



The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 18, 2019

PRELIMINARY PROSPECTUS

3,000,000 Shares



**Liquidia Technologies, Inc.**  
Common Stock

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We are offering 3,000,000 shares of our common stock.

Our common stock is listed on the Nasdaq Capital Market under the symbol "LQDA." On March 15, 2019, the last reported sale price of our common stock on the Nasdaq Capital Market was \$16.72 per share.

**We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933 and are subject to reduced public company reporting requirements. See "Prospectus Summary — Implications of Being an Emerging Growth Company".**

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 13 of this prospectus.

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.

	PER SHARE	TOTAL
Public Offering Price	\$	\$
Underwriting Discounts and Commissions <sup>(1)</sup>		
Proceeds to Liquidia Technologies, Inc. before expenses		

<sup>(1)</sup> See "Underwriting" on page 174 for additional information regarding underwriting compensation.

Delivery of the shares of common stock is expected to be made on or about \_\_\_\_\_, 2019. We have granted the underwriters an option for a period of 30 days to purchase an additional 450,000 shares of our common stock. If the underwriters exercise the option in full, the total discounts and commissions payable by us will be \$ \_\_\_\_\_, and the total proceeds to us, before expenses, will be \$ \_\_\_\_\_.

*Joint Book-Running Managers*

**Jefferies**

**Cowen**

*Co-Managers*

**Needham & Company**

**Wedbush PacGrow**

Prospectus dated \_\_\_\_\_, 2019.

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You should rely only on the information contained in this prospectus or in any free writing prospectus we file with the U.S. Securities and Exchange Commission, or the SEC. Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover page of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States. See "Underwriting."

#### **TRADEMARKS**

This prospectus includes our trademarks, trade names and service marks, such as Liquidia, the Liquidia logo and PRINT, which are protected under applicable intellectual property laws and are the property of Liquidia Technologies, Inc. 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.

#### **MARKET AND INDUSTRY DATA**

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate is based on reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources as well as our own internal estimates and research. Decision Resources Group is the primary source for the market data included in this prospectus and we compensated them for use of market data. Although we believe the data from these third-party sources is reliable, we have not independently verified any third-party information. In addition, projections, assumptions and estimates of the future performance of the industry in which we operate and our future performance are necessarily subject to uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider before deciding to invest in our common stock. You should read the entire prospectus carefully, including the "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Except where the context otherwise requires or where otherwise indicated, the terms "Liquidia," "we," "us," "our," "our company" and "our business" refer to Liquidia Technologies, Inc.*

### Overview

We are a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using 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. 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. Our lead product candidate, LIQ861, is being evaluated in an open-label Phase 3 clinical trial. LIQ861 is an inhaled dry powder formulation of treprostinil designed to improve the therapeutic profile of treprostinil by enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies. We have applied our PRINT technology to enable us to deliver LIQ861 through a convenient, disposable dry powder inhaler, or DPI. We have also applied our PRINT technology to our second product candidate, LIQ865, for which we have completed two Phase 1 clinical trials. LIQ865 is designed to deliver sustained-release particles of bupivacaine, a non-opioid anesthetic, to treat local post-operative pain for three to five days through a single administration.

Our lead product candidate, LIQ861, is being evaluated for the treatment of PAH, a chronic, progressive disease caused by the hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death. Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function that is deficient in patients with PAH. With PAH, the elevated pressure in the pulmonary arteries strains the right side of the heart as it pumps blood to the lungs. The extra stress causes the heart to enlarge and become less flexible, compromising its ability to push blood out of the heart through the lungs and into the rest of the body. PAH initially presents as exertional dyspnea, lethargy and fatigue and may be confused with other disease states with similar symptoms. PAH often goes undiagnosed or misdiagnosed until symptoms become severe, with the mean time from onset of symptoms to correct diagnosis being more than two years in the United States. As PAH progresses and right ventricular failure develops, exertional chest pain, or angina, exertional syncope and peripheral edema may develop. Following confirmation of diagnosis based on hemodynamic parameters, treatment is recommended to lower pulmonary pressures and treat the symptoms of PAH. Due to delayed diagnosis, many patients already have advanced disease requiring aggressive treatment combining multiple classes of therapy. PAH is a rare disease, with an estimated prevalence in the United States expected to be approximately 30,000 patients by 2020. PAH is most commonly diagnosed in the developed world, including the United States, Europe and Japan. Today, the mean age of diagnosis is 50 years according to both French and U.S. registries, with more women being diagnosed than men. Patients may have idiopathic PAH in which no underlying cause can be determined or a heritable form of the disease. A large number of PAH patients also have associated comorbidities such as congenital heart disease, HIV, connective tissue diseases like scleroderma, liver diseases, systemic hypertension, obesity, clinical depression, non-PAH related obstructive airways disease, sleep apnea and diabetes.

Decision Resources Group, an independent industry research firm, estimated that in 2017 products containing treprostinil across its three routes of administration (oral, inhaled and parenteral infusion)

generated revenue that represented about one-quarter of the approximately \$3.7 billion U.S. market for PAH drug therapies. The inhaled route of administration, in which medication is inhaled directly into the lungs, helps minimize the off-tissue adverse side effects of systemic delivery by delivering the drug directly where it is needed. Tyvaso® (treprostinil, inhaled solution), or Tyvaso, the inhaled form of treprostinil marketed by United Therapeutics Corporation, or United Therapeutics, in the United States, is the standard of care among the inhaled therapies, with more than 80% of inhaled prostacyclin sales in the United States. Current inhaled therapies, including Tyvaso, are delivered by a nebulizer, a device that converts a liquid formulation into mist, and require between four and nine doses per day. Nebulizers require regular care and maintenance, including daily cleaning and access to additional parts and supplies, such as distilled water and a power source, all of which compromise the portability of the device and the quality of life of patients.

We believe LIQ861, if approved, will be the first-to-market inhaled dry powder treprostinil that can be delivered using a convenient, palm-sized, disposable DPI. We believe LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs. Based on our *in vitro* studies we believe that the precise size, trefoil-like shape and uniformity of each LIQ861 particle may provide deep-lung delivery of treprostinil and may reduce deposition in the upper airway where irritation and pain have been observed with nebulized treprostinil. If approved, we believe LIQ861 will have the potential to increase the number of patients using the inhaled route of treatment for PAH by providing the benefits of inhaled prostacyclin therapy earlier in a patient's disease progression as well as delaying the burden of starting continuously infused products. As reported on March 11, 2019, we completed enrollment and met the primary endpoint in our open-label Phase 3 trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil. LIQ861 was observed to be well-tolerated in 109 patients, with 101 patients (93%) completing at least two-months of treatment. During the two month period, LIQ861 was evaluated at doses up to 150 mcg capsule strength with no study-drug related serious adverse events. The INSPIRE study is designed to evaluate patients who have either been under stable treatment with nebulizer-delivered treprostinil for at least three months and are transitioned to LIQ861 under the protocol or who have been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and have their treatment regimen supplemented with LIQ861 under the protocol. The primary objective of the study is to evaluate the long-term safety and tolerability of LIQ861. We also completed patient enrollment in our one-directional crossover sub-study to compare bioavailability and pharmacokinetics of treprostinil as the sub-study patients transitioned from Tyvaso to LIQ861. We expect to report pharmacokinetics results in the second quarter of 2019. We intend to conduct additional clinical work in support of our marketing and commercial activities in advance of our U.S. launch for LIQ861, including maintaining patients on LIQ861 up to our U.S. launch and collecting data relating to the effects of LIQ861 on hemodynamic measurements. We are targeting a New Drug Application, or NDA, submission to the U.S. Food and Drug Administration, or FDA, for LIQ861 in late 2019, which submission will include the two-week safety data, the available two-month safety and tolerability data and our bioavailability and pharmacokinetics results. We expect the NDA to also include additional data generated from our clinical studies on LIQ861 and any further safety data available at that time.

Our second product candidate, LIQ865, is an injectable, sustained-release formulation of bupivacaine for the management of local post-operative pain for three to five days after a procedure. We believe LIQ865, if approved, has the potential to provide significantly longer local post-operative pain relief compared to currently marketed formulations of bupivacaine. We estimate that there were over 40 million surgeries in our target market, which consists of orthopedic and soft tissue surgeries, performed in the United States in 2016. According to IMS Health, an independent market research firm, the global market for local

anesthetics was approximately \$761.1 million in 2017. Despite current pain-management protocols, post-operative pain is still undermanaged, with studies showing that approximately 50% of patients self-report inadequate pain relief. Post-operative pain management is becoming more important as surgeries increase in volume and complexity and hospitals seek treatments that support faster recovery and time to discharge. Concurrently, the risk of opioid abuse and diversion has led physicians, payors and the U.S. federal government to prioritize pain management strategies that minimize reliance on opioids. Local anesthetics, such as bupivacaine, provide a well-established, non-opioid option for post-operative pain management, but their duration of efficacy has been limited to eight hours or less. The FDA has approved one long-acting local anesthetic, liposomal bupivacaine, but pain relief typically lasts only 24 to 36 hours, according to physicians, and its use in combination with other local anesthetics can result in an unsafe release of drug. In LIQ865, we have engineered the size and composition of the LIQ865 PRINT particles to release bupivacaine over three to five days through a single administration. We completed a Phase 1a clinical trial of LIQ865 in Denmark and a Phase 1b clinical trial in the United States. We commenced preparation for Phase 2-enabling toxicology studies in the fourth quarter of 2018 and expect to initiate these studies in March 2019, complete these studies by the end of 2019 and commence initial Phase 2 proof of concept clinical trials in 2020.

