, by United Therapeutics, is currently in late-stage clinical development in the United States for the treatment of PAH. Under the license agreement, 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. In September, 2019, United Therapeutics commenced a clinical study (BREEZE) to evaluate the safety and pharmacokinetics of switching PAH patients from Tyvaso to TreT and announced that a second clinical study was recently completed to compare the pharmacokinetics of TreT to Tyvaso in healthy volunteers. United Therapeutics further reported that the two studies, if successful, are the only clinical studies necessary to support FDA approval.

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.

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.

In addition, we are also aware of several other agents currently in clinical development in the United States for the treatment of PAH, including those in development by Insmed, Inc. and Acceleron Pharma, Inc.

We expect LIQ865 to face competition from EXPAREL®, an existing injectable version of bupivacaine. The early success of EXPAREL may make it difficult for us to convince physicians, patients and other members of the medical community to accept and use LIQ865 over EXPAREL. Generic equivalents of EXPAREL may also enter the market following the expiry of EXPAREL's patent in 2021.

While EXPAREL is currently the only direct competitor to LIQ865 on the market, in October 2018 Heron Therapeutics, Inc., or Heron, announced the submission of its NDA to the FDA for HTX-011, an investigational long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the management of postoperative pain. HTX-011 was granted both breakthrough therapy and fast track designations from the FDA as well as priority review by the FDA. On May 1, 2019, Heron announced that it received a CRL for HTX-011 from the FDA. On October 1, 2019, Heron announced that it had resubmitted its NDA for HTX-011 to the FDA and expected a six-month review. On June 26, 2020, Heron announced that it received a CRL from the FDA for HTX-011. In addition to Heron, Durect Corporation and Innocoll Holdings plc each also have products in clinical development that are potential competitors to LIQ865.

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

If a competitor obtains orphan drug designation from the FDA for the same drug and same indication as we are seeking for a product candidate, and then obtains approval of that drug for that condition before we do, the resulting FDA exclusivity would significantly delay our ability to commercialize that product candidate. Similarly, if a competitor obtains marketing approval for a new condition of use that required new clinical investigations for support, the competitor may obtain three-year marketing exclusivity for that condition of use, and thereby delay our ability to receive marketing approval for that drug product for that condition of use by three years form the date of that approval.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition — generally a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA.

After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first applicant to receive FDA approval for a particular active ingredient to treat a particular disease or condition with orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product in that indication. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

During the exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease or condition, except in limited circumstances, such as if the second applicant demonstrates clinical superiority of its product to the product with orphan drug exclusivity through a demonstration of superior safety, superior efficacy or a major contribution to patient care, or if the manufacturer of the product with orphan exclusivity is not able to assure sufficient quantities of the product. "Same drug" means a drug that contains the same identity of the active moiety if it is a drug composed of small molecules, or of the principal molecular structural features if it is composed of macromolecules and is intended for the same use as a previously approved drug, except that if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug. Drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

The commercial success of our drug products depends on the availability and sufficiency of third-party payor coverage and reimbursement.

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, market acceptance of our drug products is dependent on the extent to which third-party coverage and reimbursement is available from government health administration authorities (including in connection with government healthcare programs, such as Medicare and Medicaid in the United States), private healthcare insurers and other healthcare funding organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Coverage decisions may not favor new drug products when more established or lower-cost therapeutic alternatives are already available. Even if we obtain coverage for a given drug product, the associated reimbursement rate may not be adequate to cover our costs, including research, development, intellectual property, manufacture, sale and distribution expenses, or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless reimbursement is adequate to cover all or a significant portion of the cost of our drug products.

Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly, which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products.

The market for our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Competition to be included in such formularies often leads to downward pricing pressures. In particular, third-party payors may refuse to include a particular drug in their formularies or otherwise restrict patient access to a drug when a less costly generic equivalent or other alternative is available. In particular, given that several therapeutically similar drug products to LIQ861, including inhaled, oral and parenteral prostacyclins, are available on the market, managed care organizations may minimize the utilization of a new to market product and accordingly, we expect that LIQ861, if and when approved, will operate in a highly cost-constrained environment. Similarly, as there are a number of generic and branded therapeutic alternatives to LIQ865 in the post-operative pain market, there is a significant risk that LIQ865 may not be placed on the formularies of key institutions and/or receive favorable reimbursement, if and when approved.

The U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drug products from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities will continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement for our drug products, the commercial success of our drug products may be greatly hindered and our financial condition and results of operations may 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.

The pharmaceutical industry is subject to rapid technological change, which could affect the commercial viability of our products.

The pharmaceutical industry is subject to rapid and significant technological change. Research, discoveries or inventions by others may result in medical insights or breakthroughs that render our products less competitive or even obsolete. Furthermore, there may be breakthroughs of new pharmaceutical technologies which may become superior to our PRINT technology that may result in the loss of our commercial advantage. Our future success will depend in part upon our ability to, among others:

- develop or license new technologies that address the changing needs of the medical community; and
- respond to technological advances and changing industry standards and practices in a cost-effective and timely manner.

Developing technology entails significant technical and business risks and substantial costs. We cannot assure you that we will be able to utilize new technologies effectively or that we will be able to adapt our existing technologies to changing industry standards in a timely or cost-effective manner, or at all. If we are unable to keep up with advancements in technology, our competitive position may suffer and our business and prospects may be materially and adversely affected.

The off-label use or misuse of our products may harm our image in the marketplace, result in injuries that lead to costly product liability suits, or result in costly investigations and regulatory agency sanctions under certain circumstances if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

We are developing LIQ861 for the treatment of PAH and LIQ865 for the treatment of local post-operative pain. If our product candidates receive marketing approval from the FDA for these specific indications, we may only promote or market our product candidates for their specifically approved indications and make promotional claims consistent with the FDA-required product labeling. We will train our marketing and sales force against promoting our product candidates for "off-label uses" that would be inconsistent with FDA law and guidance. With respect to whether communications are consistent with the FDA-required product labeling, we cannot predict whether the FDA will agree with our assessment. We also cannot prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products for uses for which they are not approved. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA determines that our promotional materials or training constitute promotion of an off-label or other improper use, it could request that we modify our training or promotional materials, or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment, refusal of government contracts, and the curtailment of our operations.

These regulations or codes may limit our ability to effectively market our products, or we could run afoul of the requirements imposed by these regulations, causing reputational harm. These regulations or codes may also impose potentially substantial costs on us.

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

Our business is exposed to the risk of product liability and other liability risks that are inherent in the development, manufacture, clinical testing and marketing of pharmaceutical products. These risks exist even if a product is approved for commercial sale by the FDA or comparable regulatory authorities in other countries and manufactured in licensed facilities. Our current product candidates, LIQ861 and LIQ865, 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.

If our product candidates are approved for commercialization outside of the United States, we may be exposed to a number of risks associated with international business operations.

If our product candidates are approved for commercialization outside of the United States, we may market our drug products ourselves, or we may enter into agreements with third parties to market the aforesaid drug products outside of the United States. In such event, we may be subject to risks related to international business operations, including, but not limited to:

- varying levels of protection for intellectual property rights;
- changes in tariffs and the imposition of trade barriers;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- compliance with tax, employment, immigration and labor laws in respect of employees living or traveling abroad;
- foreign tax laws;
- currency fluctuations; and
- business interruptions resulting from geopolitical actions, such as wars and terrorist attacks, among others, or global pandemics or natural disasters, such as fires, floods, earthquakes and hurricanes, among others.

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

We are primarily dependent on the success of our lead product candidate, LIQ861, for which we filed an NDA with, and recently received a CRL from, the FDA, and to a lesser degree, LIQ865, which is still in clinical development, and these product candidates 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 product sales. Our ability to generate revenue from product sales 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 candidates, LIQ861, a proprietary inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension, or PAH, and LIQ865, a sustained-release formulation of bupivacaine for the management of local post-operative pain. 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. Consistent with preliminary data presented in the second quarter of 2019, LIQ861 was observed to be well-tolerated and treatment-emergent adverse events, or 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. 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.

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%).

In August 2019, one of the clinical investigators in the INSPIRE study reassessed a serious adverse event, preliminarily identified as hypersensitivity pneumonitis, as being possibly related to LIQ861, whereas the clinical investigator had previously, in May and June 2019, characterized the event as not related to LIQ861. Based on the patient's medical history, two other potential alternative causes of this event noted by the clinical investigator, and the fact that the patient has been taking LIQ861 since October 2018, we do not agree with the clinical investigator's assessment. However, we reported the event to the FDA, as required, and we will continue to monitor and assess this event for any change.

In September 2019, we reported results from pharmacokinetic (PK) studies indicating that the 79.5 mcg dose of LIQ861 correlates with nine breaths of Tyvaso, the maximum recommended label dose of Tyvaso. To accurately characterize the pharmacokinetics of LIQ861, we conducted two PK studies in healthy volunteers. In the first of these studies, we observed unexpected variability in PK levels. Post-hoc analysis showed that plasma levels of treprostinil were tightly correlated to the LIQ861 dose delivered. Based upon additional non-clinical and clinical work, we believe the unexpected variability seen in this healthy volunteer study was due to an administration technique unique to the conduct of the study in the Phase 1 setting. In August 2019, we completed a second PK study in healthy volunteers in which the proper administration technique was followed. This study demonstrated significantly reduced variability, and we believe we have established comparative bioavailability to the reference listed drug.

We continued to treat patients who chose to remain on LIQ861 beyond the Month 2 timepoint of the primary endpoint. More than 80% of INSPIRE patients remained on study drug at Month 4 with no significant changes in safety or tolerability observed compared to Month 2. At the completion of the INSPIRE study, the patient with the longest duration of treatment had been on LIQ861 therapy for 18 months. 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. Currently, more than 70 patients have now received therapy with LIQ861 for more than two years. In addition, we are enrolling patients in a clinical study at certain investigational sites in Europe to characterize the hemodynamic dose-response relationship to LIQ861. Enrollment was paused in the second quarter 2020 due to concerns related to the COVID-19 pandemic, but has resumed in September 2020. We are also considering conducting other clinical trials to generate additional data on LIQ861, including a clinical trial in pediatric patients. We also continue to conduct development work in support of potential approval and commercialization of LIQ861, including label and patient-use assessments.

The FDA visited our manufacturing site in June 2019 as a qualifying participant in the Emerging Technology Program sponsored by the CDER. The program supports innovation by providing a forum for sponsors to engage FDA early in development and ensures consistency, continuity, and predictability in review and inspection. The program has allowed us to discuss PRINT® technology with Emerging Technology Team members, including personnel who would be involved in the PAI and review of the Chemistry Manufacturing Controls section of the NDA to support LIQ861.

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. We do not believe that the items raised in the CRL will be a barrier to the ultimate approval of LIQ861. The FDA also reconfirmed the need to conduct on-site pre-inspection approval, or 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. We believe that we can address the items raised in the CRL (through a resubmission) without delaying the otherwise projected launch timing of LIQ861 in the second half of 2022, subject to FDA approval.

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.

With respect to LIQ865, we initiated Phase 2-enabling toxicology studies in March 2019 in both soft tissue and bone models. The soft tissue toxicology study showed favorable results; however, our bone toxicology study showed delayed bone healing at the dose tested. We have completed an additional non-GLP study to investigate bone fracture healing using the same animal model with lower doses of LIQ865. This additional non-GLP study has established a NOAEL on bone healing and provides evidence that LIQ865 could proceed into a GLP toxicology study to support Phase 2 clinical activities. Considering our focus in advancing our lead asset, LIQ861, we will seek to advance LIQ865 through a strategic collaboration with an external partner. We cannot assure you that our toxicology studies or clinical trials, if commenced, will be successful or meet their endpoints, that the endpoints for any future Phase 3 trials that we may conduct will be sufficient to receive marketing approval, or that we will be successful in entering a strategic collaboration to further advance the program.

If we successfully complete the clinical development of LIQ861 and LIQ865, we cannot assure you that they will receive marketing approval. The FDA or comparable regulatory authorities in other countries may delay, limit or deny approval of our product candidates 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, or CMC, or other data and information, and the development and information may be time-consuming and expensive. Status as a combination product, as is the case for 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. Moreover, the applicable requirements for approval may differ from country to country.

If we successfully obtain marketing approval for LIQ861 and LIQ865, we cannot assure you that they will be commercialized in a timely manner or successfully, or at all. For example, LIQ861 and LIQ865 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 and LIQ865 will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such products, even if approved. Any delay or setback we face in the commercialization of LIQ861 or LIQ865 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 product candidates and as a result do not have a track record of successfully bringing product candidates to market. Furthermore, LIQ861 and LIQ865 have, to date, been tested only in relatively small study populations and, accordingly, the results from our earlier clinical trials may be less reliable than results achieved in larger clinical trials. 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 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 LIQ865, or any of our product candidates 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 or LIQ865. 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, or 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 and LIQ865, we may be required to terminate development of our only product candidates.

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

We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable regulatory authorities in other countries for any product candidate, and we cannot assure you that any of our product candidates will receive marketing approval. Filing an application and obtaining marketing approval for a pharmaceutical product candidate is an extensive, lengthy, expensive and inherently uncertain process, and 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 in other countries may refuse to file an NDA or similar drug approval filing if they deem the application to be incomplete;
- the FDA or comparable regulatory authorities in other countries may disagree with the number, design, size, conduct or statistical analysis of one or more of our clinical trials;
- 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 results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable regulatory authorities in other countries;
- the data collected from our clinical trials may not be sufficient to support the submission of an NDA or similar drug approval filing to the FDA or comparable regulatory authorities in other countries;
- the FDA or comparable regulatory authorities in other countries may disagree with our interpretation of data from our preclinical studies or clinical trials;
- our manufacturing processes and facilities have not been inspected by the FDA, and the FDA or comparable regulatory authorities in other countries may not ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers sufficiently demonstrate compliance with cGMP to support NDA approval;
- our product candidates may not meet the level of quality and control required by the FDA or comparable regulatory authorities in other countries;
- our product candidates may not demonstrate sufficient long-term stability to support an NDA filing or obtain approval, or the product shelf life may be limited by stability results;
- the FDA or comparable regulatory authorities in other countries may require development of a costly and extensive risk evaluation and mitigation strategy, or REMS, as a condition of approval;
- the success or further approval of competing products approved in indications similar to those of our product candidates may change the standards for approval of our product candidates in their proposed indications; and
- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our clinical data insufficient for approval.

In addition, the FDA or comparable regulatory authorities in other countries may, in their sole discretion, change their views in respect of regulatory pathways they had previously affirmed or clinical trial protocols to which they were previously not opposed. While we have consulted with the FDA on the appropriate regulatory pathway and clinical trial protocols for our product candidates, LIQ861 and LIQ865, we cannot assure you that the FDA will not revise its position significantly at a later date. In the event that this occurs, the clinical development and commercialization of our product candidates may be delayed or even derailed.