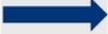
Both LIQ861 and LIQ865 are being developed using our proprietary PRINT particle engineering technology, which allows us to engineer and manufacture highly uniform drug particles with independent control over their size, three-dimensional geometric shape and chemical composition. By controlling these physical and chemical parameters of particles, PRINT enables us to target and design desirable pharmacological benefits into product candidates, including prolonged duration of drug release, increased drug loading, a more convenient method of administration, novel combination products, enhanced storage and stability and the potential to reduce adverse side effects. Controlling three-dimensional geometric shape and chemical composition of drug particles enables us to research, identify and pursue the improvement of existing therapies and creation of new therapies from existing drugs or new chemical entities, including small molecules and biologics. Our ability to design and control these features of drug particles has the potential to provide significant benefits across the breadth of pharmaceutical applications. Product characteristics and features can be tuned depending on the need of a particular application, drug substance, delivery route and other such considerations. Based on our research to date, we anticipate the ability to: (i) enhance inhaled delivery through the highly uniform geometric shape of each drug particle; (ii) design desired drug release profiles ranging from minutes post-delivery to days, weeks or months depending on need of a target therapy, by controlling the chemical composition of the drug particles and the surface area-to-volume ratio of the particles; (iii) enable combination products where one or more of the chemical constituents can destabilize or interact by encapsulating the desired constituent in a particle to shield it from another constituent during packaging and storage; and (iv) enhance the deposition and retention of topically delivered products by designing particles with a desired charge and/or Young's modulus. Our molding approach, which we branded as "PRINT", or Particle Replication In Non-wetting Templates, combines the precision of the semi-conductor industry with the high throughput of roll-to-roll manufacturing to make highly uniform micro- and nano-particles at a commercially viable scale. Our manufacturing equipment and materials used in the production of our drug particles are proprietary and protected by our patent portfolio and trade secret know-how. Our PRINT equipment is also modular, scalable and cost-effective. We protect our PRINT technology and the resulting engineered particles through a combination of patents, trade secrets, proprietary know-how and licensing arrangements. We have an active patent strategy that covers major geographic markets, including the United States, Europe and Japan.

Initially, our internal pipeline is focused on the development of improved and differentiated drug products containing FDA-approved active pharmaceutical ingredients, or APIs, with established efficacy and safety profiles, which we believe are eligible for the 505(b)(2) regulatory pathway to seek marketing approval in the United States. The 505(b)(2) regulatory pathway can be capital efficient and potentially enable a shorter time to approval. We intend to seek marketing approval in the United States for LIQ861 and LIQ865 under the 505(b)(2) regulatory pathway, which would allow us to rely in part on existing knowledge of the

safety and efficacy of the reference listed drugs. LIQ861 and the DPI together will be regulated as a combination product by the FDA and, accordingly, the DPI will be evaluated as part of our NDA filing. In addition to building our own internal pipeline, we have collaborated, and may consider collaborating, with pharmaceutical companies to develop their own product candidates, leveraging our PRINT technology across a wide range of therapeutic areas, molecule types and routes of administration. Through our collaboration arrangement with GlaxoSmithKline plc and its subsidiaries, collectively, GSK, we have applied PRINT technology to novel molecules. If our product candidates receive marketing approval, we plan to commercialize them in the United States by establishing our own sales force and commercial infrastructure. Outside of the United States, we intend to pursue the regulatory approval and commercialization of our product candidates with pharmaceutical companies with regional expertise. We intend to manufacture our product candidates using in-house capabilities. Where appropriate, we will rely on contract manufacturing organizations, or CMOs, to produce, package and distribute our approved drug products on a commercial scale.

**Product Pipeline**

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

Product	Indication	Formulation & Route	Phase 1	Phase 2	Phase 3	Next Key Milestone	Worldwide Commercial Rights
LIQ861 <sup>1</sup>	PAH	Dry powder inhalation				PK data 2Q:19	Liquidia
LIQ865	Local, post-operative pain	Sustained-release injectable				Ph2-enabling studies commencing March 2019	Liquidia

1. After consultation with the FDA, we advanced from a Phase 1 trial directly to a pivotal Phase 3 trial and will seek approval under the 505(b)(2) pathway.

**Our Strategy**

Our goal is to develop and commercialize medicines with improved and differentiated product profiles based on our PRINT particle engineering technology. To achieve this goal, we intend to execute the following key elements of our business strategy:

- § **Complete the NDA submission for our lead product candidate, LIQ861, in PAH.** We initiated INSPIRE, an open-label Phase 3 trial in patients with PAH, and we have completed enrollment and met the primary endpoint, as reported on March 11, 2019. We also completed enrollment in our one-directional crossover sub-study to compare bioavailability and pharmacokinetics of treprostinil as the sub-study patients transitioned from Tyvaso to LIQ861. We believe, based on feedback from the FDA, that this clinical trial will support the NDA filing for our novel inhaled dry powder formulation of treprostinil to treat PAH. We reported positive interim two-week safety data in January 2019, and completion of enrollment and achievement of primary endpoint on March 11, 2019, and expect to report pharmacokinetics results in the second quarter of 2019. We intend to conduct additional clinical work in support of our marketing and commercial activities in advance of our U.S. launch for LIQ861, including maintaining patients on LIQ861 up to our U.S. launch and collecting data relating to the effects of LIQ861 on hemodynamic measurements. We are targeting an NDA submission to the FDA for LIQ861 in late 2019 which submission will include the two-week safety data, the available two-month safety and tolerability data and our bioavailability and pharmacokinetics results. We expect the NDA to also include additional data generated from our clinical studies on LIQ861 and any further safety data available at that time.

- § **Advance our local post-operative pain product candidate, LIQ865, through Phase 2-enabling toxicology studies into Phase 2 clinical trials.** We completed a Phase 1a clinical trial of LIQ865, our novel long-acting formulation of bupivacaine, in Denmark in March 2017, and a Phase 1b clinical trial in the United States in April 2018. We commenced preparation for Phase 2-enabling toxicology studies in the fourth quarter of 2018 and expect to initiate these initial studies in March 2019. We anticipate that the initial Phase 2-enabling toxicology studies will result in LIQ865 being Phase 2-ready by the end of 2019, that we will complete these studies by the end of 2019 and that we will commence initial Phase 2 proof of concept clinical trials in 2020.
- § **Secure regulatory approval and commercialize our internal product candidates independently in the United States and with pharmaceutical companies globally.** We hold worldwide commercialization rights to LIQ861 and LIQ865. Subject to receiving marketing approval, which we intend to pursue in the United States via the 505(b)(2) regulatory pathway, we intend to independently pursue the commercialization of LIQ861 in the United States by establishing targeted sales and marketing teams. After reviewing the results of all of our Phase 2-enabling toxicology studies for LIQ865, and subject to the availability of sufficient funding, we will develop and commercialize LIQ865 independently, if it is ultimately approved, or seek to license this product candidate to one or more third parties. Outside of the United States, we intend to pursue the regulatory approval and commercialization of LIQ861 and LIQ865 with pharmaceutical companies with regional expertise.
- § **Expand our internal pipeline leveraging our PRINT technology.** We intend to continue targeting diseases where we believe our PRINT technology can improve the efficacy, safety and patient experience of current treatments that have been impaired by suboptimal drug product formulation and delivery. We plan to focus initially on the development of improved and differentiated drug products containing FDA-approved APIs with proven efficacy and safety profiles eligible to use the 505(b)(2) regulatory pathway. In addition, we may expand our clinical development of LIQ861 and LIQ865, where appropriate, into broader indications or new applications.
- § **Pursue strategic collaborations to maximize the value of products enabled by PRINT technology.** In addition to advancing our own internal product candidates, we have collaborated, and may consider collaborating, with pharmaceutical companies to develop their own product candidates across a wide range of therapeutic areas, molecule types and routes of administration, leveraging our PRINT technology. We believe that collaborating with pharmaceutical companies helps advance new PRINT capabilities, while adding to our intellectual property portfolio.

#### **Our Competitive Strengths**

We believe that we have several key strengths that have contributed to the development of our business and that will help us to realize our goal of becoming a biopharmaceutical company across research, development and commercialization activities. Our competitive strengths include:

- § **Our PRINT technology gives us the capability to overcome the constraints of conventional formulation and production methods and can be applied broadly across therapeutic areas, molecule types and routes of administration.** Our PRINT technology allows us to precisely engineer drug particles in a wide variety of compositions, sizes and shapes and achieve a high level of control over the physical and chemical characteristics of drug particles, as compared to conventional formulation and production methods. PRINT particles can be designed to address specific pharmacological or therapeutic objectives, such as enhancing the route of administration, improving solubility, enhancing stability or extending therapeutic effects. Using our PRINT technology, we are able to engineer, among others, small molecule and biologic particles, single agent drug and combination drug particles and vaccine particles to improve efficacy, safety and convenience for patients. Our internal pipeline strategy is currently focused on developing proprietary innovations to currently approved drug products in order to minimize development risks and increase speed to market.

In particular, we have designed LIQ861 to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs using a convenient, palm-sized, disposable DPI. We believe that this may lead to a more attractive product profile with a more convenient method of administering the drug, as compared to the existing inhaled therapies that are currently available. We have also designed LIQ865 with the intention of providing patients with local post-operative analgesia for three to five days. We believe this would provide a longer period of pain relief than the existing local-acting pain drugs that are available, which could be a positive feature in light of interest in reducing the patient's reliance on opioids and non-steroidal anti-inflammatory drugs, or NSAIDs, for local post-operative pain management.

Our PRINT technology is broadly applicable — across therapeutic areas, molecule types and routes of administration — providing us with opportunities for future drug product development.

§ **We have scaled operations with rapid and cost-effective transition to clinical development and commercial production.** We believe our research and development operations and PRINT technology allow us to transition rapidly and cost-effectively from laboratory to clinical development and ultimately commercial-scale manufacture of drug particles. Utilizing well-established techniques from other roll-to-roll manufacturing processes, we have scaled PRINT technology to support the quality and quantity needs for clinical and, we believe, commercial production of our product candidates. The physical equipment for the PRINT technology requires a relatively small footprint, low capital investment and minimal operating costs. We believe our manufacturing facilities comply with the FDA's current good manufacturing practices, or cGMP, requirements.

§ **We have a strong proprietary position through a combination of patents, trade secrets, proprietary know-how and licensing arrangements.** We protect our PRINT technology and the resulting engineered particles through a combination of patents, trade secrets, proprietary know-how and licensing arrangements. We have an active patent strategy that covers major geographic markets, including the United States, Europe and Japan. As of December 31, 2018, our patent portfolio, which includes patents and patent applications we own or co-own, as well as patents and patent applications we have licensed from third parties, such as the University of North Carolina at Chapel Hill, or UNC, comprises 112 issued patents and 51 pending patent applications worldwide. As we develop new product candidates, either independently or with collaborators, we will seek additional patent protection.

§ **We have strong capabilities in pharmaceutical research and clinical development.** Our research and development team includes 25 employees as of December 31, 2018, led by our senior management, and has extensive experience in clinical development and pharmaceutical research and development activities in our specific areas of research interest.

§ **We have a seasoned management team.** Our team includes industry veterans with significant experience in drug discovery, development and commercialization. Members of our leadership team have worked across different segments of the pharmaceutical industry, including branded and generic pharmaceuticals, medical devices and manufacturing services. Prior to joining us, our Chief Executive Officer and director, Neal Fowler, served as president of Centocor, Inc., a subsidiary of Johnson & Johnson that is focused on the development and commercialization of biomedicines used to treat chronic inflammatory diseases. Additionally, our Chief Operations Officer, Robert Lippe, previously served as executive vice president of operations and chief operations officer at Alexza Pharmaceuticals, Inc. Furthermore, our Senior Vice President, Product Development, Dr. Robert Roscigno, previously served as the executive vice president of GeNO, LLC, where he led the clinical development team working on a novel nitric oxide delivery system, and before that he served as the president and chief operating officer of Lung Rx, Inc., where he was part of the team responsible for bringing Tyvaso through Phase 3 development, and he previously served in multiple leadership positions at United Therapeutics and its subsidiaries, contributing to the successful development and worldwide commercialization of Remodulin™, which is treprostinil administered through subcutaneous or intravenous infusion, for the treatment of PAH. We believe that their experience

enables us to evaluate opportunities and build collaboration arrangements that match the breadth of the potential applications for our PRINT technology.

#### **Risks Related to Our Business**

Our ability to successfully implement our business strategy is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. These risks include, among others:

- § We are a clinical-stage 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.
- § We are primarily dependent on the success of our lead product candidate, LIQ861, and to a lesser degree, LIQ865, which are still in clinical development, and these product candidates may fail to receive marketing approval or may not be commercialized successfully.
- § Our preclinical studies and clinical trials may not be successful and delays to 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 or final results.
- § We are planning to pursue the FDA 505(b)(2) pathway to apply for marketing approval of our product candidates in the United States. If we are unable to rely on the 505(b)(2) regulatory pathway, we will be required to seek approval of these product candidates through the 505(b)(1) NDA pathway, which would require full clinical trials to establish safety and effectiveness, and the process of obtaining marketing approval for our product candidates would likely be significantly longer and more costly.
- § 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.
- § 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.
- § We may not be able to build our marketing and sales capabilities or enter into agreements with third parties to market and sell our drug products.
- § Although we have historically depended on GSK for a significant portion of our revenue, we do not expect to receive any near-term revenue from GSK.
- § We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of LIQ861.
- § Even if this offering is successful, 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 may be unable to continually develop a pipeline of product candidates, which could affect our business and prospects.
- § We may encounter difficulties in enrolling patients in our clinical trials.
- § 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.

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

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

#### **Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. As an emerging growth company:

§ we present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

§ we provide reduced disclosure about our executive compensation arrangements;

§ we are not required to have advisory votes on executive compensation or golden parachute arrangements; and

§ we have an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues 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. We have chosen to opt out of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition periods for complying with new or revised accounting standards is irrevocable. We may choose to take advantage of some but not all of these other exemptions available to emerging growth companies. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

#### **Corporate Information**

Liquidia Technologies, Inc. was incorporated in Delaware on June 8, 2004. Our principal executive offices are located at 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560 and our telephone number is (919) 328-4400. Our website is located at [www.liquidia.com](http://www.liquidia.com). The information on or that can be accessed through our website is not incorporated by reference into this prospectus, and you should not consider any such information as part of this prospectus or in deciding whether to purchase our common stock.

**THE OFFERING**

Issuer	Liquidia Technologies, Inc.
Common stock offered by us	3,000,000 shares (or 3,450,000 shares if the underwriters exercise their option to purchase additional shares in full).
Common stock to be outstanding immediately after this offering	18,519,469 shares (or 18,969,469 shares, if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	We have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to 450,000 additional shares of common stock.
Use of proceeds	We estimate that the net proceeds to us from this offering after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$45.9 million (or approximately \$52.9 million if the underwriters exercise in full their option to purchase additional shares of common stock), based on an assumed public offering price of \$16.72 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019. We currently estimate that we will use the net proceeds from this offering, together with our existing cash, to complete our ongoing Phase 3 clinical trial and other development work for LIQ861, advance LIQ865 through our Phase 2-enabling toxicology studies expected to commence in March 2019 and into initial Phase 2 proof of concept clinical trials expected to commence in 2020 and fund operations supporting the development of, and commercial activities for, LIQ861 and LIQ865. We will use the remainder for working capital and general corporate purposes.  See "Use of Proceeds" for more information.
Risk factors	You should read the "Risk Factors" section beginning on page 13 of this prospectus for a discussion of the factors you should carefully consider before deciding to purchase any shares of our common stock.
Nasdaq Capital Market symbol	"LQDA"

The number of shares of our common stock to be outstanding after this offering is based on 15,519,469 shares of our common stock outstanding as of December 31, 2018, and excludes:

- § 1,658,112 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2018, with a weighted average exercise price of \$8.76 per share, of which 14,328 shares of common stock were subsequently issued upon the exercise of stock options after December 31, 2018;
- § 395,408 shares of common stock issuable upon the exercise of stock options granted after December 31, 2018, with an exercise price of \$14.20 per share;

- § 170,925 shares of common stock issuable upon the exercise of warrants outstanding as of December 31, 2018, with a weighted average exercise price of \$0.0168 per share, of which 64,629 shares of common stock were subsequently issued upon the exercise of warrants after December 31, 2018;
- § 34,551 former restricted stock units granted to Kevin Gordon, our former President and Chief Financial Officer whose consulting period with the Company will expire on March 31, 2019, which settled in common stock after December 31, 2018;
- § an aggregate of 151,217 shares of common stock issuable upon the vesting of restricted stock units granted to Neal Fowler, our Chief Executive Officer, and Mr. Gordon; and
- § an additional 1,193,329 shares of common stock available for future issuance under the Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan, or the 2018 Plan.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- § no exercise of outstanding options after December 31, 2018; and
- § no exercise by the underwriters of their option to purchase up to 450,000 additional shares of common stock in this offering.