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 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.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon our development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Any serious adverse or undesirable side effects identified during the development of our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenue from their sale. In addition, if any of our product candidates receive regulatory approval and we or others later identify undesirable adverse effects caused by the product, we could face one or more of the following consequences:

- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication, or other safety labeling changes;
- regulatory authorities may require a REMS;
- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may seize the product;
- we may be required to change the way that the product is administered;
- we may be required to conduct additional clinical trials;
- we may be required to recall the product;
- we may be subject to litigation or product liability claims, fines, injunctions or criminal penalties; and
- our reputation may suffer.

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 all of our current product candidates. If we are unable to rely on the 505(b)(2) regulatory pathway to apply for marketing approval of our product candidates in the United States, seeking approval of these product candidates through the 505(b)(1) NDA pathway would require full reports of investigations of safety and effectiveness, and the process of obtaining marketing approval for our product candidates would likely be significantly longer and more costly.

We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505(b)(2) regulatory pathway, which permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us for a particular product candidate, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We plan to pursue this pathway for our current product candidates, LIQ861 and LIQ865, and have submitted a 505(b)(2) NDA for LIQ861. 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 FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, or the Orange Book, the 505(b)(2) applicant is required to make a claim after filing their 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, or GCP, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. The FDA must also be able to validate the data from the study through an onsite inspection if the agency deems it necessary. In addition, foreign clinical data submitted to support FDA applications should be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.

We conducted the early Phase 1a clinical trial of LIQ865 in Denmark, and not under an IND, we plan to conduct an additional clinical trial in Europe that explores the hemodynamic effects of LIQ861 in PAH patients when we are able to resume enrolling patients following the end of the COVID-19 pandemic, and we may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data, and in such event, we may be required to re-conduct relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.

Risks Related to the Business of RareGen

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

Sandoz holds the FDA approval (the ANDA) for and controls the Product and is responsible among other things for the compliant manufacture, distribution, labeling, and advertising of the Product. RareGen's role is one of a specialized service provider to Sandoz. As a result, RareGen is dependent on Sandoz to manufacture and supply the Product, and dependent on Sandoz for the continued FDA compliance of the Product. RareGen does not have control over Sandoz's compliance with laws and regulations applicable to drug manufacturers and ANDA holders (for example, applicable current good manufacturing practices, or 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, RareGen has 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 the Product 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 the Product or identifies safety or efficacy concerns related to the Product, or if Sandoz otherwise is unable to comply with applicable laws, regulations and standards, Sandoz's ability to manufacture, sell and supply the Product could be limited, which would cause an adverse effect on RareGen's business, financial condition and results of operations. Sandoz's ability to consistently manufacture and supply the Product 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. RareGen's 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 the Product, including in the event that the Product expires prior to sale. Currently, the Product expires 24 months after the date of manufacture. If Sandoz's manufacturing costs increase, or its ability to sell the Product within 24 months of the date of manufacture is interrupted, there would be an adverse effect on RareGen's business, financial condition and results of operations.

RareGen's ability to sell the Product is 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.

RareGen's ability to sell the Product is dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third-party payors. If the Product does not achieve an adequate level of acceptance, RareGen may not generate sufficient revenue to remain profitable.

At the same time, arrangements with healthcare providers, physicians, third-party payors and customers, and RareGen's sales, marketing and educational activities, may expose it 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 the Product will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- RareGen's ability to offer the Product for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- whether the Product may be administered subcutaneously;
- 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;
- RareGen's ability to hire and retain sales and marketing personnel and their ability to support Sandoz under RareGen's 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 the Product;
- the prevalence and severity of any side effects;
- any restrictions on the use of the Product together with other medications; and
- the services provided by specialty pharmacies related to use of the Product.

RareGen's business may also be impacted by the need to maintain compliant operations (including oversight and monitoring of personnel and their activities) in relation to interactions with the persons and parties noted above, relative to FDA and healthcare law requirements.

RareGen faces substantial competition, which may result in a smaller than expected commercial opportunity.

RareGen faces substantial competition. 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.'s received approval in May 2020 for generic treprostinil for parenteral administration, and Alembic Pharmaceuticals Ltd's has settled with United Therapeutics in order to launch a generic treprostinil for parenteral administration, though it has not yet been approved to date. Such increased competition may result in a smaller than expected commercial opportunity for RareGen.

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 RareGen's competitors. RareGen's ability to sell the Product and earn revenue is affected by the number of companies selling competitive products, including new market entrants, and the timing of their approvals.

Furthermore, 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 the Product.

Many of the companies against which RareGen competes, or against which RareGen may compete in the future, including United Therapeutics, have significantly greater financial resources than does RareGen.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors may also compete with RareGen in recruiting and retaining qualified sales personnel.

RareGen's future success depends on its ability to attract, retain and motivate qualified sales personnel, with experience specific to the pharmaceutical industry and relevant disease area.

RareGen is highly dependent on the expertise of its sales personnel. Each member of its sales team may terminate his or her employment with RareGen at any time. RareGen does not maintain "key person" insurance for any of its employees.

Recruiting and retaining qualified sales and marketing personnel is critical to RareGen's success. The loss of the services of members of RareGen's sales team could seriously harm its ability to successfully implement its business strategy. Furthermore, replacing sales personnel may be difficult and may take an extended period of time because of the limited number of individuals in RareGen's industry with the breadth of skills and experience required to successfully sell and market products such as treprostinil. Competition to hire from this limited pool is intense, and RareGen may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If RareGen is unable to continue to attract and retain high quality sales personnel, its ability to pursue its growth strategy will be limited.

Medical devices, which RareGen does not control, are necessary for the administration of the Product.

In order for the Product to be administered with patients, patients must use certain other medical equipment, including pumps, cartridges and infusion sets. RareGen does 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. RareGen's 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, RareGen's sales may be adversely impacted.

RareGen is seeking to work with third parties to develop or procure pumps and cartridges that can be used to administer the Product. Such pumps and cartridges may require FDA 510(k) clearance before they can be sold. There is no guarantee that RareGen or a third party will receive FDA 510(k) clearance. Failure by RareGen 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 the Product.

RareGen must comply with various laws in jurisdictions around the world that restrict certain marketing practices in the pharmaceutical and medical device industries. Failure to comply with such laws could result in penalties and have a material adverse effect on RareGen's business, financial condition and results of operations.

RareGen's business activities may be subject to challenge under laws in jurisdictions around the world restricting particular marketing practices, such as among others, anti-kickback and various false claim statutes, the Foreign Corrupt Practices Act and the United Kingdom Bribery Act. Any penalties imposed upon RareGen for failure to comply could have a material adverse effect on its business and financial condition.

In the United States, the Federal Anti-Kickback Statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving compensation to induce, or in return for, the purchase, lease, order or arranging the purchase, lease or order of any health care product or service reimbursable under any federally financed health-care program. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, formulary managers, patients, and others.

The exemptions and safe harbors under this statute may be narrow, and practices that involve compensation may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

The Federal False Claims Act, as amended by the PPACA, prohibits any person from presenting or causing to be presented a false or fraudulent claim or making or causing a false statement material to a false or fraudulent claim. For example, several pharmaceutical and health care companies have been investigated under this law for allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the free product. Other companies have been prosecuted for causing false claims to be submitted because of these companies' marketing of a product for unapproved, or "off-label", and non-reimbursable uses. Potential liability under the Federal False Claims Act includes mandatory treble damages and significant per-claim penalties. The majority of states also have statutes similar to the Federal Anti-Kickback Statute and the Federal False Claims Act. Sanctions under these federal and state laws may include treble civil monetary penalties, exclusion of a manufacturer's product from reimbursement under state government programs, debarment, criminal fines, additional reporting requirements and regulatory oversight and imprisonment.

Although federal enforcement is most commonly directed toward those actors who file or cause to be filed claims for reimbursement, both parties to certain sales and marketing transactions are equally liable. Enforcement trends change periodically, and RareGen may receive governmental inquiries into the nature of its sales and marketing arrangements. Such investigations or reviews could result in punitive enforcement including fines and penalties, reputational damage, and market loss.

The U.S. Physician Payments Sunshine Act established reporting requirements for certain pharmaceutical, biologic and device manufacturers, or "applicable manufacturers", regarding direct and indirect payments or other transfers of value made to physicians and teaching hospitals, as well as reporting of investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties, which may increase significantly for "knowing failures." In 2022, the Sunshine Act will be extended to payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). These laws are relevant to companies providing sales and marketing services on behalf of "applicable manufacturers," for example, resulting in the need to track and report certain information to the applicable manufacturer, to allow the applicable manufacturer to meet its obligation under the law. In addition, Section 6004 of the ACA requires annual reporting of information about drug samples that manufacturers and authorized distributors provide to healthcare providers. A number of states have also implemented laws relevant to the licensure or registration of pharmaceutical sales representatives, as well as other laws addressing compliance program expectations, transparency regarding sales and marketing activities and prohibitions or restrictions on certain financial arrangements or activities. Tracking, assessing, and complying with laws which may apply on a state-by-state basis can be challenging and time consuming.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that certain business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that 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.

Government healthcare reform and other reforms could adversely affect RareGen's revenue, costs and results of operations.

RareGen provides services within the pharmaceutical industry, which is highly regulated by federally funded healthcare programs and, therefore, subject to those programs' controls of pricing, rebates, and marketing. In recent years, there have been numerous initiatives on the federal and state levels in the United States for comprehensive reforms affecting the marketing, payment for, the availability of and reimbursement for healthcare services. For example, Congress and many states have proposed legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing by requiring drug manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. At least five relevant bills have been introduced in Congress since 2019, and H.R. 3 passed in the House. Current and future U.S. legislative healthcare reforms and the recent Executive Orders issued in July 2020 by the President on drug pricing, may result in price and marketing controls and other restrictions for any approved products, if covered, and could adversely impact RareGen's business.

In addition, rebate policies could allow state Medicaid programs to request additional supplemental rebates on the Product as a result of the increase in the federal base Medicaid rebate. Private insurers could also use the enactment of any federal policies to exert pricing pressure on the Product, and to the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules.

The COVID-19 pandemic is affecting the delivery model and coverage parameters for some prescription drugs. In April 2020, HHS published an interim final rule that expanded the permissible circumstances for administering some drugs to increase access to care as patients avoid office visits. In some instances, coverage for Part B drugs could potentially be shifted from Part D, which affects reimbursement rates and copayment obligations. Similarly, HPMS Memo (Mar. 10, 2020) authorizes Part D sponsors to loosen refill restrictions, allow reimbursement for out-of-network pharmacies, permit home and mail delivery of prescription drugs, and waive prior authorization requirements. The effect of these waivers on pricing, distribution, and sales volume is still uncertain. It is unknown how long the emergency and pandemic declarations will remain in effect, whether all of these measures will be extended past the current emergency, or whether COVID-19 will result in any other material or long-term effects on the market.

The Patient Protection and Affordable Care Act of 2010 (Pub.L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (Pub.L 111-152, 124 Stat. 1029), as amended and collectively known as the ACA, is a broad measure intended to expand health care coverage within the United States and introduce additional measures to protect the integrity of federally funded health programs. The 21st Century Cures Act of 2016 (Pub.L. 114-255), meanwhile, contains a wide range of provisions designed to promote clinical research and streamline and expedite the FDA review and approval process. The reforms imposed by these laws significantly impact the pharmaceutical industry. The ACA, however, remains subject to pending legal and constitutional challenges in the United States Supreme Court (*California, et al v. Texas, et al*, Cause No. 19-840). The full effects of the ACA and the 21st Century Cures Act may be unknown until all outstanding legal issues are resolved, the statutory provisions are fully implemented, and CMS, the FDA, and other federal and state agencies issue final applicable regulations or guidance. RareGen may also face uncertainties as a result of federal executive, Congressional and administrative efforts to repeal, substantially modify or invalidate some or all of the relevant provisions of the ACA.

Moreover, in the coming years, additional changes could be made to governmental health care programs or FDA regulations that could significantly impact the success of the Product. There is no assurance that the ACA and other laws, as currently enacted or as amended in the future, will not adversely affect RareGen's business and financial results, and RareGen cannot predict how future federal or state legislative, regulatory, or administrative changes related to healthcare reform will affect its business. The future stability of applicable laws and regulations, and the resulting impact on RareGen's business is thus uncertain and could be material.

The successful commercialization of the Product depends on a variety of factors, including the extent to which drug prices are scrutinized and potentially limited, and governmental authorities and health insurers establish adequate coverage and reimbursement levels for the Product.

In recent years, there have been numerous initiatives on the federal and state levels in the United States for a broad range of reforms regarding the pricing of pharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, increasing transparency regarding pricing, and otherwise addressing government control and other changes to the healthcare system in the United States. Specifically, there have been several United States Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

Some states have implemented, and other states are considering, pharmaceutical price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices. Efforts by government officials or legislators to implement measures to regulate prices or payments for pharmaceutical products, including legislation on drug importation, could adversely affect our business if implemented.

Successful sales of the Product depend, in part, on the extent to which coverage and reimbursement for the Product is available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of drug products and require increasing levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. If the Product is unable to obtain coverage and adequate levels of reimbursement from third party payors, the commercial success and marketability will be negatively and materially impacted.

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. If our supplier is unable to supply treprostinil to us in the quantities we require, or at all, or otherwise default 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. Furthermore, LIQ861 is administered using the RS00 Model 8 DPI, or dry powder inhaler, which is manufactured by Plastiape S.p.A., or Plastiape, which is located in Italy. We also rely on a sole supplier for encapsulation and packaging services. We purchase treprostinil, our DPI supply and encapsulation and packaging services pursuant to purchase orders and do not have long-term contracts with these suppliers. In the event of any prolonged disruption to our supply of treprostinil, the manufacture and supply of RS00 Model 8 DPI or encapsulation and packaging services, 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, or coronavirus, was reported to have surfaced in Wuhan, China and has become a global pandemic as of the date of this Registration Statement on Form S-3. The full impact of the coronavirus is unknown and rapidly evolving. 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 pre-approval inspections 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. 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 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, as the holder of such patents, asserted a patent challenge directed to the Orange Book listed patents 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, 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 it is 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. If any of our patents are narrowed or invalidated, our business and prospects may be materially and adversely affected. 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, contract research organizations, or CROs, contract manufacturing organizations, or 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 The University of North Carolina at Chapel Hill, or UNC, under the UNC Amended and Restated License Agreement, dated as of December 15, 2008, as amended, or 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 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 the subject of FDA manufacturing inspections, 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 and LIQ865. To our knowledge, no regulatory authority has granted approval to market or commercialize drugs made using our PRINT technology. Further, manufacturing facilities and processes utilizing our PRINT technology have not been the subject of FDA manufacturing inspections. 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. 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

An active trading market for our common stock may not be sustainable. If an active trading market is not sustained, our ability to raise capital in the future may be impaired.

We completed our initial public offering in July 2018. Prior to this time, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Capital Market, an active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell shares of our common stock without depressing the market price for the shares or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

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.

Upon consummation of the Merger Transaction, we issued to RareGen's members an aggregate of 5,550,000 shares of our common stock. Additionally, 6,166,666 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 RareGen members. In addition, we may issue up to 2,708,333 shares of HoldCo common stock in 2022, which are referred to in the Merger Agreement as "Net Sales Earnout Shares", if RareGen 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 RareGen members on the closing date of the Merger Transaction are subject to a six-month lock-up. 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 November 30, 2020, 43,335,808 shares of our common stock were outstanding, of which 33,228,796 shares of common stock, or 76.7% of our outstanding shares as of November 30, 2020, are freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144. The resale of the remaining 10,107,012 shares held by our stockholders as of November 30, 2020 is currently prohibited or otherwise restricted as a result of securities law provisions. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

As of November 30, 2020, the holders of 7,437,937 shares, or 17.2%, of our outstanding shares as of November 30, 2020, have rights, subject to some conditions, to require us to file registration statements, including this Registration Statement on Form S-3, 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 clinical trials of LIQ861, LIQ865 or any product candidate we may develop, or those of our competitors;
- the success of Sandoz's generic version of Remodulin® to which RareGen has commercial rights to pursuant to that certain Promotion Agreement between Sandoz and RareGen;
- 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 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 31.8% of our capital stock as of November 30, 2020, of which 16.6% are beneficially owned by our executive officers and directors. 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 2019 assessment of the effectiveness of internal control over financial reporting, or ICFR, indicate that we have multiple material weaknesses.

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

As required by the Sarbanes Oxley Act 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 for the fiscal year ended December 31, 2019. In connection with the assessment of the effectiveness of our ICFR, our management identified the following material weaknesses that existed as of December 31, 2019:

During 2019, we experienced significant turnover in finance personnel that reduced the complement and skill of the resources within the Company. As a result, we did not maintain an effective control environment as we lacked a sufficient complement of resources with an appropriate level of knowledge, experience and training to design, maintain and monitor our ICFR commensurate with our financial reporting requirements. As a result, this material weakness contributed to the following material weaknesses:

- We did not design and maintain controls to ensure adequate segregation of duties within our financial reporting function, including the preparation and review of journal entries. Specifically, some key accounting personnel had the ability to both prepare and post journal entries without an independent review by someone without the ability to prepare and post journal entries.

- We did not design and maintain effective controls over certain information technology general controls for information systems that are relevant to the preparation of our consolidated financial statements. Specifically, we did not design and maintain effective user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications and data to appropriate Company personnel.

These material weaknesses did not result in a material misstatement of the annual or interim financial statements. However, these material weaknesses could result in a misstatement of the relevant account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

Additionally, we could be subject to regulatory scrutiny, a loss of public and investor confidence, and to litigation from investors and stockholders, all of which could have a material adverse effect on our business and the trading price of our shares. Subsequent to our December 31, 2019 year end, we began taking a number of actions, including designing and implementing new controls and revising existing controls, in order to remediate the material weaknesses described above. See Part I, Item 4. Controls and Procedures in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 filed on November 6, 2020. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could result in charges by the SEC with violating the books and records and internal control provisions of the federal securities laws which may result in penalties and fines to our company, directors and officers, and also could restrict our future access to the capital markets.

For as long as we are an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to an additional four years. An independent assessment of the effectiveness of our internal controls could detect additional problems that our management’s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur additional remediation expenses.

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, or the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any stockholder owning in excess of 15% of our outstanding stock for a period of three years following the date on which the stockholder obtained such 15% equity interest in us.

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

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

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

Our certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; or (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 A&R LSA with PWB 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

We may acquire businesses, products or product candidates, or form strategic alliances or create joint ventures, in the future, and we may not realize the benefits of such transactions.

We may acquire additional businesses, products or product candidates, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, although we have no current agreements, commitments or understandings to do so. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products or product candidates resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, strategic alliance or joint venture, we will achieve the expected synergies to justify the transaction.

General Risks Related to the Commercialization of our Product Candidates

Disruptions at the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including global pandemics, natural disasters, geopolitical actions, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in December 2019, a novel strain of COVID-19, or coronavirus, was reported to have surfaced in Wuhan, China and has become a global pandemic as of the date of this Registration Statement on Form S-3. The full impact of the coronavirus is unknown and rapidly evolving. For example, after generally suspending in-person inspections due to COVID-19, the FDA recently announced it would resume domestic facility inspections, although the agency continues its general suspension of foreign facility inspections (although "mission-critical" inspections may be considered on a case-by-case basis). Because of the global pandemic, decision-making around facility inspections by the FDA (including preapproval inspections) continues to evolve. Additionally, over the last several years, including from December 22, 2018 until January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA and other government employees and stop critical activities. In addition, there may be personnel and other changes following the 2020 Presidential election and other developments, the impact of which is currently unknown. If a prolonged government disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, prolonged government disruptions, global pandemics and other natural disasters or geopolitical actions could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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, most of our employees are working remotely, with only essential personnel working on site as needed to produce LIQ861 and prepare for a pre-approval inspection by the FDA.

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. For example, as a result of the pandemic, we have paused enrollment in our hemodynamic study, which has been conducted in Europe.

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 Registration Statement on Form S-3, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the 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." 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.

Our products may be subject to reduced prices negotiated by certain group purchasing organizations that could adversely impact our product revenue.

Our customers may organize with each other or with third parties, such as distributors, manufacturers or hospitals, to negotiate prices that are lower than we may have been able to obtain from each of them individually. In such event, our ability to generate product revenue, and consequently our 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 RareGen, we acquired RareGen's sales force to market generic treprostinil in accordance with the Promotion Agreement and we intend to expand our sales and marketing capabilities with respect to such product. 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 develop 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.

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

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

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

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

We may not be able to respond effectively to changing consumer preferences and demand.

Our success depends, in part, on our ability to anticipate and respond to changing consumer trends and preferences in the pharmaceutical industry. We may not be able to respond to these changes in a timely or commercially effective manner or at all. Our failure to accurately predict these trends could negatively impact our inventory levels, sales and reputation. The commercial success of our drug products will depend upon a number of factors, including our ability to, among others:

- anticipate consumers' therapeutic needs;
- innovate, develop and commercialize new drug products in a timely manner;
- competitively price our drug products;
- procure and maintain our drug products in sufficient volumes and in a timely manner; and
- differentiate our drug products from those of our competitors.

If we are unable to introduce new drug products, develop improvements to our existing drug products or maintain the appropriate inventory levels to meet our customers' demand in a timely manner or at all, our business and prospects could be materially and adversely affected.

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 Our Dependence on Third Parties

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

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

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

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

General Risks Related to Legal Compliance Matters

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

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

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

- refuse to allow us to enter into government contracts.

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

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

The terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue, and may present risks of regulatory enforcement and litigation.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off-label marketing.

The FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirement that promotional labeling be truthful and not misleading. Any claim of effectiveness made in prescription drug promotion, including comparative effectiveness, must be supported by substantial evidence or substantial clinical experience.

In addition, making comparative claims may draw concerns from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor (or that the competitor's product is inferior), this creates a risk of a lawsuit by the competitor under federal and state false advertising or unfair and deceptive trade practices law, and possibly also state libel law. Such a suit may seek injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by law.

We, and any potential collaborators we may have in the future, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or our collaborators obtain marketing approval. Thus, if either of our current product candidates receive marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, such as ensuring that quality control and manufacturing procedures conform to cGMP applicable to drug manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our future collaborators, licensees and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

Our drug products may be subject to recalls, withdrawals, seizures or other enforcement actions by the FDA or comparable regulatory authorities in other countries if we fail to comply with regulatory requirements or previously unknown problems with our drug products are discovered after they reach the market.

The FDA or comparable regulatory authorities in other countries may withdraw approval of our drug products if we fail to maintain compliance with regulatory requirements or if problems occur after our drug products reach the market. The discovery of previously unknown problems with a drug product, including adverse events of unanticipated severity or frequency, problems with manufacturing processes or failure to comply with regulatory requirements, including the requirement to promote a drug product only for its approved indications and in accordance with the provisions of its approved label, may result in, among others:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs or comparable regulatory authorities refusing to approve any pending marketing applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of the product; or
- injunctions or the imposition of civil or criminal penalties.

In the event that our drug products are subject to recalls, withdrawals, seizures or other enforcement actions by the FDA or comparable regulatory authorities, our reputation and demand for our drug products could be materially and adversely affected. In addition, we may incur significant and unexpected expenditures and management attention may be diverted in connection with any such recall, withdrawal, seizure or other enforcement action or any corrective action required to be taken, which could have a material and adverse impact on our business and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

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.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed to us alleged trade secrets of their former employers or other clients.

As is common in our industry, a number of our employees, including our Chief Executive Officer and a number of our executive officers, were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors, among others, and may have entered into proprietary rights, non-disclosure and non-competition agreements or similar agreements, in connection with such previous employment. Moreover, we engage the services of scientific advisers and consultants to assist us in the development of our products, many of whom were previously employed at or may have previously been or are currently providing consulting or advisory services to, other biotechnology or pharmaceutical companies, and who may have also entered into proprietary rights, non-disclosure and non-competition (or similar) agreements with such other companies.

While we require that our employees, scientific advisers and consultants do not use the proprietary information or know-how of others in their work for us, we cannot assure you that we will not be subject to claims that we or these employees, scientific advisers or consultants have inadvertently or otherwise used or disclosed the trade secrets or proprietary information of their former employers or former or present clients in their work for us, especially where such former employers or former or present clients are our competitors or potential competitors. Claims brought against us could cause us to incur unexpected and substantial costs, as well as divert our management's attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities. Consequently, our business may be materially and adversely affected.

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 U.S. Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Act, permits patent owners to request a patent term extension, based on the regulatory review period for a product, of up to five years beyond the normal expiration of the patent, which is limited to one patent claiming the approved drug product or use in an indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO, in the United States, and comparable regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or grant more limited extensions than we had requested. In such event, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our preclinical and clinical data in their marketing approval applications with the FDA to launch their drug product earlier than might otherwise be the case.

If we fail to comply with various procedural, document submission, fee payment or other requirements imposed by the USPTO or comparable patent agencies in other countries, our patent protection could be reduced or eliminated.

We are required, over the lifetime of an issued patent, to pay periodic maintenance fees to the USPTO and comparable patent agencies in other countries. We are also required by such patent agencies to comply with a number of procedural, documentary, fee payment and other conditions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in the partial or complete loss of patent rights in the relevant jurisdiction. Such situations include, but are not limited to:

- a failure to respond to official actions within the prescribed time limits;
- the non-payment of fees; and
- a failure to properly legalize and submit formal documents.

If we or our licensors, which control the prosecution and maintenance of patents which we license, fail to maintain the patents or patent applications covering our product candidates or technology, such rights would be reduced or eliminated and, consequently, our competitive position, business and prospects may be materially and adversely affected.

Changes in patent laws or interpretations of patent laws in the United States or elsewhere may diminish the value of our intellectual property or narrow the scope of protection of our patents.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, and many of the substantive changes became effective in March 2013. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including changing the United States patent system from a “first to invent” system to a “first inventor to file” system, expanding the definition of prior art and developing a post-grant review system. The provisions under the Leahy-Smith Act changed the way patent applications are prosecuted and may also affect patent litigation. It may have also weakened our ability to obtain patent protection in the United States for applications filed after March 16, 2013.

Further, the post-grant review and *inter partes* review proceedings established under the Leahy-Smith Act have been used by certain parties to cause a cancellation of selected or all claims in relation to the issued patents of their competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than that used in civil actions in the U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in litigation in a U.S. federal court. We cannot assure you that we, our licensors or our collaborators will be successful in defending any challenge by a third party in a USPTO proceeding, or, conversely, that we, our licensors or our collaborators will be successful in challenging a third party in such a proceeding.

In addition, recent court rulings in the United States have narrowed the scope of patent protection available and weakened the rights of patent owners, particularly in the pharmaceutical industry. In 2012, the Supreme Court of the United States, or the Supreme Court, issued a decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc. invalidating patent claims directed to a process of measuring a metabolic product in a patient to optimize a drug dosage for the patient. In 2013, the Supreme Court issued its decision in Association for Molecular Pathology v. Myriad Genetics, Inc. invalidating patent claims directed to the breast cancer susceptibility genes BRCA1 and BRCA2. In 2017, the Supreme Court issued its decision in TC Heartland v. Kraft Food Group Brands, holding that patentees can only sue alleged infringers in their state of incorporation. These rulings deviated from precedents and, accordingly, have created uncertainty with regard to our ability to obtain patents in the future as well as the value of such patents, once obtained. Depending on future actions by Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would affect our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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 current good manufacturing practices, or cGMP, requirements. These regulations cover all aspects of the manufacturing, testing, quality control and record-keeping of our drug products. Furthermore, the facilities where our product candidates are manufactured may be subject to inspection by the FDA before we can obtain marketing approval and remain subject to periodic inspection even after our product candidates have received marketing approval. Suppliers of components and materials, such as active pharmaceutical ingredients, used to manufacture our drug products are also required to comply with the applicable regulatory standards.

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

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

We may not be able to engage third-party CMOs to manufacture our drug products, if and when approved, on a commercial scale to meet commercial demand for our drug products.

We may, in the future, need to rely on third-party CMOs or enter into contractual arrangements with third parties to manufacture our drug products, if and when approved, on a commercial scale. However, we cannot assure you that we will be able to contract with such third parties on acceptable terms, if at all, or that such third parties will satisfy our quality standards or meet our supply requirements in a timely manner, if at all. In addition, only a limited number of manufacturers are capable of supplying pharmaceutical products. The manufacturing process for our drug products will be highly regulated, and we will need to contract with manufacturers that can meet the relevant regulatory requirements on an ongoing basis. If the third-party manufacturers with whom we contract fail to perform their obligations, we may not be able to meet commercial demand for our drug products, which would have a material and adverse impact on our business.

System failures may disrupt our business operations and delay our product development programs and commercialization activities.

Our systems, including computer systems, and those of our collaborators, contractors and consultants are vulnerable to, among others, unauthorized access, equipment failure and damage from computer viruses as well as cyber hackers. In the event of a material system failure or security breach of, or significant damage to, our systems, our business operations may be disrupted, and our product development programs and commercialization activities may be delayed. For example, failure of, or damage to, equipment leading to a loss of our clinical trial data could result in delays to the process of obtaining marketing approval for our product candidates, as well as significant and unexpected expenditure to recover or reproduce the lost data. To the extent that any disruption or damage to, or security breach of, the systems of our collaborators, contractors or consultants results in a loss of our data or applications, or the disclosure of our confidential information, our business may be adversely affected.

General Risks Related to Healthcare Regulation

We are subject to various laws and regulations, such as healthcare fraud and abuse laws, false claim laws and health information privacy and security laws, among others, and failure to comply with these laws and regulations 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. 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 and distribute our drug products for which we obtain marketing approval.