**SUMMARY FINANCIAL DATA**

The following tables set forth, for the periods and at the dates indicated, our summary financial data. The statement of operations data for the years ended December 31, 2017 and 2018 are derived from our audited financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period. You should read the following information together with the more detailed information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the accompanying notes thereto appearing elsewhere in this prospectus. The summary financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2017	2018
<b>Statement of Operations Data:</b>		
Revenues	\$ 7,258,123	\$ 2,706,981
Costs and expenses:		
Cost of sales	319,759	121,391
Research and development	24,753,876	28,699,576
General and administrative	10,212,774	8,754,088
Total costs and expenses	<u>35,286,409</u>	<u>37,575,055</u>
Loss from operations	(28,028,286)	(34,868,074)
Other income (expense):		
Interest income	268	304,981
Interest expense	(13,010,475)	(18,988,176)
Gain on early extinguishment of long-term debt	—	137,695
Derivative and warrant fair value adjustments	11,884,253	277,715
Total other income (expense), net	<u>(1,125,954)</u>	<u>(18,267,785)</u>
Net loss	(29,154,240)	(53,135,859)
Comprehensive loss	<u>\$ (29,154,240)</u>	<u>\$ (53,135,859)</u>
Net loss per common share:		
Basic	<u>\$ (51.78)</u>	<u>\$ (7.42)</u>
Diluted	<u>\$ (51.78)</u>	<u>\$ (7.51)</u>
Weighted average common shares outstanding:		
Basic	<u>563,076</u>	<u>7,163,304</u>
Diluted	<u>563,076</u>	<u>7,078,757</u>

<b>Balance Sheet Data:</b>	<b>As of December 31, 2018</b>	
	<b>Actual</b>	<b>As Adjusted<sup>(1)</sup></b>
Cash	\$ 39,534,985	\$ 85,483,785
Working capital <sup>(2)</sup>	31,777,741	77,726,541
Total assets	49,418,258	95,367,058
Total debt and capital leases	12,773,334	12,773,334
Capital stock and additional paid-in capital	185,741,568	231,690,368
Accumulated deficit	(167,053,897)	(167,053,897)
Total stockholders' (deficit) equity	18,687,671	64,636,471

<sup>(1)</sup> The as adjusted balance sheet data give effect to our sale of 3,000,000 shares of our common stock in this offering at an assumed public offering price of \$16.72 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

<sup>(2)</sup> We define working capital as current assets less current liabilities.

The as adjusted information discussed above is illustrative only and will depend on the actual public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$16.72 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019, would increase or decrease each of as adjusted cash, working capital, total assets and total stockholders' equity by \$2.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million in the number of shares offered by us would increase or decrease each of as adjusted cash, working capital, total assets and total stockholders' equity by \$15.5 million, assuming that the assumed public offering price remains the same, and after deducting estimated underwriting discounts and commissions.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

### Risks Related to Our Company and our Financial Condition

#### **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 \$29.2 million and \$53.1 million for the years ended December 31, 2017 and 2018, respectively. We also had negative operating cash flows in the years ended December 31, 2017 and 2018. As of December 31, 2017 and 2018, we had an accumulated deficit of \$113.4 million and \$167.1 million, respectively.

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 are primarily dependent on the success of our lead product candidate, LIQ861, and to a lesser degree, LIQ865, which are still in clinical development, and these product candidates may fail to receive marketing approval or may not be commercialized successfully.**

We have no 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, which is intended as an inhaled therapy for 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 product sales for at least the next few years, if ever.

We have completed a Phase 1 clinical trial for LIQ861 and an early Phase 1a clinical trial in Denmark for LIQ865 and a Phase 1b clinical trial for LIQ865 in the United States. We commenced a Phase 3 clinical trial for LIQ861 in the first quarter of 2018 and reported completion of enrollment and achievement of the primary endpoint in the INSPIRE trial in the first quarter of 2019. LIQ861 was observed to be well-tolerated in 109 patients, with 101 patients (93%) completing at least two months of treatment. During the two-month period, LIQ861 was evaluated at doses up to 150 mcg capsule strength with no study-drug related serious adverse events. We also commenced preparations for Phase 2-enabling toxicology studies for LIQ865 in the fourth quarter of 2018 and we expect to initiate these initial studies in March

2019. We anticipate that, following the initial Phase 2-enabling toxicology studies, which we expect to complete by the end of 2019, we will commence initial Phase 2 proof of concept clinical trials for LIQ865 in 2020. We cannot assure you that our toxicology studies or clinical trials, if commenced, will be successful or meet their endpoints.

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. 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. 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.

**We are 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.**

We are 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 GlaxoSmithKline plc and/or its subsidiaries, collectively, 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.

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

Our financial statements for the years ended December 31, 2017 and 2018 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. If we are unable to obtain sufficient funding, 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. Our ability to continue as a going concern could also materially limit our ability to raise additional funds through the issuance of new debt or equity securities or generate revenues

from licensing and collaboration arrangements. Following completion of this offering, 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.

**Even if this offering is successful, 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.

In the event that funds generated from our operations are insufficient to fund our future growth, we may raise additional funds through an 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.

**Although we have historically depended on GSK for a significant portion of our revenue, we do not expect to recognize any near-term revenue from GSK.**

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 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. For the years ended December 31, 2017 and 2018, 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 84% and 16%, respectively, of our total revenue.

GSK has informed us of changes to its plans with respect to the GSK ICO Agreement that has materially affected the amounts we received from GSK under this agreement for the year ended December 31, 2018 and which we expect will continue to materially affect the amounts we will receive from GSK under this agreement for the year ending December 31, 2019. In December 2017, GSK informed us of its modified plans under the GSK ICO Agreement that reduced its requirements and budget for our research and development that reduced its requirements and budget for our research and development support in 2018. Revenues from research and development services under the GSK ICO Agreement were \$0.2 million for the year ended December 31, 2018. We do not expect to recognize

additional revenues from GSK during fiscal year 2019 as a result of GSK's modified plans. In response, in January 2018 we reduced our research and development workforce accordingly, and incurred approximately \$400,000 in expense relating to the modification. Further, in June 2018, GSK notified us of its intention to review continuation of development of an inhaled antiviral for viral exacerbations in chronic obstructive pulmonary disease, or COPD, under the GSK ICO Agreement, after completion of its related Phase 1 clinical trial. On July 20, 2018, GSK confirmed that it will not continue the COPD program. We do not expect to incur additional expenses directly associated with the COPD program. GSK continues to express an interest in using PRINT technology for new inhaled programs, though no specific assets or activities have been identified at this time.

As a result of these changes, we do not expect to recognize any near-term revenue from GSK from our collaboration and licensing arrangements. We do not expect to generate comparable revenue from our other existing or future collaboration and licensing agreements in the near term, and we do not know if GSK will initiate development of a new program that will generate comparable revenue. In the event there are any further modifications to these arrangements, including if GSK exercises its right to terminate the ICO Agreement in its entirety or in respect of a particular product, or if GSK makes further changes to any existing development plans with us, we may not recognize the potential benefits of this collaboration.

**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, or 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 on October 26, 2018 in an initial tranche and \$5.0 million may be accessed at our option through June 30, 2019 upon the achievement of certain clinical milestones, we may not, among other things, 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 either New Enterprise Associates or Canaan Partners or their respective affiliates to serve as a voting member, in each case 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.

**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 that they enter into 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 developing blocking patents to which we do not have a license.

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 approved products are expected to face competition from drug products that are already on the market, as well as those in our competitors' development pipelines. In particular, we expect that LIQ861 will face competition from Tyvaso®, and Ventavis®, which are existing drug products indicated for the treatment of PAH, potential new entrants such as Insmed Inc.'s INS-1009, as well as generic equivalents of Tyvaso following the expiry of Tyvaso's patent in 2018. We are aware that MannKind Corporation, or MannKind, has recently filed an Investigational New Drug application, or IND, and completed a Phase 1 trial evaluating an inhaled dry powder treprostinil product for the treatment of PAH. On October 15, 2018, United Therapeutics Corporation, or United Therapeutics, and MannKind closed their worldwide exclusive licensing and collaboration agreement for the development and commercialization of a dry powder formulation of treprostinil, an investigational product currently being evaluated in clinical trials for the treatment of PAH. Under the agreement, United Therapeutics will be 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. Additionally, we are aware that Arena Pharmaceuticals, Inc., or Arena, has commenced a Phase 3 trial evaluating ralinepag, an oral treprostinil product for the treatment of patients suffering from PAH. On January 24, 2019, Arena and United Therapeutics closed on a global license agreement for ralinepag. Under the agreement, United Therapeutics is now responsible for the development, manufacture and commercialization of ralinepag. These new collaborations may accelerate competition for LIQ861. 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. In addition, while EXPAREL is currently the only direct competitor to LIQ865 on the market, Durect Corporation, Innocoll Holdings plc and Heron Therapeutics, Inc., or Heron, each have products in the pipeline that are potential competitors to LIQ865, which are estimated to enter the market in 2019, and generic equivalents of EXPAREL may enter the market following the expiry of EXPAREL's patent in 2018. In October 2018, 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 and a Prescription Drug User Fee Act, or PDUFA, goal date of April 30, 2019. If we are unable to maintain our competitive position, our business and prospects will be materially and adversely affected. See "Business — Competition" for further details.