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:

- the federal Anti-Kickback Statute, which 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, order or recommendation of an item or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. The term “remuneration” expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including, for example, gifts, discounts, waivers of payment, ownership interest and providing anything at less than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The U.S. Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, amended the False Claims Act to provide that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which 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. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government, directly or indirectly. Although we do not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, marketing products of sub-standard quality, or, as noted above, paying a kickback that results in a claim for items or services. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. Penalties under the False Claims Act include treble damages and per claim penalty amounts ranging from $11,665 to $23,331. The ACA further codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a per se false or fraudulent claim for purposes of the federal False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose, among other things, obligations, impose requirements relating to the privacy, security and transmission of individually identifiable health information. Following enactment of the HITECH Act, HIPAA's privacy and security standards now directly apply to business associates of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. We are not a covered entity under HIPAA but in certain situations, we may be considered a business associate. HITECH also created four new tiers of civil monetary penalties, gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. The U.S. Department of Health and Human Services Office for Civil Rights, or the OCR, has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. The OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement;

- even when HIPAA does not apply, according to the U.S. Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA. 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. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. The FTC's authority under Section 5 is concurrent with HIPAA's jurisdiction and with any action taken under state law;

- the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the ACA which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Federal legislation enacted in 2018 has extended the scope of reporting requirements to apply to payments and transfers of value to not only physicians, but also physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021);

- 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, and state laws governing the privacy and security of health information and the use of prescriber-identifiable data in certain circumstances. 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 (for example, California recently enacted legislation — the CCPA, which went into effect on January 1, 2020 and among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of the sale of their information, and creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach; although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context, and final regulations are expected to be issued by the California Attorney General in 2020, and it remains unclear what language the final regulations will contain and how the legislation and regulations will be interpreted); and

- price reporting laws that require us to calculate and report 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.

Further, we are subject to a number of environmental and health and safety laws and regulations, including those governing laboratory processes and the handling, use, storage, treatment and disposal of hazardous materials and waste.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that certain business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between pharmaceutical companies and providers and patients, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that 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, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid or other government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government and the curtailment or restructuring of our operations as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Legislative or regulatory reform of the healthcare system in our target markets may affect our operations and profitability.

In recent years, there have been numerous initiatives on the federal and state levels in the United States for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Current and future U.S. legislative healthcare reforms may result in price controls and other restrictions for any approved products, if covered, and could seriously harm our business. Given that drug pricing controls is a key legislative and administration priority, it is likely that additional pricing controls will be enacted and could harm our business, financial condition and results of operations.

The ACA, which was signed into law in the United States in March 2010, contained several provisions affecting the pharmaceutical industry:

- the Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of HHS, as a condition of Medicare Part B and Medicaid coverage of the manufacturer's outpatient drugs furnished to Medicaid patients;

- the expansion of eligibility criteria for Medicaid programs which potentially increases both the volume of sales and manufacturers' Medicaid rebate liability;

- in order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B Drug Pricing Program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer;

- the ACA imposed a requirement on manufacturers of branded drugs to provide a 70% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., the donut hole);

- the ACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- the ACA implemented the Physician Payments Sunshine Act;

- the ACA requires annual reporting of drug samples that manufacturers and distributors provide to physicians;

- the ACA expanded healthcare fraud and abuse laws in the United States, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;

- the ACA established a licensing framework for follow-on biologics; and

- the ACA established the new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with the funding for such research.

The Trump Administration and the Congressional Republicans have proposed several efforts to repeal and replace the ACA. President Trump has also signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Additionally, the ACA remains subject to pending legal and constitutional challenges in the United States Supreme Court. See California, et al v. Texas, et al, Cause No. 19-840. The Supreme Court heard oral arguments in *California et. al. v. Texas et. al.* on November 10, 2020. This ongoing litigation challenges the ACA's minimum essential coverage provision (known as the individual mandate) and raises questions about the entire law's survival.

There is no assurance that any future replacement, modification or repeal of the ACA – were that to occur – would not adversely affect our business and financial results. The full effects of the ACA may be unknown until all outstanding legal issues are resolved, the statutory provisions are fully implemented, and CMS, the FDA, and other federal and state agencies issue final applicable regulations or guidance. These developments could potentially alter coverage and marketing requirements, thereby affecting our pricing and market share if individuals lose coverage for certain benefits.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, federal budget proposals have included measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. The U.S. Congress and the Trump Administration have indicated that they will continue to seek new legislative and administrative measures to control drug costs, including by addressing the role of PBMs in the supply chain. Drug pricing is and will remain a key bipartisan issue in the coming year.

Additionally, for example, on July 24, 2020, President Trump signed Executive Orders directing the Department of Health and Human Services (HHS) to take several steps to lower costs on prescription drugs. The Executive Orders cover a range of policies, including but not limited to (i) tying the prices paid by the U.S. government (e.g., Medicare) for drugs and biological products to prices paid in other countries; (ii) ensuring that rebates that drug makers pay to pharmacy benefit managers and insurers in the Medicare Part D program are passed directly to patients when they purchase a medication, so long as the change is not projected to increase Federal spending, Medicare beneficiary premiums or patients' total out-of-pocket costs; and (iii) allowing states, wholesalers and pharmacies to import FDA-approved drugs from Canada and other countries and sell them in the United States if the FDA deems them safe. The impact and timing of these Executive Orders, and other drug pricing initiatives released on September 24, 2020, is uncertain, as the directives contained therein would require agency rulemaking and implementation. These policy proposals, if implemented, could significantly impact the pharmaceutical industry in the United States and adversely affect our ability to generate revenues or commercialize our product candidates in the United States. Policies to be pursued in the future relative to drug pricing may be more aggressive, regardless of which party controls the White House.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The boom in state laws targeting drug pricing is unprecedented and the requirements are not uniform from state to state, creating additional compliance and commercialization challenges for manufacturers.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including drugs and biologics. The fate of the ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Healthcare laws and regulations may affect the pricing of our drug products and may affect our profitability.

In certain countries, the government may provide healthcare at a subsidized cost to consumers and regulate prices, patient eligibility or third-party payor reimbursement policies to control the cost of drug products. Such a system may lead to inconsistent pricing of our drug products from one country to another. The availability of our drug products at lower prices in certain countries may undermine our sales in other countries where our drug products are more expensive. In addition, certain countries may set prices by reference to the prices of our drug products in other countries. Our inability to secure adequate prices in a particular country may adversely affect our ability to obtain an acceptable price for our drug products in existing and potential markets. If we are unable to obtain a price for our drug products that provides an appropriate return on our investment, our profitability may be materially and adversely affected.

General Risk Related to our Employees

Our employees and our independent contractors, principal investigators, CROs, CMOs, consultants or commercial collaborators, as well as their respective subcontractors, if any, may engage in misconduct or fail to comply with certain regulatory standards and requirements, which could expose us to liability and adversely affect our reputation.

Our employees and our independent contractors, principal investigators, CROs, CMOs, consultants or commercial collaborators, as well as their respective subcontractors, if any, may engage in fraudulent conduct or other illegal activity, which may include intentional, reckless or negligent conduct that violates, among others, (a) FDA laws and regulations, or those of comparable regulatory authorities in other countries, including those laws that require the reporting of true, complete and accurate information to the FDA, (b) manufacturing standards, (c) healthcare fraud and abuse laws or (d) laws that require the true, complete and accurate reporting of financial information or data. For example, such persons may improperly use or misrepresent information obtained in the course of our clinical trials, create fraudulent data in our preclinical studies or clinical trials or misappropriate our drug products, which could result in regulatory sanctions being imposed on us and cause serious harm to our reputation. It is not always possible for us to identify or deter misconduct by our employees and third parties, and any precautions we may take to detect or prevent such misconduct may not be effective. Any misconduct or failure by our employees and our independent contractors, principal investigators, CROs, CMOs, consultants or commercial collaborators, as well as their respective subcontractors, if any, to comply with the applicable laws or regulations may subject us to enforcement action or otherwise expose us to liability or compliance costs, which, depending on the nature of the violation, may include but not necessarily be limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid or other government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government and the curtailment or restructuring of our operations as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. If any action is instituted against us as a result of the alleged misconduct of our employees or other third parties, regardless of the final outcome, our reputation may be adversely affected and our business may suffer as a result. If we are unsuccessful in defending against any such action, we may also be liable to significant fines or other sanctions, which could have a material and adverse effect on us.

General Risks Related to our Common Stock

Future sales and issuances of equity securities, convertible securities or other securities could result in additional dilution of the percentage ownership of holders of our common stock.

Our stockholders may experience dilution upon future equity issuances, including any other convertible debt or equity securities we may issue in the future, the exercise of stock options to purchase common stock granted to our employees, consultants and directors, including options to purchase common stock granted under our stock option and equity incentive plans, the issuance of common stock in settlement of previously issued awards under our stock option and equity incentive plans that may vest in the future or the issuance of common stock pursuant to our employee stock purchase plan.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell equity securities, convertible securities or other securities in one or more transactions at prices and in a manner we determine from time to time. If we sell equity securities, convertible securities or other securities, current investors may be materially diluted by such subsequent sales. We may also need our stockholders to authorize the issuance of additional shares of common stock under our amended and restated certificate of incorporation, as amended, if we do not have sufficient authorized shares to raise such additional capital or issue future awards under our incentive plan. New investors could also gain rights, preferences and privileges senior to those of holders of our existing equity securities.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases research coverage of us, fails to regularly publish reports on us or issues an adverse opinion about our business, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred costs associated with recently adopted corporate governance requirements, including requirements of the U.S. Securities and Exchange Commission and the Nasdaq Stock Market LLC, or Nasdaq. These rules and regulations have increased our legal and financial compliance costs and made some activities more time-consuming and costly. These rules and regulations also make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage that we received as a private company. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Board or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

When we cease to be an “emerging growth company” and when our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 of the Sarbanes-Oxley Act will correspondingly increase. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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 candidates, LIQ861 and LIQ865. 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 11 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 11 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 or LIQ865, 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.

You should read and interpret any forward-looking statements together with the following documents:

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

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

USE OF PROCEEDS

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

SELLING STOCKHOLDERS

Information about selling stockholders of Liquidia Corporation, where applicable, will be set forth in a prospectus supplement, in a post-effective amendment, or in filings we make with the SEC which are incorporated into this prospectus by reference.

DESCRIPTION OF THE SECURITIES WE MAY OFFER

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

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

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

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

DESCRIPTION OF CAPITAL STOCK

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

General

The total number of shares of capital stock that the Company has authorized is 90,000,000, divided into two classes consisting of (i) 80,000,000 shares of common stock, $0.001 par value per share, and (ii) 10,000,000 shares of preferred stock, par value per share $0.001.

As of September 30, 2020, there were 37,752,261 shares of common stock issued and outstanding and an additional 2,675,636 shares issuable upon exercise of outstanding options and warrants. Of the 2,675,636 shares of common stock issuable upon exercise of outstanding options and warrants, 1,566,103 shares were issuable to executive officers, directors and principal stockholders of the Company and 1,004,207 shares were issuable to other employees. Furthermore, as of September 30, 2020, 104,898 shares of common stock were issuable upon the vesting of outstanding restricted stock units.

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

Common Stock

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

Preferred Stock

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

Warrants

As of September 30, 2020, we had outstanding warrants to purchase an aggregate of 106,274 shares of our common stock at an exercise price of $0.0168 per share. These warrants expire on December 31, 2026.

Registration Rights

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

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

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

Demand Registration Rights. At any time after six months following the closing of our initial public offering, or January 30, 2019, subject to certain exceptions set forth in the Seventh Amended and Restated IRA, if the Holders of at least a majority of the common stock issued upon conversion of the Series C, Series C-1 and Series D preferred stock, or the Required Holders, demand that we file a registration statement covering the registration of Registrable Securities with an anticipated aggregate offering price of at least $10 million, we are required to use all commercially reasonable efforts to effect, as soon as practicable, the registration under the Securities Act of all Registrable Securities requested to be registered.

Form S-3 Registration Rights. If we receive from the Holders of Registrable Securities a written request that we effect a registration on Form S-3, we are required to provide written notice of the proposed registration to all other Holders and use all commercially reasonable efforts to effect the registration of such shares on Form S-3; provided, however, that such Form S-3 registration right is subject to a number of exceptions, such as us being eligible to use Form S-3 at the time such Form S-3 registration request is made, the proposed sale of Registrable Securities to be registered on Form S-3 having an aggregate price to the public (net of any underwriters' discounts or commissions) of at least $5 million and us not being required to file more than two registration statements on Form S-3 in a 12-month period. Furthermore, we have the ability to delay the filing of a registration statement under specified conditions, such as for a period of time following the effective date of a prior registration statement, if our Board deems it detrimental to us and our stockholders to delay the filing. Such postponements cannot exceed 90 days during any 12-month period and cannot be made more than once in any 12-month period.

Piggyback Registration Rights. If we propose to register any of our securities under the Securities Act in connection with the public offering of such securities, we are required to, at such time, promptly give each Holder party to the Seventh Amended and Restated IRA written notice of such registration. Upon the written request of each such Holder given within 20 days after receipt of our registration notice, we are required to use all commercially reasonable efforts to cause to be registered under the Securities Act all of the Registrable Securities that each holder requests to be registered. In connection with any such offering, we are not required to include any of the Holders' securities in such underwriting unless they accept the terms of the underwriting as agreed between us and the underwriters selected by us and enter into an underwriting agreement in customary form with such underwriters, and then only in such quantity as the underwriters determine in their sole discretion will not jeopardize the success of the offering by us. If marketing factors require a limitation of the number of shares to be underwritten, then the number of shares that may be included in the underwriting will be allocated, first, to us; second, to the Holders other than the Common Holders on a pro rata basis based on the total number of Registrable Securities held by such Holders; third, to the Common Holders on a pro rata basis based on the total number of Registrable Securities held by the Common Holders; and fourth, to any stockholder other than a Holder and/or Common Holder on a pro rata basis. The requisite Holders who are party to the Seventh Amended and Restated IRA have waived their piggyback registration rights in connection with the filing of this registration statement and the offerings contemplated hereby.

Expenses of Registration. We will pay all expenses, other than underwriting discounts and commissions, related to any demand, Form S-3 or piggyback registration, including without limitation all registration, filing and qualification fees, printers' and accounting fees, fees and disbursements of counsel for us and the reasonable fees and disbursements of one counsel for the selling Holders, not to exceed $50,000.

Indemnification. The Seventh Amended and Restated IRA contains customary cross-indemnification provisions under which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions or other "Violation," as defined in the Seventh Amended and Restated IRA, in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions or other Violation attributable to them.

Termination of Registration Rights. All registration rights granted under the IRA will terminate on the fifth anniversary of the completion of our initial public offering, or July 30, 2023.

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

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

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

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

Election and Removal of Officers

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

Authorized but Unissued Shares. The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without any further vote or action by our stockholders. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of our common stock and our preferred stock could render more difficult or discourage an attempt to obtain control over us by means of a proxy contest, changes in our management, tender offer, merger or otherwise. In particular, the authorization of undesignated preferred stock makes it possible for our Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company.

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

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

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

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

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

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

Limitation of Liability and Indemnification

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

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL (governing distributions to stockholders); or
- for any transaction from which the director derived any improper personal benefit.

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

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

Exclusive Forum

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

Transfer Agent

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. and its address is 250 Royall Street, Canton, MA 02021.

DESCRIPTION OF DEBT SECURITIES

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

DESCRIPTION OF WARRANTS

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

DESCRIPTION OF UNITS

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

LEGAL OWNERSHIP OF SECURITIES

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

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depositary on behalf of other financial institutions that participate in the depositary's book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

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

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

Street Name Holders

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

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

Legal Holders

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

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

Special Considerations for Indirect Holders

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

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book entry form, how the depositary's rules and procedures will affect these matters.

Global Securities

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

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

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

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

Special Considerations for Global Securities

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

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

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non global certificates for his or her interest in the securities, except in the special situations we describe below;

- an investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe under "—Legal Holders" above;

- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book entry form;

- an investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;

- the depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in a global security. We and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in a global security. We and the trustee also do not supervise the depositary in any way;

- the depositary may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book entry system use immediately available funds, and your broker or bank may require you to do so as well; and

- financial institutions that participate in the depositary's book entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities. There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When A Global Security Will Be Terminated

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

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

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;

- if we notify any applicable trustee that we wish to terminate that global security; or

- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

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

PLAN OF DISTRIBUTION

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

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

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

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

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

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

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

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

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

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

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

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

General Information

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

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

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

Syndicate covering transactions involve purchases of the offered securities in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the representative of the underwriters to reclaim a selling concession from a syndicate member when the offered securities originally sold by such syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Such stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the offered securities to be higher than it would otherwise be in the absence of such transactions. These transactions may be effected on a national securities exchange and, if commenced, may be discontinued at any time.

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

Selling stockholders may use this prospectus in connection with resales of securities they hold as described in the applicable prospectus supplement, in a post-effective amendment, in a free writing prospectus or in filings we make with the SEC under the Exchange Act that are incorporated by reference. Selling stockholders may be deemed to be underwriters under the Securities Act in connection with the securities they resell and any profits on the sales may be deemed to be underwriting discounts and commissions under the Securities Act.

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

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.

- 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;
- Liquidia Technologies' Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Commission on March 16, 2020;
- Liquidia Technologies' Definitive Proxy Statement on Schedule 14A, filed with the Commission on April 28, 2020;
- Liquidia Technologies' Quarterly Reports on Form 10-Q for the periods ended March 31, 2020, June 30, 2020 and September 30, 2020, filed with the Commission on May 11, 2020, August 10, 2020 and November 6, 2020, respectively; and
- Liquidia Technologies' Current Reports on Form 8-K filed with the Commission on January 27, 2020, March 20, 2020, March 30, 2020, April 8, 2020, April 13, 2020, April 30, 2020, May 18, 2020, June 5, 2020, June 19, 2020, June 29, 2020, July 2, 2020, July 24, 2020 August 20, 2020, October 14, 2020, October 19, 2020, November 2, 2020, November 16, 2020 and November 18, 2020.
- Our Current Reports on Form 8-K filed with the Commission on November 25, 2020, December 1, 2020 and December 16, 2020.

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, PO Box 110085, Research Triangle Park, NC 27709, (919) 328-4400. A copy of all documents that are incorporated by reference into this prospectus can also be found on our website by accessing *www.liquidia.com*.

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

LEGAL MATTERS

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

EXPERTS

The financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2019 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 2 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

$200,000,000

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

PROSPECTUS

, 2020

The information in this prospectus is not complete and may be changed. The selling stockholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell the securities and the selling stockholders named in this prospectus are not soliciting offers to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 16, 2020

PROSPECTUS

16,039,533 Shares

Common Stock

This prospectus relates to the resale, from time to time, of up to 16,039,533 shares of our common stock by the selling stockholders (which term, as used in this prospectus, includes pledgees, donees, transferees or other successors-in-interest) identified in this prospectus. The selling stockholders acquired 7,164,534 of the shares of our common stock in our December 2019 private placement, and 5,550,000 of the shares were issued pursuant to the Agreement and Plan of Merger, dated as of June 29, 2020, among Liquidia Technologies, Inc., RareGen, LLC, Liquidia Corporation, Gemini Merger Sub I, Inc., Gemini Merger Sub II, LLC, and PBM RG Holdings, LLC (the "Merger Agreement"). Additionally, up to 616,666 shares of the shares may be issued as Holdback Shares pursuant to the Merger Agreement, and up to 2,708,333 of the shares may be issued as Net Sales Earnout Shares pursuant to the Merger Agreement.

We are not selling any securities under this prospectus and we will not receive any proceeds from the sale of the shares.

We have agreed to bear all of the expenses incurred in connection with the registration of these shares. The selling stockholders will pay or assume discounts, commissions, fees of underwriters, selling brokers or dealer managers and similar expenses, if any, incurred for the sale of shares of our common stock.

The selling stockholders identified in this prospectus may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. For additional information on the methods of sale that may be used by the selling stockholders, see the section entitled "Plan of Distribution" on page 23. For a list of the selling stockholders, see the section entitled "Selling Stockholders" on page 20.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Our common stock is listed on the Nasdaq Capital Market under the symbol "LQDA." On December 15, 2020, the last reported sale price of our common stock was $2.92 per share. You are urged to obtain current market quotations for the common stock.

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and, as such, have elected to comply with certain reduced public company disclosure requirements for this prospectus and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in our securities involves risk. See "Risk Factors" on page 11 of this prospectus. You should carefully read this 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 , 2020

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You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus may only be used where it is legal to offer and sell shares of our common stock. If it is against the law in any jurisdiction to make an offer to sell these shares, or to solicit an offer from someone to buy these shares, then this prospectus does not apply to any person in that jurisdiction, and no offer or solicitation is made by this prospectus to any such person. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock. Our business, financial condition, results of operations and prospects may have changed since such date.

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 Liquidia Corporation. 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.

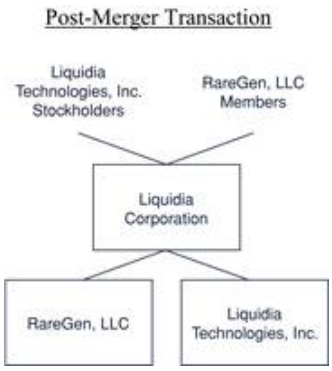
PROSPECTUS SUMMARY

ABOUT LIQUIDIA CORPORATION

This summary highlights selected information contained elsewhere in this prospectus or incorporated by reference into this prospectus. This summary does not contain all the information that you should consider before investing in our securities. You should carefully read this entire prospectus, the applicable prospectus supplement and any related free writing prospectus, including each of the documents incorporated herein or therein by reference, before making an investment decision. Unless the context otherwise requires, references in this prospectus to "Liquidia," "we," "us," "our," "our company" and "our business" refer to Liquidia Corporation, a Delaware corporation, and its subsidiaries (except for periods prior to November 18, 2020, which refer to Liquidia Technologies, Inc.).

Closing of RareGen Merger

On November 18, 2020, or the Closing Date, Liquidia Corporation 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, or the Merger Agreement, by and among Liquidia Corporation, Liquidia Technologies, Inc., a Delaware corporation, or Liquidia Technologies, RareGen, LLC, a Delaware limited liability company, or RareGen, Gemini Merger Sub I, Inc., a Delaware corporation, or Liquidia Merger Sub, Gemini Merger Sub II, LLC, a Delaware limited liability company, or RareGen Merger Sub, and PBM RG Holdings, LLC, a Delaware limited liability company, as Members' Representative. Pursuant to the Merger Agreement, Liquidia Merger Sub, a wholly owned subsidiary of Liquidia Corporation, merged with and into Liquidia Technologies, or the Liquidia Technologies Merger, and RareGen Merger Sub, a 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. The organization of Liquidia Corporation, Liquidia Technologies, and RareGen following the Merger Transaction is illustrated below:



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, or 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, or 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.

Overview

We are a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing our proprietary PRINT® technology to transform the lives of patients. PRINT is a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. Our primary objective has been to pursue marketing approval of LIQ861 and to commercialize such product if approved by the U.S. Food and Drug Administration, or the FDA.

Pursuant to its Promotion Agreement with Sandoz, Inc., or Sandoz, as described below, RareGen owns the exclusive rights to conduct any and all promotional and non-promotional activities to encourage the appropriate use of the first-to-file fully substitutable generic treprostinil injection for the treatment of patients with PAH in the United States. To that end, RareGen has a small, targeted sales force focused on PAH which it employs to conduct such marketing activities.

Product Pipeline

We are currently focused on the development of two product candidates for which we hold worldwide commercial rights: LIQ861 for the treatment of pulmonary arterial hypertension, or PAH, and LIQ865 for the treatment of local post-operative pain.

The following table summarizes our clinical-stage product candidates being developed using PRINT technology:

Program	Indication	Formulation	Phase 1	Phase 2	Phase 3	NDA	Worldwide Rights
LIQ861	PAH	treprostinil, inhalation powder					LIQUIDIA
LIQ865	Local, post-surgical pain	bupivacaine, sustained-release					LIQUIDIA

LIQ861

Our lead product candidate, treprostinil, is a potential treatment for patients with PAH. Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function, which is deficient in patients with PAH. We believe that LIQ861 has the potential to improve the therapeutic profile of existing formulations of treprostinil by enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies. We are developing LIQ861 under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug, which allows us to rely in part on the FDA's previous findings of efficacy and safety of Tyvaso and the active ingredient treprostinil, which has been approved in four different products administered through the oral, inhaled and continuous infusion (parenteral) routes.

In January 2020, we submitted an NDA to the FDA for LIQ861, and in April 2020, the FDA accepted the NDA for review and provided a Prescription Drug User Fee Act, or PDUFA, goal date of November 24, 2020. On November 25, 2020, we announced the FDA issued a complete response letter, or CRL, for our NDA for LIQ861. The CRL identified the need for additional information and clarification on chemistry, manufacturing and controls, or CMC, data pertaining to the drug product and device biocompatibility. We do not believe that the items raised in the CRL will be a barrier to the ultimate approval of 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. We believe that we can address the items raised in the CRL (through a resubmission) without delaying the otherwise projected launch timing of LIQ861 in the second half of 2022, subject to FDA approval.

Under the Hatch-Waxman Act, as a result of the Hatch-Waxman Litigation commenced by United Therapeutics on June 4, 2020, 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 precluded from approving 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 requirements for approval 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.

Our NDA submission was based in part upon the results of our open-label Phase 3 clinical trial, INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, for LIQ861, the initiation of which we announced in January 2018. The primary objective of the INSPIRE study was to evaluate the long-term safety and tolerability of LIQ861. The study was designed to evaluate patients who have either been under stable treatment with Tyvaso (nebulizer-delivered treprostinil) for at least three months and were transitioned to LIQ861 under the protocol, or Transition patients, or 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, or Add-On patients.

In August 2019, we completed the pivotal INSPIRE trial. 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. Consistent with preliminary data presented in the second quarter of 2019, LIQ861 was observed to be well-tolerated and treatment-emergent adverse events, or 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. 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.

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%).

Analysis of the exploratory endpoints from the INSPIRE study indicates that LIQ861 may provide functional and quality-of-life benefits to PAH patients in New York Heart Association, or NYHA, functional classes II and III. More than 70% of patients were able to titrate to a LIQ861 dose greater than or equal to 79.5 mcg, the LIQ861 dose-level comparable to 54 mcg of nebulized treprostinil, the maximum recommended dose in the Tyvaso® package insert. More than 95% of all patients who completed two months of treatment maintained (75.9%) or improved (20.5%) their NYHA functional class. We observed improvements in median six-minute-walk-distance (+10.1 meter increase). Quality-of-life as measured by the MLHFQ showed an improved total score (>5-point reduction), as well as improvements in both emotional and physical dimensions. We observed a greater percentage of subjects who met two or three PAH low-risk criteria at month 2 compared to baseline. We did not see clinically meaningful changes in N-terminal pro b-type natriuretic peptide (NT-proBNP). The majority of Transition patients preferred the LIQ861 dry-powder inhaler to the Tyvaso® Inhalation System.

In September 2019, we reported results from pharmacokinetic (PK) studies indicating that the 79.5 mcg dose of LIQ861 correlates with nine breaths of Tyvaso, the maximum recommended label dose of Tyvaso. To accurately characterize the pharmacokinetics of LIQ861, we conducted two PK studies in healthy volunteers. In the first of these studies, we observed unexpected variability in PK levels. Post-hoc analysis showed that plasma levels of treprostinil were tightly correlated to the LIQ861 dose delivered. Based upon additional non-clinical and clinical work, we believe the unexpected variability seen in this healthy volunteer study was due to an administration technique unique to the conduct of the study in the Phase 1 setting. In August 2019, we completed a second PK study in healthy volunteers in which the proper administration technique was followed. This study demonstrated significantly reduced variability, and we believe we have established comparative bioavailability to the reference listed drug.

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

We 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 70 patients have now received therapy with LIQ861 for more than two years. We have also observed that more than 70 percent of patients who have been enrolled in the INSPIRE and extension studies have received LIQ861 doses of 100 mcg or more.

Prior to submission of the NDA in January 2020, the FDA visited our manufacturing site in June 2019 as a qualifying participant in the Emerging Technology Program sponsored by the Center for Drug Evaluation and Research (CDER). The program supports innovation by providing a forum for sponsors to engage the FDA early in development and ensures consistency, continuity, and predictability in review and inspection. The program has allowed us to discuss PRINT® technology with Emerging Technology Team members, including personnel who may be involved in the prior approval inspection (PAI) and review of the Chemistry Manufacturing Controls section of the NDA to support LIQ861.

The FDA communicated in August 2020 that inspections of two sites involved in the manufacturing of LIQ861, both of which are located in the United States, would be required before the FDA can approve the NDA for LIQ861. The FDA also informed us that because of restrictions on travel due to the COVID-19 pandemic, the FDA may be unable to conduct inspections of those two sites prior to the PDUFA date of November 24, 2020. In the CRL, the FDA reconfirmed the need to conduct on-site PAIs of two U.S. manufacturing facilities before our NDA can be approved, and noted it had been unable to conduct these inspections during the initial review cycle due to COVID-19 related travel restrictions.

In addition to the studies submitted in the NDA for FDA review, we are conducting a clinical study at certain investigational sites in France and Germany to characterize the hemodynamic dose-response relationship to LIQ861 (LTI-201). After pausing enrollment due to the COVID-19 pandemic in the second quarter of 2020, we resumed enrollment in September 2020 at sites in Germany as allowed by local regulatory authorities. French sites will remain closed and not reopen due to the COVID-19 pandemic.

We are considering conducting other clinical trials to generate additional data on LIQ861, including a clinical trial in pediatric patients. We will continue to conduct development work in support of potential approval and commercialization of LIQ861, including label and patient-use assessments.

LIQ865

LIQ865 is our proprietary injectable, sustained-release formulation of bupivacaine, a non-opioid pain medication. We have engineered the size and composition of the LIQ865 PRINT particles to release bupivacaine over three to five days through a single administration for the management of local post-operative pain after a surgical procedure. We completed a Phase 1a clinical trial of LIQ865 in Denmark in 2017 and a Phase 1b clinical trial in the United States in 2018.