**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 which 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, in part, depend on 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.

**Inadequate funding for the FDA, the SEC 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 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 the SEC and 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, 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, SEC and other government employees and stop critical activities. If a prolonged government shutdown 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, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

**Risks Related to our Business Operations**

**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

non-U.S. regulatory authorities, we intend to enter into strategic relationships with international collaborators for the commercialization of such products outside of the United States.

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 others. 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 in the case of our exclusivity arrangements 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 approved products, 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, including GSK, may have significant discretion in determining the efforts and resources that they will contribute;
- § our collaborators, including GSK, 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);
- § 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;
- § 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 (for example, our development and licensing agreement with G&W Laboratories, Inc., which we mutually terminated in April 2018), and if terminated, may result in our need for additional capital to pursue further drug product development or commercialization;
- § 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.

**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, 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, LGM Pharma, LLC, or LGM Pharma, for treprostinil, the active pharmaceutical ingredient of LIQ861. If LGM Pharma is unable to supply treprostinil to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, or if it ceases its relationship with us, we may not be able to obtain alternative supplies of treprostinil from other suppliers on acceptable terms, in a timely manner, or at all. Furthermore, LIQ861 is administered using RS00 Model 8 DPI, a DPI manufactured by Plastiapè S.p.A. We also rely on a sole supplier, Xcellence LLC (now a Lonza Group Ltd company), 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.

**Our operations are concentrated in Morrisville, North Carolina and interruptions due to natural disasters or other unforeseen events could materially and adversely affect our operations.**

All 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 for 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.

**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.

**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.

**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 and clinical 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 those in senior management, including Neal Fowler, our Chief

Executive Officer, and if we are unable to identify and retain a skilled Chief Financial Officer to succeed Kevin Gordon, our former President and Chief Financial Officer, following Mr. Gordon's departure on March 1, 2019, our business and prospects may be materially and adversely affected.

**Our employees and our independent contractors, principal investigators, contract research organizations, or CROs, consultants or commercial collaborators, as well as their respective sub-contractors, 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, consultants or commercial collaborators, as well as their respective sub-contractors, 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, consultants or commercial collaborators, as well as their respective sub-contractors, 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.

**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.

**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.

#### **Risks Related to the Development and Commercialization of our 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 design, scope or implementation 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 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;
- § 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 we may not be able to satisfy the FDA requirements for our processes or facilities;
- § 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 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 not approve of our manufacturing processes or facilities or those of our third-party manufacturers, which would be required to be corrected prior to marketing approval;
- § 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 they were previously not opposed to. 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 their 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 what we requested approval for, 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 approved drug products in commercial quantities and at acceptable prices, or at all.

**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 that 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.

**Our preclinical studies and clinical trials may not be successful and delays to 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 the safety and efficacy traits 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. We have not successfully completed the clinical development of any of our product candidates and, accordingly, 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.

**We are planning to pursue 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.**

Our business model is to develop our own drug products in addition to collaborating with, among others, pharmaceutical companies to develop drug products. 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, 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. 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 decision or action relative to our product 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 patent infringement lawsuits in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the review or 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. A claim by the applicant that a patent is invalid or will not be infringed is subject to challenge by the patent holder, requirements may give rise to patent litigation and mandatory 30-month delays in approval of a 505(b)(2) application. It is not uncommon for a manufacturer of an approved product 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 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.

**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 and, accordingly, the DPI will be evaluated as part of our NDA filing. When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable interactions between the drug and the delivery system, including the potential to negatively impact the safety or effectiveness of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. We rely on third parties for the design and manufacture of the delivery systems for our products, including the DPI for 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.

**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 PRINT technology and products based on it, including LIQ861 and LIQ865. To our knowledge, no regulatory authority has granted approval to any person or entity, including us, to market and commercialize drugs using our novel delivery system. 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.

**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; and
- § the number and nature of competing therapies and clinical trials.

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.

In particular, we will be required to identify and enroll a sufficient number of patients with PAH for the Phase 3 clinical trial, pharmacokinetics sub-study, hemodynamic clinical trial and other trials and studies of LIQ861. PAH is a rare disease with a relatively small patient population, and our enrollment of clinical trial participants may be slow as a result. 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 approval 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.

**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.**

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 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 the 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.

**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 intend to conduct an additional clinical trial in Europe that explores the hemodynamic effects of LIQ861 in PAH patients, and we may, in the future, conduct the 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 the 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.

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

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

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

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

**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, 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.

**Our current pipeline product candidates, LIQ861 and LIQ865, require extensive clinical data analysis, regulatory review and additional testing. Clinical trials and data analysis can be very 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. 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.

**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 revenues 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, or conduct additional clinical trials or we may need to recall the product;
- § we may be subject to litigation or product liability claims fines, injunctions or criminal penalties; and
- § our reputation may suffer.

**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 the 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.

**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.**

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 products may not achieve market acceptance.**

Our business model is to develop our own drug products in addition to collaborating with, among others, pharmaceutical companies to develop drug products. 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 approved drug products 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 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 reference listed drug in their formularies or otherwise restrict patient access to a reference listed drug when a less costly generic equivalent or other alternative is available. In particular, given that several therapeutically similar drug products to LIQ861, including 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 it is 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 we may not be placed on the formularies of key institutions and/or receive favorable reimbursement for LIQ865, if and when it is 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 drugs 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 to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more 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 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 any product revenue, and consequently, our results of operations may be materially and adversely affected.

**We may not be able to build our 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 approved drug products, we will be required to build our marketing and sales capabilities. 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 outside of the United States. 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 outside of the United States 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.

**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 are cleared by the FDA for these specific indications, we may only promote or market our product candidates for their specifically cleared or approved indications. We will train our marketing and sales force against promoting our product candidates for uses outside of the cleared or approved indications for use, known as "off-label uses." We cannot, however, 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 these 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 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 and impose potentially substantial costs on us.

**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, 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 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.

**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 approved 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 natural disasters, such as fires, floods, earthquakes and hurricanes, among others.

**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 labelling 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.

**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 suspension or revocation of product license 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 expenditure 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.

**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.

**We may not be able to engage third-party contract manufacturing organizations, or CMOs, to manufacture our approved drug products on a commercial scale to meet commercial demand for our drug products.**

We may, in the future, rely on third-party CMOs or enter into manufacturing joint ventures with third parties to manufacture our approved drug products 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.

**Risks Related to our Intellectual Property**

**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. The standards that patent offices in different jurisdictions use to grant patents are not always applied predictably or uniformly and may be changed.

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 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, or the duration of the patent protection of our drug products and 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 claims. 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, the patent protecting our product candidates may expire before or shortly after such product candidates are commercialized, if at all.

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 strengthen our patent position.

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

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

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

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

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

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

In addition, we license certain patent rights for our PRINT technology from 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 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.

**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, we may be required to include a certification of patent invalidity or non-infringement, or a paragraph IV certification, in an NDA submitted under the 505(b)(2) regulatory pathway, to certify that a patent over a reference listed drug is invalid, unenforceable or will not be infringed by the manufacture, use or sale of our product candidate. The holder of such patent may file a patent infringement lawsuit against us after receiving notice of the paragraph IV certification. Any such patent infringement lawsuit, if filed, will trigger a one-time, automatic, 30-month stay of the FDA's ability to approve our application, unless the patent litigation is resolved in our favor or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of a product candidate only to be subject to significant delay and incur substantial costs in litigation before such product candidate may be commercialized, if at all. Companies that produce reference listed drugs routinely bring claims for patent infringement against applicants under the 505(b)(2) regulatory pathway that are seeking regulatory approval to manufacture and market generic or reformulated forms of their reference listed drugs.

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.

**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 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 U.S. Patent and Trademark Office, or 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 may affect the way patent applications will be prosecuted and may also affect patent litigation. It may also weaken our ability to obtain patent protection in the United States for those 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 a 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.

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.

**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 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;
- § 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. 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. In addition, federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may also implicate the False Claims Act. Although the False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes;

- § 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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- § 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, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, and business associates. Among other things, HITECH made certain aspects of HIPAA's rules (notably the Security Rule) directly applicable to business associates — independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and 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 Department of Health and Human Services Office of 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, with one recent penalty exceeding \$16 million;
- § 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 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. On October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act." This law, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine Act"), extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act, to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments and transfers of value 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 which differ from each other in significant ways and may not have the same effect, and may apply more broadly thus complicating compliance efforts (for example, California recently enacted legislation — the California Consumer Privacy Act, or CCPA — which goes into effect 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 certain disclosures 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; legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations, and 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 it remains unclear what, if any, modifications will be made to this legislation or how it 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 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.

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 revenues 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. For example, the ACA which was signed into law in the United States in March 2010, is one such law that has affected the pharmaceutical industry.

Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- § 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 Health and Human Services, or HHS, as a condition of Medicare Part B and Medicaid coverage of the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, establishing new methodologies by which AMP is calculated and rebates owed by manufacturers under the Medicaid Drug Rebate Program are collected for drugs that are inhaled, infused, instilled, implanted or injected, adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, expanding the universe of Medicaid utilization subject to drug rebates to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, and expanding the population potentially eligible for Medicaid drug benefits;
- § the expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133.0% of the federal poverty level beginning in 2014, thereby potentially increasing 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. Effective in 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Recent proposed guidance from the HHS Health Resources and Services Administration, if adopted in its current form, may affect manufacturers' rights and liabilities in conducting audits and resolving disputes under the 340B program;
- § 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;
- § the ACA established a 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 research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products by influencing decisions relating to coverage and reimbursement rates; and

- § the ACA established the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid Center, or Innovation Center, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. The Innovation Center has been funded through 2019, and funding will be automatically renewed for each 10-year budget window thereafter.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. President Trump has 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. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or the TCJA, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. While the decision has been stayed pending outcome of an appeal to the Fifth Circuit Court of Appeals, so the ruling does not have immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. It is also unclear how regulations and sub regulatory policy, which fluctuate continually, may affect interpretation and implementation of the ACA and its practical effects on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2.0% per fiscal year, which went into effect in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, then-President Barack Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among others, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws, and other legislative, regulatory, and judicial developments may result in additional reductions in

Medicare and other healthcare funding, which could have a material and adverse effect on our customers and accordingly, our financial operations.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent 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. Recent 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. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS is soliciting feedback on some of these measures and has begun implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019; in October 2018, CMS proposed a new rule that if finalized in its current form would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product; and in early 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although some of these, and other, proposals may require additional authorization to become effective, 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 pharmacy benefit managers in the supply chain. 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for patients to access certain investigational new drug products that have completed a Phase I clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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. 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.

#### **Risks Related to this Offering and Our Common Stock**

##### **An active trading market for our common stock may not be sustained.**

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.

As of March 2, 2019, 15,566,692 shares of our common stock were outstanding, of which approximately 8.3 million shares of common stock, or 53.4% of our outstanding shares as of March 2, 2019, 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 approximately 7.3 million shares held by our stockholders is currently prohibited or otherwise restricted as a result of securities law provisions or 90-day lock-up agreements entered into by our stockholders with the underwriters. 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, or Rule 701. For more information see the section of this prospectus captioned "Shares Eligible for Future Sale."

As of March 2, 2019, the holders of approximately 10.2 million shares, or 65.4%, of our outstanding shares as of March 2, 2019, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans. 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 the lock-up agreements described in the section of this prospectus captioned "Underwriting."

**In the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.**

The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights, limitations on declaring dividends and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through collaborations, strategic alliances or licensing arrangements with third parties, and we could be required to do so at an earlier stage than otherwise would be desirable. In connection with any such collaborations, strategic alliances or licensing arrangements, we may be required to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

**Our management has broad discretion in using the net proceeds from this offering and may not use them effectively.**

We expect to use the net proceeds of this offering to complete our ongoing Phase 3 clinical trial and other development work for LIQ861, advance LIQ865 through our Phase 2-enabling toxicology studies expected to commence in March 2019 and into initial Phase 2 proof of concept clinical trials expected to commence in 2020, fund operations supporting the development of, and commercial activities for, LIQ861 and LIQ865, and for working capital and general corporate purposes. Our management will have broad discretion in the application of the balance of the net 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 available 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 the net proceeds from this offering in short-term, investment-grade, interest-bearing securities, which may not yield favorable returns.

**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. The trading price of our common stock following this offering may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- § the results of our or our competitors' clinical trials;
- § adverse results or delays in the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- § any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- § regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products and product candidates, including clinical trial requirements for approvals;

- § our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- § failure to commercialize our product candidates or if the size and growth of the markets we intend to target fail to meet expectations;
- § additions or departures of key scientific or management personnel, including the departure of Mr. Gordon, our former President and Chief Financial Officer, effective March 1, 2019;
- § unanticipated serious safety concerns related to the use of our product candidates;
- § introductions or announcements of new products offered by us or significant acquisitions, strategic collaborations, joint ventures or capital commitments by us, our collaborators or our competitors and the timing of such introductions or announcements;
- § the introduction by our competitors of new products or technologies, or the success of our competitors' products or technologies;
- § our ability or inability to effectively manage our growth;
- § changes in the structure of healthcare payment systems;
- § our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- § publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- § market conditions in the pharmaceutical and biotechnology sectors or the economy generally;
- § our ability or inability to raise additional capital through the issuance of equity or debt or collaboration arrangements and the terms on which we raise it;
- § trading volume of our common stock;
- § disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- § period-to-period fluctuations in our quarterly results of operations or those of our competitors;
- § discrepancies between our actual operating results and the estimates or projections of investors or securities analysts;
- § fluctuations in the share price and trading volumes of other publicly traded companies engaged in similar business activities as us;
- § market conditions in the pharmaceutical industry and in general;
- § research and reports published by securities and industry analysts on our company or other companies engaged in similar business activities as us;
- § safety concerns in relation to the use of any of our product candidates or approved products; and/or
- § our involvement in significant lawsuits, including patent or stockholder litigation.

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.

**As a new investor, you will immediately experience substantial dilution as a result of this offering. Furthermore, 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.**

The purchasers of shares of our common stock in this offering will experience immediate and substantial dilution of \$13.23 per share, based on an assumed public offering price of \$16.72 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019. This dilution represents the amount by which the per share purchase price of our common stock offered in this offering exceeds the as adjusted net tangible book value per share of our common stock immediately following this offering. In addition, you may also experience additional 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, or 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. See "Dilution."

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 in more than one transaction, investors in this offering may be materially diluted by subsequent sales. Such sales would also likely result in material dilution to our existing equity holders, and new investors could gain rights, preferences and privileges senior to those of holders of our existing equity securities.

**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 named executive officers, other executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned 49.6% of our capital stock as of March 1, 2019 and, upon completion of this offering, that same group will beneficially own 43.1% of our capital stock, of which 2.9% will be beneficially owned by our executive officers (assuming no exercise of the underwriters' option to purchase additional shares). Accordingly, after this offering, our named executive officers, other executive officers, directors and principal stockholders will be substantially able to determine the composition of the Board and retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and will 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.

**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. We do not currently have, and may never obtain research coverage by securities and industry analysts. If no or few analysts commence research coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

**If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.**

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 financial statements or identify other areas for further attention or improvement.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2019. However, 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 five years. An independent assessment of the effectiveness of our internal controls could detect 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 the expense of remediation.

**We will incur increased costs now as a public company.**

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur 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. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may 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. 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.

**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 revenues 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 amended and restated certificate of incorporation and amended and restated 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. See the section of this prospectus captioned "Description of Capital Stock — Anti-Takeover Effects of Provisions of our Certificate of Incorporation and Bylaws and Delaware Law" for additional information.

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.

**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 existing or any future debt agreements 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.

**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 this offering, the initial public offering as well as other past transactions and any ownership changes that we may experience in the future as a result of subsequent shifts in ownership of our shares of common stock, we may trigger an "ownership change" limitation. Should this occur, and if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

**The TCJA could adversely affect our business and financial condition.**

On December 22, 2017, 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 revenues 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 have completed our accounting for the TCJA during the fourth 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, including purchasers of common stock in this offering, to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

**Our amended and restated 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 amended and restated 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 amended and restated certificate of incorporation or our amended and restated bylaws; or (d) any action asserting a claim against us governed by the internal affairs doctrine. 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.

#### CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus may be forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "should," "expects," "plans," "anticipates," "could," "would," "intends," "targets," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

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

You should refer to the "Risk Factors" section of this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. The forward-looking statements in this prospectus are only predictions, and we may not actually achieve the plans, intentions or expectations included in our forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

These forward-looking statements speak only as of the date of this prospectus. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained in this prospectus after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

## USE OF PROCEEDS

We estimate that the net proceeds to us from our issuance and sale of shares of our common stock in this offering will be \$45.9 million, based on an assumed public offering price of \$16.72 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise in full their option to purchase additional shares, we estimate that the net proceeds from this offering will be \$52.9 million.