We initiated Phase 2-enabling toxicology studies in 2019 to assess LIQ865 in multiple non-clinical tissue models. Results from a study to assess incision tensile strength after healing were acceptable and not statistically different from controls. A nonclinical study to examine soft tissue healing was also completed, and the results were acceptable and comparable to vehicle-treated, saline-treated, and Marcaine-treated sites. We believe this data supports progression to Phase 2 hernia repair studies.

In a toxicology study to assess bone fracture healing, we observed dose-dependent delayed healing at the two LIQ865 doses studied; however, there were no adverse effects noted on surrounding soft tissues. We have completed an additional non-Good Laboratory Practice (GLP) study to investigate bone fracture healing using the same animal model with lower doses of LIQ865. This additional non-GLP study has established a no adverse effect level, or NOAEL, on bone healing and provides evidence that LIQ865 could proceed into a GLP toxicology study to support Phase 2 clinical activities.

Considering our focus in advancing our lead asset, LIQ861, we will seek to advance LIQ865 through a strategic collaboration with an external partner. We believe LIQ865, if successfully developed and approved, has the potential to provide significantly longer local post-operative pain relief compared to currently marketed formulations of bupivacaine.

Other Potential Applications of PRINT

We believe that our PRINT technology can be applied to a wide range of therapeutic areas, molecule types and routes of administration. We are currently focused on developing product candidates that we believe are eligible to be approved under the 505(b)(2) regulatory pathway, which can be capital efficient and potentially enable a shorter time to approval, as it allows us to rely in part on existing knowledge of the safety and efficacy of the relevant reference listed drugs to support our applications for approval in the United States. If any of our product candidates are approved, we intend to conduct initial commercial manufacturing of drug product using in-house capabilities, and to outsource packaging and distribution to third parties. Where appropriate, we may also transition the commercial manufacture of our drug product to third parties. In addition to developing our two product candidates, we have provided specific field-limited licenses to our PRINT technology to pharmaceutical companies seeking to develop their own potential drugs and biological therapies.

RareGen's Business

Overview

Pursuant to its Promotion Agreement with Sandoz, as described below, RareGen owns the exclusive rights to conduct any and all promotional and non-promotional activities to encourage the appropriate use of the first-to-file fully substitutable generic treprostinil injection for the treatment of patients with PAH in the United States. To that end, RareGen has a small, targeted sales force focused on PAH which it employs to conduct such marketing activities.

Treprostinil, Remodulin® and the Generic Version of Remodulin®

Treprostinil/Remodulin® Generally

Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function that is deficient in patients with PAH. Treprostinil can be administered as a continuous infusion through the use of an infusion pump or continuous intravenous infusion through the use of a central venous catheter. PAH is a rare disease, with an estimated prevalence in the United States of approximately 30,000 patients. Of such patients, approximately 3,000 patients are on Remodulin®. Remodulin® is treprostinil administered through subcutaneous or intravenous infusion and is marketed by United Therapeutics. Because parenteral agents are considered to offer the greatest efficacy, but also carry the most significant side effects related to infusion site pain, risk of infection, and significant limitations on quality of life, they are usually reserved for patients later in the course of the disease.

Treprostinil is currently sold mainly through specialty pharmacies, such as Accredo and CVS, and hospitals through traditional distributors. Treprostinil generally has a two-year shelf life, although Remodulin® has a four-year shelf life.

Remodulin® was approved by the FDA for subcutaneous and intravenous administration in 2002 and 2004, respectively, and has been sold commercially in the United States since 2002. United Therapeutics sells Remodulin® to specialty pharmaceutical distributors in the United States and to pharmaceutical distributors internationally. Remodulin® is indicated to treat patients with PAH, to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with functional class II-IV (moderate to severe) symptoms. Outside of the United States, Remodulin® is marketed and sold for the treatment of PAH throughout most of Europe, and various countries throughout Asia, the Middle East and South America.

Remodulin® has many qualities that make it an appealing alternative to other parenteral therapies for the treatment of PAH. Remodulin® is stable at room temperature, so it does not need to be cooled during infusion and patients do not need to use cooling packs or refrigeration to keep it stable. Treprostinil is highly soluble under certain circumstances and highly potent in concentrated solutions. This allows therapeutic concentrations of Remodulin® to be delivered at very low flow rates via miniaturized infusion pumps for both subcutaneous and intravenous infusion. Remodulin® can be continuously infused for up to 48 hours before refilling the external infusion pump. This profile contrasts favorably with non-treprostinil based, continuously infused prostacyclin therapies that are presently available — Flolan®, Veletri® and generic epoprostenol. Flolan® and generic epoprostenol are not stable at room temperature (and therefore require refrigeration or the use of cooling packs), but Veletri® may be stable at room temperature depending on its concentration. Flolan®, generic epoprostenol, and Veletri® have shorter half-lives than Remodulin, requiring mixing prior to pump refills. None of these other parenteral products may be administered via subcutaneous infusion, and therefore may only be delivered intravenously.

Patients must use external pumps manufactured by third parties to deliver Remodulin®. 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®.

There are serious side effects associated with Remodulin®. For example, when infused subcutaneously, Remodulin® causes varying degrees of infusion site pain and reaction (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.

It is estimated that branded sales of Remodulin® recorded approximately $466 million in U.S. revenue in 2019 (and approximately $587 million in total, including approximately $121 million of non-U.S. sales), of which approximately 50% of branded Remodulin® sales derived from intravenous administration and 50% of branded Remodulin® sales derived from subcutaneous administration. The majority of sales made pursuant to the Promotion Agreement are made through specialty pharmacies. In consideration for RareGen conducting certain responsibilities associated with the commercialization of the Product, RareGen receives a portion of the net profits generated from the sales of the Product.

Sandoz

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.

Generic Version of Remodulin®

In 2011, Sandoz filed an ANDA with the FDA to market a generic version of treprostinil for parenteral administration. Sandoz claimed that United Therapeutics' patents for Remodulin® were invalid, unenforceable and/or not infringed by its generic version of treprostinil. United Therapeutics then sued Sandoz for patent infringement and the parties settled that litigation in 2015. Pursuant to that settlement agreement, Sandoz was permitted to market its generic treprostinil alternative in June 2018 and United Therapeutics agreed to not interfere with Sandoz's efforts to launch its generic product. In August 2018, Sandoz partnered with RareGen to jointly market and commercialize its generic version of treprostinil pursuant to a Promotion Agreement, as described below. 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 launched the first-to-file fully substitutable generic treprostinil for parenteral administration in March 2019, followed by Teva Pharmaceuticals in October 2019. Par Pharmaceutical, Inc. launched a generic treprostinil for parenteral administration after receiving approval in September 2019, Dr. Reddy's Laboratories Inc.'s received approval in May 2020 for generic treprostinil for parenteral administration, and Alembic Pharmaceuticals Ltd's has settled with United Therapeutics in order to launch a generic treprostinil for parenteral administration, though it has not yet been approved to date. In March 2020, Teva obtained the rights to sell its generic product to CVS, which rights were previously held by RareGen and Sandoz. Currently, RareGen sells Sandoz's generic product mainly through Accredo. The generic product launched by Sandoz and RareGen is a fully substitutable generic for Remodulin®, with 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. This product is currently used only for intravenous administration.

RareGen and Sandoz allege 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.

Promotion Agreement

RareGen entered into a Promotion Agreement with Sandoz on August 1, 2018, as amended on May 8, 2020, or the Promotion Agreement, pursuant to which Sandoz engaged RareGen on an exclusive basis to promote the appropriate use of Sandoz's treprostinil, or the Product, for the treatment of PAH in the United States, including its commonwealths, territories, possessions and military bases, or the Territory. Under the Promotion Agreement, RareGen also works jointly with Sandoz on commercial strategy for the Product and has responsibility for identifying, manufacturing and developing medical devices, including pumps and cartridges, that may be used to administer the Product. Sandoz retains all rights in and to the Product. Sandoz is the holder of the ANDA for the Product. As the ANDA holder, Sandoz maintains responsibility for compliance with FDA regulatory and healthcare laws including any regulatory communications with the FDA or any other regulatory authorities as it pertains to, for example, reporting obligations for the ANDA, maintaining regulatory approvals, inspections, and meeting all submission requirements for the product label and for promotional labeling materials at the time of initial dissemination.

Under the Promotion Agreement, Sandoz retains responsibility for: the specifications, manufacture and supply, distribution and future development of treprostinil; regulatory submission and interactions with the FDA pertaining to treprostinil, including maintaining all necessary regulatory approvals; reporting to the FDA or other regulatory authorities on matters relating to manufacturing, sale or promotion, such as any safety events involving treprostinil; internally reviewing and, as it determines appropriate, approving promotional materials developed by RareGen, and making submissions to the FDA's Office of Prescription Drug Promotion; handling safety activities including adverse event reporting, and initiating and managing any recalls of treprostinil.

RareGen's activities and obligations related to regulatory matters conducted under the Promotion Agreement include: promotional and non-promotional activities, including sales and marketing activities for treprostinil, and engagement of healthcare professionals for advisory boards; developing, with prior written approval from Sandoz, marketing and educational materials consistent with FDA approved labeling and applicable laws; notifying Sandoz of notices from governmental authorities about adverse event reports or regulatory inquiries related to the safety of treprostinil, product complaints or alleged defects, unsolicited requests for off-label medical information; providing certain data and information to Sandoz in order to fulfill its transparency and reporting obligations under the Physician Payment Sunshine Act; complying with applicable laws relevant to the activities conducted under the Promotion Agreement; establishing a compliance program and mechanism for disclosure of any violations of RareGen policies and procedures and submission of an annual report and certification to Sandoz of its compliance activities; and managing, with oversight and participation from Sandoz, negotiations and arrangements for managed care activities.

The Promotion Agreement, unless earlier terminated, initially extends until the eight (8) year anniversary of the first commercial sale of the Product by Sandoz, which occurred on or about March 25, 2019. The Promotion Agreement automatically renews for successive two-year terms unless earlier terminated.

RareGen paid Sandoz an initial payment of $10 million on August 1, 2018 and, upon the successful quality release by Sandoz of 9,000 units of the Product on August 3, 2018, RareGen paid Sandoz an additional $10 million as further consideration for the right to conduct the activities as contemplated in the Promotion Agreement and to receive a portion of the "Net Profits" (as defined below). The portion of Net Profits are allocated to RareGen as follows: (i) for that portion of aggregate Net Profits less than or equal to $500 million, RareGen shall receive between 50-80% of all such Net Profits; and (ii) for that portion of aggregate Net Profits greater than $500 million, RareGen shall receive 75% of all such Net Profits.

"Net Profits" are calculated based on net sales of the Product less (i) certain manufacturing costs incurred by Sandoz or its affiliates or any third party, if applicable, (ii) certain write-offs resulting from or relating to unsold and expired Products or components, (iii) costs associated with patient starter kits and (iv) certain other fees, charges and expenses charged by customers. RareGen also has the right to inspect and audit the records and books of account maintained by Sandoz, or any affiliate, as applicable, with respect to Net Profits and related factors.

RareGen also is required to use good faith efforts to bring to market 3ml cartridges for use in a Smiths Medical CADD-MS® 3 (MS-3) ambulatory infusion pump with treprostinil, or the Cartridges, and to market and make the Cartridges available for use with the Product. Upon termination of the Promotion Agreement, Sandoz may make and market the Cartridges pursuant to a license agreement as negotiated between RareGen and Sandoz in good faith.

The Promotion Agreement required the formation of a joint steering committee, or JSC, which meets quarterly and consists of three representatives from each of RareGen and Sandoz. The purpose and responsibilities of the JSC include: (i) reviewing and approving updates or amendments to the "RareGen Activity Plan and Budget" (as defined in the Promotion Agreement); (ii) planning and implementating RareGen promotional activities; (iii) coordinating and implementing commercialization strategy; (iv) discussing the forecasting, procurement and manufacture of the Product and constituent parts; and (v) discussing status and terms of agreements with customers.

RareGen and Sandoz may terminate the Promotion Agreement for cause upon a number of customary events, such as a material breach of the Promotion Agreement that remains uncured, complete withdrawal of marketing approval of the Product or upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings with respect to the other party. Further, either party may terminate the Promotion Agreement upon written notice to the other party at any time after the initial eight (8) year term in the event Sandoz is then procuring 100% of its supply of Product from a single third party upon (a) expiration of the supply agreement with such third party and (b) Sandoz's failure, after exercise of commercially reasonable efforts, to secure continued supply of the Product from such third party or other third parties within 12 months of the termination of such supply agreement. RareGen and Sandoz also each have a right to terminate the Promotion Agreement on not more than 90 days' written notice in the event that Net Profits in the last calendar year are less than $5 million.

Sandoz may terminate the Promotion Agreement on not more than 90 days' written notice after the conclusion of any full 12-month calendar year in the event that Net Profits in such calendar year are less than or equal to 10% of the net sales in such calendar year; *provided*, *however*, that Sandoz may not terminate the Promotion Agreement in such instance unless and until (i) aggregate amounts received by RareGen under the sharing of Net Profits have reached $32.5 million, or (ii) both (x) Net Profits or the profit margin were adversely affected in such calendar year by any temporary event or circumstance and (z) the JSC makes a determination that such profit margin deficiency is not likely to continue in the subsequent calendar year. Sandoz may also terminate the Promotion Agreement upon a change of control of RareGen.

RareGen may terminate the Promotion Agreement on not more than 90 days' written notice after the conclusion of any full 12-month calendar year in the event that RareGen's share of the Net Profits in such calendar year are less than or equal to RareGen's operating expenses relating to the Product for such calendar year; *provided*, *however*, that RareGen may not terminate the Promotion Agreement in such instance unless and until (i) aggregate amounts received by Sandoz under the share of Net Profits have reached $28.125 million, or (ii) both (x) Net Profits or its operating expenses relating to the Product were adversely affected in such calendar year by a temporary event or circumstance and (z) the JSC makes a determination that RareGen's share of the Net Profits is not likely to continue to be less than its operating expenses relating to the Product in the subsequent calendar year.

Pursuant to the terms of the Promotion Agreement, Sandoz and RareGen also entered into a pharmacovigilance agreement on January 9, 2019, or the Pharmacovigilance Agreement. Under the Promotion Agreement, Sandoz is responsible for all pharmacovigilance activities regarding the Product while RareGen's sole obligations related to pharmacovigilance is to notify Sandoz in the event that it receives safety information regarding the Product or information regarding any safety-related regulatory request or inquiry. The Pharmacovigilance Agreement establishes the procedures and guidelines that RareGen must follow when fulfilling its pharmacovigilance notification responsibilities.

Joint Development Agreement

Pursuant to a Joint Development Agreement, dated May 6, 2019, by and between RareGen and Carelife USA Inc., or Carelife, RareGen has engaged Carelife to perform certain development and manufacturing services, and to furnish finished cartridges when ready for commercial sale. Currently, RareGen is working with Carelife to develop a medication cartridge for use with CADD-MS® 3 (MS-3) ambulatory infusion pumps. Pursuant to the Joint Development Agreement, Carelife or an affiliate of Carelife will manufacture the medication cartridge for use with CADD-MS® 3 ambulatory infusion pumps that is currently under development by RareGen and Carelife. Such manufacturer will then sell cartridges to a distributor who will import the cartridges into the United States and sell them to specialty pharmacies and other customers. It is contemplated that RareGen will only receive a commission or fee on sales of the cartridges to the specialty pharmacies and other customers. The amount of RareGen's fee is to be negotiated. All other amounts received with respect to the manufacture and sale of such cartridges will be paid to the manufacturer, distributor and/or other third parties.

Each party is responsible for providing the necessary systems, personnel and materials to perform the tasks assigned to it according to the terms of the Joint Development Agreement. Additionally, RareGen is responsible for (i) costs and expenses related to the production of product molds, and (ii) third party costs and expenses relating to testing of any products manufactured by Carelife in accordance with the Joint Development Agreement. RareGen retains all intellectual property and technology created pursuant to the Joint Development Agreement.

The initial term of the Joint Development Agreement expires on May 6, 2027, and RareGen may terminate at any time upon 30 days' prior written notice.

THE OFFERING

Common stock offered by selling stockholders	16,039,533 shares, which includes 5,550,000 shares of Common Stock issued pursuant to the Merger Agreement, up to 616,666 shares of Common Stock that may be issued as Holdback Shares pursuant to the Merger Agreement, up to 2,708,333 shares of Common Stock that may be issued as Net Sales Earnout Shares pursuant to the Merger Agreement, and 7,164,534 shares of Common Stock registered for resale by the selling stockholders, sold in a private placement that closed in December 2019.
Use of proceeds of	We will not receive any proceeds from the sale shares in this offering
Risk Factors	You should read the “Risk Factors” section included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq Capital Market Symbol	“LQDA”

DESCRIPTION OF PRIVATE PLACEMENT WITH THE SELLING STOCKHOLDERS

On December 23, 2019, we entered into a common stock purchase agreement for a private placement with the selling stockholders whereby, on December 27, 2019 we issued and sold 7,164,534 shares of our common stock at a price of $3.13 per share for aggregate gross proceeds of approximately $22.4 million, which we refer to as the Private Placement. For a detailed description of the transactions contemplated by the common stock purchase agreement with the selling stockholders and the shares issued pursuant thereto, see the section captioned “Selling Stockholders” in this prospectus. We filed the registration statement on Form S-3, of which this prospectus forms a part, to fulfill our contractual obligations under the registration rights agreement entered into concurrently with the common stock purchase agreement with the selling stockholders to provide for the resale by the selling stockholders of the shares of common stock offered hereby, or the Registration Rights Agreement.

DESCRIPTION OF MERGER AGREEMENT

On November 18, 2020, or the Closing Date, Liquidia Corporation 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, or the Merger Agreement, by and among Liquidia Corporation, Liquidia Technologies, RareGen, LLC, a Delaware limited liability company, or RareGen, Gemini Merger Sub I, Inc., a Delaware corporation, or Liquidia Merger Sub, Gemini Merger Sub II, LLC, a Delaware limited liability company, or RareGen Merger Sub, and PBM RG Holdings, LLC, a Delaware limited liability company, as Members’ Representative. Pursuant to the Merger Agreement, Liquidia Merger Sub, a wholly owned subsidiary of Liquidia Corporation, merged with and into Liquidia Technologies, or the Liquidia Technologies Merger, and RareGen Merger Sub, a wholly owned subsidiary of Liquidia Corporation, merged with and into RareGen, or 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 continue as wholly owned subsidiaries of Liquidia Corporation. Pursuant to the Merger Agreement, on the Closing Date the members of RareGen received an aggregate of 5,550,000 shares of Liquidia Corporation Common Stock. Furthermore, on the Closing Date 616,666 shares of Liquidia Corporation Common Stock were withheld from RareGen members to secure the indemnification obligations of RareGen member. Additionally, RareGen members are also entitled to receive up to an aggregate of 2,708,333 shares of Liquidia Corporation, based on the amount of 2021 net sales of the first-to-file substitutable generic treprostinil injection for the treatment of patients with PAH in the United States, pursuant to that certain Promotion Agreement, dated as of August 1, 2018, as amended, between RareGen and Sandoz Inc.

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

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should carefully consider the below risk as well as the risks described in the section captioned “Risk Factors” in the most recent Annual Report on Form 10-K for Liquidia Technologies, the most recent Quarterly Report on Form 10-Q for Liquidia Technologies and other filings we make, or Liquidia Technologies has made, with the Securities and Exchange Commission, or SEC, from time to time, which are incorporated by reference herein in their entirety, together with the other information in this prospectus and documents incorporated by reference in this prospectus. The below risk and the risks described in the Liquidia Technologies most recent Annual Report on Form 10-K, the Liquidia Technologies most recent Quarterly Report on Form 10-Q and the other filings incorporated by reference herein are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If the below risk or if any of the risks described in the Liquidia Technologies most recent Annual Report on Form 10-K, the Liquidia Technologies most recent Quarterly Report on Form 10-Q and the other filings incorporated by reference herein occurs, our business, financial condition, results of operations and future growth prospects could be harmed. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

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 candidates, LIQ861 and LIQ865. 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 11 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 11 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 or LIQ865, 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.

You should read and interpret any forward-looking statements together with the following documents:

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

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

USE OF PROCEEDS

We are filing the registration statement of which this prospectus is a part to permit holders of the shares of our common stock described in the section entitled “Selling Stockholders” to resell such shares. We are not selling any securities under this prospectus and we will not receive any proceeds from the sale of shares by the selling stockholders.

The selling stockholders will pay any discounts, commissions, fees of underwriters, selling brokers or dealer managers and expenses incurred by the selling stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the selling stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, printing fees, Nasdaq listing fees and fees and expenses of our counsel and our accountants.

DESCRIPTION OF CAPITAL STOCK

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

General

The total number of shares of capital stock that the Company has authorized is 90,000,000, divided into two classes consisting of (i) 80,000,000 shares of common stock, $0.001 par value per share, and (ii) 10,000,000 shares of preferred stock, par value per share $0.001.

As of September 30, 2020, there were 37,752,261 shares of common stock issued and outstanding and an additional 2,675,636 shares issuable upon exercise of outstanding options and warrants. Of the 2,675,636 shares of common stock issuable upon exercise of outstanding options and warrants, 1,566,103 shares were issuable to executive officers, directors and principal stockholders of the Company and 1,004,207 shares were issuable to other employees. Furthermore, as of September 30, 2020, 104,898 shares of common stock were issuable upon the vesting of outstanding restricted stock units.

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

Common Stock

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

Preferred Stock

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

Warrants

As of September 30, 2020, we had outstanding warrants to purchase an aggregate of 106,274 shares of our common stock at an exercise price of $0.0168 per share. These warrants expire on December 31, 2026.

Registration Rights

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

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

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

Demand Registration Rights. At any time after six months following the closing of our initial public offering, or January 30, 2019, subject to certain exceptions set forth in the Seventh Amended and Restated IRA, if the Holders of at least a majority of the common stock issued upon conversion of the Series C, Series C-1 and Series D preferred stock, or the Required Holders, demand that we file a registration statement covering the registration of Registrable Securities with an anticipated aggregate offering price of at least $10 million, we are required to use all commercially reasonable efforts to effect, as soon as practicable, the registration under the Securities Act of all Registrable Securities requested to be registered.

Form S-3 Registration Rights. If we receive from the Holders of Registrable Securities a written request that we effect a registration on Form S-3, we are required to provide written notice of the proposed registration to all other Holders and use all commercially reasonable efforts to effect the registration of such shares on Form S-3; provided, however, that such Form S-3 registration right is subject to a number of exceptions, such as us being eligible to use Form S-3 at the time such Form S-3 registration request is made, the proposed sale of Registrable Securities to be registered on Form S-3 having an aggregate price to the public (net of any underwriters' discounts or commissions) of at least $5 million and us not being required to file more than two registration statements on Form S-3 in a 12-month period. Furthermore, we have the ability to delay the filing of a registration statement under specified conditions, such as for a period of time following the effective date of a prior registration statement, if our Board deems it detrimental to us and our stockholders to delay the filing. Such postponements cannot exceed 90 days during any 12-month period and cannot be made more than once in any 12-month period.

Piggyback Registration Rights. If we propose to register any of our securities under the Securities Act in connection with the public offering of such securities, we are required to, at such time, promptly give each Holder party to the Seventh Amended and Restated IRA written notice of such registration. Upon the written request of each such Holder given within 20 days after receipt of our registration notice, we are required to use all commercially reasonable efforts to cause to be registered under the Securities Act all of the Registrable Securities that each holder requests to be registered. In connection with any such offering, we are not required to include any of the Holders' securities in such underwriting unless they accept the terms of the underwriting as agreed between us and the underwriters selected by us and enter into an underwriting agreement in customary form with such underwriters, and then only in such quantity as the underwriters determine in their sole discretion will not jeopardize the success of the offering by us. If marketing factors require a limitation of the number of shares to be underwritten, then the number of shares that may be included in the underwriting will be allocated, first, to us; second, to the Holders other than the Common Holders on a pro rata basis based on the total number of Registrable Securities held by such Holders; third, to the Common Holders on a pro rata basis based on the total number of Registrable Securities held by the Common Holders; and fourth, to any stockholder other than a Holder and/or Common Holder on a pro rata basis. The requisite Holders who are party to the Seventh Amended and Restated IRA have waived their piggyback registration rights in connection with the filing of this registration statement and the offerings contemplated hereby.

Expenses of Registration. We will pay all expenses, other than underwriting discounts and commissions, related to any demand, Form S-3 or piggyback registration, including without limitation all registration, filing and qualification fees, printers' and accounting fees, fees and disbursements of counsel for us and the reasonable fees and disbursements of one counsel for the selling Holders, not to exceed $50,000.

Indemnification. The Seventh Amended and Restated IRA contains customary cross-indemnification provisions under which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions or other "Violation," as defined in the Seventh Amended and Restated IRA, in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions or other Violation attributable to them.

Termination of Registration Rights. All registration rights granted under the IRA will terminate on the fifth anniversary of the completion of our initial public offering, or July 30, 2023.

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

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

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

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

Election and Removal of Officers

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

Authorized but Unissued Shares. The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without any further vote or action by our stockholders. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of our common stock and our preferred stock could render more difficult or discourage an attempt to obtain control over us by means of a proxy contest, changes in our management, tender offer, merger or otherwise. In particular, the authorization of undesignated preferred stock makes it possible for our Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company.

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

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

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

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

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

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

Limitation of Liability and Indemnification

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

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL (governing distributions to stockholders); or
- for any transaction from which the director derived any improper personal benefit.

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

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

Exclusive Forum

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

Transfer Agent

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. and its address is 250 Royall Street, Canton, MA 02021.

SELLING STOCKHOLDERS

December 2019 Private Placement

On December 23, 2019, we entered into a common stock purchase agreement, or the Purchase Agreement, with the selling stockholders, pursuant to which we issued and sold 7,164,534 shares of our common stock at a price of $3.13 per share for gross proceeds of approximately $22.4 million, which we refer to as the Private Placement.

In connection with the Private Placement, on December 23, 2019 we entered into the Registration Rights Agreement with the selling stockholders, pursuant to which we agreed to file a registration statement with the SEC covering the resale of the shares of common stock sold in the Private Placement. We agreed to file such registration statement within 60 days following the date of the Registration Rights Agreement, and use best efforts to file one or more replacement registration statements if necessary. The Registration Rights Agreement includes customary indemnification rights in connection with the registration statement. The registration statement of which this prospectus is a part has been filed in accordance with the Registration Rights Agreement.

The foregoing summary descriptions of the Purchase Agreement and the Registration Rights Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such documents, which were filed as exhibits to the Liquidia Technologies Current Report on Form 8-K, dated December 26, 2019, and are incorporated by reference herein.

Merger Transaction

On the Closing Date, RareGen members received an aggregate of 5,550,000 shares of Liquidia Corporation Common Stock. Furthermore, on the Closing Date 616,666 shares of Liquidia Corporation Common Stock, or the Holdback Shares, were withheld from RareGen members to secure the indemnification obligations of RareGen members, as further described below. RareGen members are also entitled to receive up to an aggregate of 2,708,333 shares of Liquidia Corporation Common Stock, or the Net Sales Earnout Shares, based on the amount of 2021 net sales of the first-to-file substitutable generic treprostinil injection for the treatment of patients PAH in the United States, pursuant to that certain Promotion Agreement, dated as of August 1, 2018, as amended, between RareGen and Sandoz.

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

Selling Stockholder Table

The table below sets forth, to our knowledge, information concerning the beneficial ownership of shares of our common stock held by the selling stockholders that purchased shares of our Common Stock in the Private Placement or pursuant to the Merger Agreement as of November 30, 2020. The information in the table below with respect to the selling stockholders has been obtained from the selling stockholders. The selling stockholders may sell all, some or none of the shares of common stock subject to this prospectus. See “Plan of Distribution.” We have based our calculation of the percentage of beneficial ownership on 43,335,808 shares of common stock outstanding as of November 30, 2020.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to shares. Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below.

With the exception of (i) Canaan VIII L.P., a principal stockholder of Liquidia Technologies prior to the Private Placement which is represented by Dr. Stephen Bloch, our Chairman, on the Board, (ii) PD Joint Holdings, LLC Series 2016-A, an entity controlled by Paul B. Manning, a director of our company effective November 18, 2020, (iii) Serendipity BioPharma LLC, an entity controlled by Roger A. Jeffs, Ph.D., a director of our company effective November 18, 2020, and (iv) Damian deGoa, our Chief Executive Officer and director effective December 14, 2020, none of the selling stockholders has held any position or office, or has otherwise had a material relationship, with us within the past three years.

	Shares of Common Stock Beneficially Owned Prior to Offering		Number of Shares of Common Stock Being	Shares of Common Stock to be Beneficially Owned After Offering(1)	
Name of Selling Stockholder	Number	Percentage	Offered(1)(2)	Number	Percentage
Eshelman Ventures LLC(3)	6,745,942	15.6%	5,159,744	1,586,198	3.7%
PD Joint Holdings, LLC Series 2016-A(4)	4,460,308	10.3%	4,400,308	60,000	*
Canaan VIII L.P.(5)	2,917,169	6.7%	319,488	2,597,681	6.0%
Serendipity BioPharma LLC(6)	1,387,500	3.2%	1,387,500	—	—
BKB Growth Investments, LLC(7)	479,233	1.1%	479,233	—	—
Samsara BioCapital, L.P.(8)	479,233	1.1%	479,233	—	—
Sovereign's Capital II, LP(9)	192,847	*	79,872	112,975	*
AMDG 1, LLC(10)	169,744	*	159,744	10,000	*
Sean Stalfort(11)	83,250	*	83,250	—	—
Jayson Rieger(12)	55,500	*	55,500	—	—
Damian deGoa(13)	43,091	*	41,625	1,466	*
Eugene Scavola(14)	41,625	*	41,625	—	—
Russell Schundler(15)	19,425	*	19,425	—	—
Brent Burgess(16)	13,747	*	7,987	5,760	*

* Less than 1%.