Each \$1.00 increase or decrease in the assumed public offering price of \$16.72 per share would increase or decrease the net proceeds to us from this offering by \$2.8 million (or \$3.2 million if the underwriters exercise their option to purchase additional shares), assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million in the number of shares of common stock offered by us at the assumed public offering price of \$16.72 per share would increase or decrease the net proceeds to us from this offering by \$15.5 million, after deducting estimated underwriting discounts and commissions.

We currently estimate that we will use the net proceeds from this offering, together with our existing cash, as follows:

- § approximately \$42.0 million to \$44.0 million to complete our ongoing Phase 3 clinical trial and other development work for LIQ861;
- § approximately \$9.0 million to \$9.5 million to advance LIQ865 through our Phase 2-enabling toxicology studies expected to commence in March 2019 and into initial Phase 2 proof of concept clinical trials expected to commence in 2020;
- § approximately \$17.0 million to \$18.0 million to fund operations supporting the development of, and commercial activities for, LIQ861 and LIQ865; and
- § the remainder for working capital and general corporate purposes.

This expected use of the net proceeds from this offering and our existing cash represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development and commercialization efforts, the status of and results from clinical trials and actual results of operations, as well as any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

We may also use a portion of the remaining net proceeds to in-license, acquire or invest in complementary businesses, technologies, products or assets, although we have no current agreements, commitments or understandings to do so.

As of December 31, 2018, we had cash of \$39.5 million. Based on our planned use of the net proceeds from this offering and our existing cash and current revenue forecasts, we estimate that such funds will be sufficient to enable us to support research and development needs and to fund our operating expenses and capital expenditure requirements into the third quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We do not expect that the net proceeds from this offering and our existing cash will be sufficient to enable us to fund the completion of development and commercialization of any of our product candidates.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

**DIVIDEND POLICY**

We currently expect to retain all future earnings, if any, for use in the operation and expansion of our business. We have never declared nor paid any dividends on our common stock and do not anticipate paying cash dividends to holders of our common stock in the foreseeable future. In addition, our loan agreement with our commercial lender prohibits our ability to pay dividends without the lender's prior written consent, with certain exceptions. See "Risk Factors — 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."

**CAPITALIZATION**

The following table sets forth our cash and our capitalization as of December 31, 2018:

- § on an actual basis; and
- § on an as adjusted basis to give effect to our issuance and sale of 3,000,000 shares of our common stock in this offering at an assumed public offering price of \$16.72 per share, the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this "Capitalization" section in conjunction with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Use of Proceeds" sections and other financial information contained in this prospectus.

	<u>As of December 31, 2018</u>	
	<u>Actual</u>	<u>As adjusted</u>
	<u>(in thousands, except share and per share data)</u>	
Cash	\$ 39,535	\$ 85,484
Long-term debt, including current portion	\$ 11,945	\$ 11,945
Capital leases, including current portion	829	829
Stockholders' deficit:		
Common stock, \$0.001 par value; 40,000,000 shares authorized, 15,519,469 shares issued and outstanding, actual; 40,000,000 shares authorized, 18,519,469 shares issued and outstanding, as adjusted	16	19
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding, actual and as adjusted	—	—
Additional paid-in capital	185,726	231,672
Accumulated deficit	(167,054)	(167,054)
Total stockholders' (deficit) equity	18,688	64,637
Total capitalization	<u>\$ 31,462</u>	<u>\$ 77,411</u>

Our cash and our capitalization following the completion of this offering will depend on the actual public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$16.72 per share, which is the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019, would increase or decrease the as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity and total capitalization by \$2.8 million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase or decrease of 1.0 million in the number of shares we are offering at the assumed public offering price of \$16.72 per share would increase or decrease the as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity and total capitalization by \$15.5 million.

The table above does not include:

- § 1,658,112 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2018, with a weighted average exercise price of \$8.76 per share, of which

14,328 shares of common stock were subsequently issued upon the exercise of stock options after December 31, 2018;

- § 395,408 shares of common stock issuable upon the exercise of stock options granted after December 31, 2018, with an exercise price of \$14.20 per share;
- § 170,925 shares of common stock issuable upon the exercise of warrants outstanding as of December 31, 2018, with a weighted average exercise price of \$0.0168 per share, of which 64,629 shares of common stock were subsequently issued upon the exercise of warrants after December 31, 2018;
- § 34,551 former restricted stock units granted to Kevin Gordon, our former President and Chief Financial Officer whose consulting period with the Company will expire on March 31, 2019, which settled in common stock after December 31, 2018;
- § an aggregate of 151,217 shares of common stock issuable upon the vesting of restricted stock units granted to Neal Fowler, our Chief Executive Officer, and Mr. Gordon; and
- § an additional 1,193,329 shares of common stock available for future issuance under the Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan, or the 2018 Plan.

**DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after this offering. Net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of shares of common stock then issued and outstanding.

Our net tangible book value as of December 31, 2018 was \$18.7 million, or \$1.20 per share of common stock.

After giving effect to the issuance and sale by us of shares of 3,000,000 common stock in this offering at an assumed public offering price of \$16.72 per share, which is the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2018 would have been \$64.6 million, or \$3.49 per share. This amount represents an immediate increase in as adjusted net tangible book value of \$2.29 per share to our existing stockholders and an immediate dilution in as adjusted net tangible book value of \$13.23 per share to new investors purchasing common stock in this offering at the assumed public offering price. We determine dilution by subtracting the as adjusted net tangible book value per share of common stock after this offering from the amount of cash that a new investor paid for a share of common stock.

The following table illustrates this dilution to new investors on a per share basis:

Assumed public offering price per share	\$ 16.72
Historical net tangible book value per share as of December 31, 2018	\$ 1.20
Increase in net tangible book value per share attributable to the adjustments described above	<u>2.29</u>
As adjusted net tangible book value per share after this offering	3.49
Dilution per share to new investors in this offering	<u>\$ (13.23)</u>

The as adjusted information discussed above is illustrative only and will depend on the actual public offering price and other terms of this offering determined at pricing. A \$1.00 increase or decrease in the assumed public offering price of \$16.72 per share, which is the last reported sales price of our common stock on the Nasdaq Capital Market on March 15, 2019, would increase or decrease the as adjusted net tangible book value after this offering by \$2.8 million, the as adjusted net tangible book value per share by \$0.15 and dilution per share to new investors purchasing shares in this offering by \$0.85, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. An increase of 1.0 million in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the as adjusted net tangible book value per share after this offering by \$15.5 million and decrease the dilution per share to new investors participating in this offering by \$0.62, assuming no change in the assumed public offering price and after deducting estimated underwriting discounts and commissions. A decrease of 1.0 million in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the as adjusted net tangible book value per share after this offering by \$15.5 million and increase the dilution per share to new investors participating in this offering by \$0.69, assuming no change in the assumed public offering price and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise their option in full to purchase additional shares of common stock in this offering, the as adjusted net tangible book value per share after the offering would be \$3.78, the increase in the as adjusted net tangible book value per share to existing stockholders would be \$0.29 and the dilution per share to new investors purchasing shares in this offering would be \$12.94.

If any shares are issued upon exercise of outstanding options, or if additional options or other equity awards are granted and exercised or become vested, or if other issuances of common stock are made, you will experience further dilution.

The number of shares purchased from us by existing stockholders is based on 15,519,469 shares of common stock outstanding as of December 31, 2018 and excludes:

- § 1,658,112 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2018, with a weighted average exercise price of \$8.76 per share, of which 14,328 shares of common stock were subsequently issued upon the exercise of stock options after December 31, 2018;
- § 395,408 shares of common stock issuable upon the exercise of stock options granted after December 31, 2018, with an exercise price of \$14.20 per share;
- § 170,925 shares of common stock issuable upon the exercise of warrants outstanding as of December 31, 2018, with a weighted average exercise price of \$0.0168 per share, of which 64,629 shares of common stock were subsequently issued upon the exercise of warrants after December 31, 2018;
- § 34,551 former restricted stock units granted to Kevin Gordon, our former President and Chief Financial Officer whose consulting period with the Company will expire on March 31, 2019, which settled in common stock after December 31, 2018;
- § an aggregate of 151,217 shares of common stock issuable upon the vesting of restricted stock units granted to Neal Fowler, our Chief Executive Officer, and Mr. Gordon; and
- § an additional 1,193,329 shares of common stock available for future issuance under the 2018 Plan.

**SELECTED FINANCIAL DATA**

The selected statement of operations data for the years ended December 31, 2017 and 2018 and the balance sheet data as of December 31, 2017 and 2018 are derived from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period.