(1) We do not know when or in what amounts a selling stockholder may offer shares for sale. The selling stockholders might not sell any or all of the shares offered by this prospectus. Because the selling stockholders may offer all or some of the shares pursuant to this offering, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of the shares that will be held by the selling stockholders after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders.

(2) For purposes of this selling stockholder table, we have excluded the issuance of any Holdback Shares or Net Sales Earnout Shares to RareGen members, as such shares are not potentially issuable within 60 days of November 30, 2020.

(3) Consists of (i) 6,570,369 shares of common stock held by Eshelman Ventures LLC and (ii) 175,573 shares held by Mr. Eshelman directly. Fredric N. Eshelman is the founder, principal and managing member of Eshelman Ventures, and has sole voting and investment power with respect to the shares of common stock held by Eshelman Ventures. The address for Eshelman Ventures is 319 North 3rd Street, Suite 301, Wilmington, NC 28401.

(4) It is expected that the shares of Liquidia Corporation Common Stock which PBM Capital Finance, LLC, or PBM Capital Finance, received under the Merger Agreement will be transferred to PD Joint Holdings, LLC Series 2016-A, or PD Joint Holdings. Consists of 4,460,308 shares of HoldCo common stock held by PD Joint Holdings, giving effect to (i) the 3,921,075 shares of Liquidia Corporation Common Stock acquired in the Merger Transaction on the Closing Date, and (ii) the expected transfer of the shares acquired by PBM Capital Finance in the Merger Agreement to PD Joint Holdings. In December 2019, PD Joint Holdings purchased 479,233 shares of our common stock from us in the Private Placement. Paul B. Manning and Bradford Manning are each managers of Tiger Lily Capital, LLC, the manager of PD Joint Holdings, and have joint voting and investment power with respect to the shares held by PD Joint Holdings. The address for PD Joint Holdings is c/o Tiger Lily Capital LLC, 200 Garrett Street, Suite O, Charlottesville, VA 22902.

(5) Consists of 2,917,169 shares of Liquidia Corporation Common Stock held by Canaan VIII L.P, or Canaan. Canaan Partners VIII LLC is the general partner of Canaan and may be deemed to have sole investment and voting power over the shares held by Canaan. Brenton K. Ahrens, John V. Balen, Stephen M. Bloch, Wende S. Hutton, Maha S. Ibrahim, Deepak Kamra, Guy M. Russo and Eric A. Young are the managing members of Canaan Partners VIII LLC. Investment, voting and dispositive decisions with respect to the shares held by Canaan are made by the managers of Canaan Partners VIII LLC, or Canaan LLC and, together with Canaan, the Canaan Entities, collectively. Dr. Bloch, a member of our and HoldCo's board of directors, is a managing member of Canaan Partners VIII LLC. No manager or member of Canaan LLC has beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of any shares held by Canaan. The address of Canaan is 285 Riverside Avenue, Suite 250, Westport, CT 06880.

(6) Consists of 1,387,500 shares of Liquidia Corporation Common Stock acquired in the Merger Transaction. Dr. Jeffs is a manager of Serendipity BioPharma LLC, or Serendipity, and has sole voting and dispositive power over the common units held by Serendipity. The address of Serendipity is 339 W. Barbee Chapel Road, Unit 343, Chapel Hill, NC 27517.

(7) Consists of 479,233 shares of Liquidia Corporation Common Stock. Paul B. Manning and Bradford Manning are each managers of Tiger Lily Capital, LLC, the manager of BKB Growth Investments, LLC, or BKB, and have joint voting and investment power with respect to the shares held by BKB. The address for BKB is c/o Tiger Lily Capital LLC, 200 Garrett Street, Suite O, Charlottesville, VA 22902.

(8) Consists of 479,233 shares of Liquidia Corporation Common Stock. Srinivas Akkaraju, MD, Ph.D., the managing member of Samsara BioCapital GP, LLC, the general partner of Samsara BioCapital, L.P., or Samsara, has sole voting and dispositive power with respect to the shares held by Samsara. Dr. Akkaraju disclaims beneficial ownership of the shares held by Samsara except to the extent of his pecuniary interest, if any. The address for Samsara is 628 Middlefield Road, Palo Alto, CA 94301.

(9) Consists of 192,847 shares of Liquidia Corporation Common Stock. Lukas Roush, the manager of Sovereign's Capital II, LP, or Sovereign's, has sole voting and dispositive power with respect to the shares held by Sovereign's. No manager or member of Sovereign's has beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of any shares held by Sovereign's. The limited partners of Sovereign's are the sole beneficial owners of the shares held by Sovereign's. The address for Sovereign's is 310 S. West Street, Suite 100, Raleigh, NC 27603.

(10) Consists of 169,744 shares of Liquidia Corporation Common Stock. Henry R. Kaestner, the manager of AMDG 1, LLC, or AMDG, has sole voting and investment power with respect to the shares held by AMDG. The address for AMDG is c/o Keel Point, 8065 Leesburg Pike, Suite 300, Vienna, VA 22182.

(11) Consists of 83,250 shares of Liquidia Corporation Common Stock acquired in the Merger Transaction. The address for Sean Stalfort is 200 Garrett Street, Suite S, Charlottesville, VA 22903.

(12) Consists of 55,500 shares of Liquidia Corporation Common Stock acquired in the Merger Transaction. The address for Jayson Rieger is 610 Ragged Mountain Drive, Charlottesville, VA 22903.

(13) Consists of 43,091 shares of Liquidia Corporation Common Stock, 41,625 of which were acquired in the Merger Transaction. The address for Damian deGoa is c/o Liquidia Corporation, 419 Davis Drive, Morrisville, NC 27560.

(14) Consists of 41,625 shares of Liquidia Corporation Common Stock acquired in the Merger Transaction. The address for Eugene Scavola is 815 Carlyle Place, Charlottesville, VA 22903.

(15) Consists of 19,425 shares of Liquidia Corporation Common Stock acquired in the Merger Transaction. The address for Russell Schundler is 50 Gooseneck Lane, Charlottesville, VA 22903.

(16) Consists of 13,747 shares of Liquidia Corporation Common Stock. The address for Brent Burgess is 821 Cranbrook Road, Raleigh, NC 27609.

PLAN OF DISTRIBUTION

The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- 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 effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

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, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act 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.

In connection with the sale of our 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 common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the 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 the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares 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 aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be "underwriters" within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, to the extent applicable we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders to use commercially reasonable efforts to cause the registration statement of which this prospectus constitutes a part effective and to remain continuously effective until the earlier of (1) the date on which all of the shares covered by this prospectus have been sold or (2) the date on which all of the shares cease to be "Registrable Securities" (as defined pursuant to the registration rights agreement entered into in connection with the Private Placement).

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.

- 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;
- Liquidia Technologies' Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Commission on March 16, 2020;
- Liquidia Technologies' Definitive Proxy Statement on Schedule 14A, filed with the Commission on April 28, 2020;
- Liquidia Technologies' Quarterly Reports on Form 10-Q for the periods ended March 31, 2020, June 30, 2020 and September 30, 2020, filed with the Commission on May 11, 2020, August 10, 2020 and November 6, 2020, respectively; and
- Liquidia Technologies' Current Reports on Form 8-K filed with the Commission on January 27, 2020, March 20, 2020, March 30, 2020, April 8, 2020, April 13, 2020, April 30, 2020, May 18, 2020, June 5, 2020, June 19, 2020, June 29, 2020, July 2, 2020, July 24, 2020 August 20, 2020, October 14, 2020, October 19, 2020, November 2, 2020, November 16, 2020 and November 18, 2020.
- Our Current Reports on Form 8-K filed with the Commission on November 25, 2020, December 1, 2020 and December 16, 2020.

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 PO Box 110085, Research Triangle Park, NC 27709, (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, 2019 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 2 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

16,039,533 Shares

Common Stock

PROSPECTUS

, 2020

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

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

Securities and Exchange Commission Registration Fee	$	11,798
Printing		*
Accounting Fees and Expenses		*
Transfer Agent and Registrar Fees		*
Legal Fees and Expenses		*
Miscellaneous		*
Total	$	*

* Estimated expenses not presently known

Item 15. Indemnification of Directors and Officers

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

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

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

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

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

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

Item 16. Exhibits

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

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(i) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) to include any prospectus required by Section 10(a)(3) of the Securities Act; (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

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

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer and sell such securities to such purchaser:

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

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

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

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

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

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

(ii) Each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(7) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(8) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Morrisville, North Carolina on December 16, 2020.

LIQUIDIA CORPORATION

By: /s/ Damian deGoa
Damian deGoa
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Damian deGoa and Michael Kaseta his true and lawful attorney-in-fact, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments including post-effective amendments to this Registration Statement on Form S-8 (including, without limitation, any additional registration statement filed pursuant to Rule 462 under the Securities Act of 1933), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

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

SIGNATURE	TITLE	DATE
/s/ Damian deGoa Damian deGoa	Chief Executive Officer and Director (Principal Executive Officer)	December 16, 2020
/s/ Michael Kaseta Michael Kaseta	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 16, 2020
/s/ Dr. Stephen Bloch Dr. Stephen Bloch	Chairman of the Board of Directors	December 16, 2020
/s/ Katherine Rielly-Gauvin Katherine Rielly-Gauvin	Director	December 16, 2020
/s/ Dr. Joanna Horobin Dr. Joanna Horobin	Director	December 16, 2020
/s/ Roger A. Jeffs, Ph.D. Roger A. Jeffs, Ph.D.	Director	December 16, 2020
/s/ Arthur Kirsch Arthur Kirsch	Director	December 16, 2020
/s/ Paul B. Manning Paul B. Manning	Director	December 16, 2020
/s/ Dr. Seth Rudnick Dr. Seth Rudnick	Director	December 16, 2020
/s/ Raman Singh Raman Singh	Director	December 16, 2020

EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement **
4.1	Certificate of Incorporation of Liquidia Corporation (incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-240421)).
4.2	Bylaws of Liquidia Corporation (incorporated by reference to Exhibit 3.2 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-240421)).
4.3	Form of Specimen Common Stock Certificate of Liquidia Corporation (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-240421)).
4.4	Form of Warrant to Purchase Shares of Preferred Stock, issued by Liquidia Technologies, Inc. in January 2017 and February 2017 (incorporated herein by reference to Exhibit 4.4 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018).
4.5	Seventh Amended and Restated Investors' Rights Agreement, dated as of February 2, 2018, by and among Liquidia Technologies, Inc., the Investors party thereto and the Common Holders party thereto (incorporated herein by reference to Exhibit 4.5 to Liquidia Technologies, Inc.'s Registration Statement on Form S-1, filed with the SEC on June 28, 2018).
4.6	Form of Senior Indenture **
4.7	Form of Subordinated Indenture **
4.8	Certificate of Designations of Preferred Stock **
4.9	Form of Preferred Stock Certificate **
4.10	Form of Warrant **
4.11	Form of Unit Certificate**
5.1	Opinion of DLA Piper LLP (US)*
12.1	Statement of Computation of Ratios of Earnings to Fixed Charges **
23.1	Consent of PricewaterhouseCoopers LLP, Independent Auditors *
23.2	Consent of DLA Piper LLP (US) (included in Exhibit 5.1) *
24.1	Power of Attorney (included on signature page to this Registration Statement) *
25.1	Statement of Eligibility on Form T-1 under the Trust Indenture Act of 1939, as amended, of the Trustee under the Senior Indenture***
25.2	Statement of Eligibility on Form T-1 under the Trust Indenture Act of 1939, as amended, of the Trustee under the Subordinated Indenture***

* Filed herewith.

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

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

Exhibit 5.1

DLA Piper LLP (US)
51 John F. Kennedy Parkway, Suite 120
Short Hills, New Jersey 07078-2704
www.dlapiper.com

T 973.520.2550
F 973.520.2571

Partner Responsible for Short Hills Office:
Andrew P. Gilbert

December 16, 2020

Liquidia Corporation
419 Davis Drive, Suite 100
Morrisville, North Carolina 27560

Re: Liquidia Corporation Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to Liquidia Corporation, a Delaware corporation (the "Company"), in connection with the filing by the Company of the referenced Registration Statement (the "Registration Statement") under the Securities Act of 1933, as amended (the "Act") with the Securities and Exchange Commission (the "SEC") pursuant to Rule 415 under the Act. The Registration Statement relates to the proposed offering and sale of (A) an indeterminate number of (i) shares of common stock, par value $0.001 per share (the "Common Stock"), of the Company, (ii) shares of preferred stock, par value $0.001 per share (the "Preferred Stock"), of the Company, (iii) debt securities (the "Debt Securities"), (iv) warrants representing rights to purchase Common Stock, Preferred Stock, or Debt Securities (the "Warrants"), and (v) units representing an interest in two or more Debt Securities, shares of Common Stock, shares of Preferred Stock, or Warrants which may or may not be separable from one another (the "Units"), and (B) an aggregate of 16,039,533 shares (the "Resale Shares") of Common Stock of the Company. Collectively, the Common Stock, Preferred Stock, Debt Securities, Warrants and Units are referred to herein as the "Securities". All of the Resale Shares are being registered for resale on behalf of certain stockholders of the Company (the "Selling Stockholders").

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

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

Our opinion below, insofar as it relates to the Resale Shares being fully paid, is based solely on a certificate of the Chief Financial Officer of the Company confirming the Company's receipt of the consideration called for by the applicable resolutions authorizing the issuance of such Resale Shares.

We assume that the appropriate action will be taken, prior to the offer and sale of the Resale Shares by the Selling Stockholders, to register and qualify the Resale Shares for sale under all applicable state securities or "blue sky" laws.

Based upon the foregoing, we are of the opinion that (i) the Securities have been duly authorized by the Company and when issued and sold by the Company and delivered by the Company against receipt of the purchase price therefor, in the manner contemplated by the Registration Statement and the Prospectus Supplement, will be validly issued, fully paid and non-assessable, and (ii) the Resale Shares have been duly authorized for issuance and are validly issued, fully paid and nonassessable. It is understood that the opinion in subsection (ii) is to be used only in connection with the offer and sale of the Resale Shares while the Registration Statement is in effect.

The opinions expressed herein are limited to the General Corporation Law of the State of Delaware.

Please note that we are opining only as to the matters expressly set forth herein, and no opinion should be inferred as to any other matters. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein.

We hereby consent to the use of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to us under the caption “Legal Matters” in the base prospectus and resale prospectus included in the Registration Statement. In giving such consent, we do not hereby admit that we are acting within the category of persons whose consent is required under Section 7 of the Act or the rules or regulations of the SEC thereunder.

Very truly yours,

/s/ DLA Piper LLP (US)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement on Form S-3 of Liquidia Corporation of our report dated March 16, 2020 relating to the financial statements, which appears in Liquidia Technologies, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP
Raleigh, North Carolina
December 16, 2020