The following selected financial data should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus. The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2017	2018
<b>Statement of operations data:</b>		
Revenues	\$ 7,258,123	\$ 2,706,981
Costs and expenses:		
Cost of sales	319,759	121,391
Research and development	24,753,876	28,699,576
General and administrative	10,212,774	8,754,088
Total costs and expenses	<u>35,286,409</u>	<u>37,575,055</u>
Loss from operations	(28,028,286)	(34,868,074)
Other income (expense):		
Interest income	268	304,981
Interest expense	(13,010,475)	(18,988,176)
Gain on early extinguishment of long-term debt	—	137,695
Derivative and warrant fair value adjustments	11,884,253	277,715
Total other income (expense), net	<u>(1,125,954)</u>	<u>(18,267,785)</u>
Net loss	<u>(29,154,240)</u>	<u>(53,135,859)</u>
Comprehensive loss	<u>\$ (29,154,240)</u>	<u>\$ (53,135,859)</u>
Net loss per common share:		
Basic	<u>\$ (51.78)</u>	<u>\$ (7.42)</u>
Diluted	<u>\$ (51.78)</u>	<u>\$ (7.51)</u>
Weighted average common shares outstanding:		
Basic	<u>563,076</u>	<u>7,163,304</u>
Diluted	<u>563,076</u>	<u>7,078,757</u>

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	As of December 31,	
	2017	2018
<b>Balance Sheet Data:</b>		
Cash	\$ 3,418,979	\$ 39,534,985
Total assets	14,843,602	49,418,258
Total debt and capital leases	22,145,554	12,773,334
Capital stock and additional paid-in capital	79,721,075	185,741,568
Accumulated deficit	(113,413,311)	(167,053,897)
Total stockholders' (deficit) equity	(33,692,236)	18,687,671

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## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis. See "Cautionary Note Regarding Forward-Looking Statements."*

### Overview

We are a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using 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. 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. Our lead product candidate, LIQ861, is being evaluated in an open-label Phase 3 clinical trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, as a potential treatment for PAH. LIQ861 is an inhaled dry powder formulation of treprostinil that is administered using a convenient, disposable dry powder inhaler, or DPI. Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function, 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. As reported on March 11, 2019, we completed enrollment and met the primary endpoint in our INSPIRE trial. LIQ861 was observed to be well-tolerated in 109 patients, with 101 patients (93%) completing at least two months of treatment. During the two-month period, LIQ861 was evaluated at doses up to 150 mcg capsule strength with no study-drug related serious adverse events. The INSPIRE study is designed to evaluate patients who have either been under stable treatment with nebulizer-delivered treprostinil for at least three months and are transitioned to LIQ861 under the protocol or who have been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and have their treatment regimen supplemented with LIQ861 under the protocol. The primary objective of the study is to evaluate the long-term safety and tolerability of LIQ861. We also completed enrollment in our one-directional crossover sub-study comparing bioavailability and pharmacokinetics of treprostinil as sub-study patients transitioned from Tyvaso to LIQ861. We expect to report our bioavailability and pharmacokinetics results in the second quarter of 2019. We intend to conduct additional clinical work in support of our marketing and commercial activities in advance of our U.S. launch for LIQ861, including maintaining patients on LIQ861 up to our U.S. launch and collecting data relating to the effects of LIQ861 on hemodynamic measurements. We are targeting a New Drug Application, or NDA, submission to the U.S. Food and Drug Administration, or FDA, for LIQ861 in late 2019.

We have completed two Phase 1 clinical trials of our second product candidate, LIQ865, for the treatment for local post-operative pain. LIQ865 is our proprietary injectable, sustained-release formulation of bupivacaine, a non-opioid pain medicine. We have designed LIQ865 to be administered as a single treatment for the management of local post-operative pain for three to five days after a procedure, which we believe, if approved, has the potential to provide significantly longer post-operative pain relief compared to currently marketed formulations of bupivacaine. We commenced preparation for Phase 2-enabling toxicology studies in the fourth quarter of 2018 and expect to initiate these initial studies in March 2019, complete these studies by the end of 2019 and commence initial Phase 2 proof of concept clinical trials in 2020.

In addition to developing our two current product candidates, we license our PRINT technology to pharmaceutical companies seeking to develop their own potential drug and biologic therapies. 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 manufacture them using in-house capabilities. Where appropriate, we will rely on third-party CMOs to produce, package and distribute our approved drug products on a commercial scale.

We have not generated any revenue to date from the sale of pharmaceutical products, and we have historically financed our operations in large part with an aggregate of \$170.0 million of gross proceeds from sales of our capital stock, convertible promissory notes, \$11.0 million in term loans from a bank and a \$2.1 million loan from UNC. We do not expect to generate significant product revenue unless and until we obtain marketing approval for and commercialize LIQ861, LIQ865 or one of our other future product candidates.

Since our inception, we have incurred significant operating losses. Our net loss was \$29.2 million and \$53.1 million for the years ended December 31, 2017 and 2018, respectively, and as of December 31, 2018, we had an accumulated deficit of \$167.1 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, and seek regulatory approval and pursue commercialization of any approved product candidate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

As of December 31, 2018, we had cash of \$39.5 million. We believe that our existing cash together with funds available under the A&R LSA (as described below), will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2019. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. See "— Liquidity and Capital Resources."

#### **Our Collaborations**

Our only revenue, which has been derived from collaborating and licensing our proprietary PRINT technology to pharmaceutical companies, amounted to \$7.3 million and \$2.7 million for the years ended December 31, 2017 and 2018, respectively. GSK accounted for \$6.1 million and \$0.4 million for the years ended December 31, 2017 and 2018, respectively, or 84% and 16%, respectively, of our total revenue during those periods. See "— GSK." Our collaborators make up-front fees or technology access payments, pay us to achieve clinical milestones, pay us fees to develop their drug products through research and

development services like particle formulation and manufacturing and will pay us royalties upon ultimate commercial sales of the related products.

## **GSK**

We have actively collaborated with GSK on the use of our PRINT technology in respiratory disease since 2012.

In June 2012, we entered into an Inhaled Collaboration and Option Agreement with GSK, or the GSK ICO Agreement, under which we granted GSK exclusive options and licenses to further develop and commercialize inhaled therapies using our PRINT technology. In September 2015, GSK exercised its option to obtain an exclusive, worldwide license to certain of our know-how and patents relating to our PRINT technology, for the purpose of, among others, conducting preclinical studies of inhaled therapeutics developed, manufactured or otherwise produced using our PRINT technology. In consideration for GSK's exercise of this option, we received a non-refundable up-front payment of \$15.0 million, which amount is being amortized into revenue over a period of time based on the estimated remaining development period and on a similar basis as research and development services are expected to be performed, a period of 93 months as of December 31, 2018. Under the terms of the GSK ICO Agreement, we are also entitled to certain milestone payments aggregating up to \$158 million upon the achievement of specified milestone events for new non-rescue therapeutic products. Rescue therapeutic products are therapeutics that GSK develops with our PRINT technology that had previously been discontinued from development. We are also entitled to tiered royalties on the worldwide sales of the licensed products at percentages ranging from the mid-single digits to low-single digits depending on the total number of products developed and other royalty step-down events, with a fixed low-single digit royalty floor under the GSK ICO Agreement. Revenues from research and development services under the GSK ICO Agreement amounted to \$3.1 million and \$0.2 million for the years ended December 31, 2017 and 2018, respectively.

In December 2017, GSK informed us of its modified plans under the GSK ICO Agreement that reduced its requirements and budget for our research and development support in 2018. In response, in January 2018, we reduced our research and development workforce accordingly, and we incurred approximately \$400,000 in expense relating to the workforce reduction. We do not expect to recognize additional revenues from GSK in 2019 as a result of GSK's modified plans.

We also entered into other engagements with GSK under the GSK ICO Agreement, primarily for platform research services. GSK is in the reporting phase of a Phase 1 clinical trial of an inhaled chronic obstructive pulmonary disease, or COPD, product candidate that was formulated as an inhaled dry powder using the PRINT technology. In June 2018, GSK notified us of its intention to review continuation of development of an inhaled antiviral for viral exacerbations in COPD, part of the GSK ICO Agreement, after completion of its related Phase 1 clinical trial. On July 20, 2018, GSK confirmed that it will not continue the COPD program. We do not expect to incur additional revenues or expenses directly associated with the COPD program. GSK continues to express an interest in using PRINT technology for new inhaled programs, though no specific assets or activities have been identified at this time.

## **G&W Laboratories**

In June 2016, we entered into a development and license agreement, or the G&W Labs Agreement, with G&W Laboratories, Inc., or G&W Labs, to develop multiple products for topical delivery in dermatology using our PRINT technology. We received the first non-refundable up-front fee of \$1.0 million under this agreement in June 2016, which amount was being amortized into revenue over a period of time based upon the estimated remaining development period and on a similar basis as research and development services are expected to be performed. We began performing research and development services under this agreement in July 2016. In April 2018, we and G&W Labs mutually agreed to terminate the G&W Labs Agreement. As a result, during the year ended December 31, 2018, the remaining unamortized balances in the related deferred revenue and deferred sublicense payments of \$0.9 million and \$0.1 million,

respectively, were fully recorded as Revenues and Cost of sales, respectively, in the accompanying Statement of Operations and Comprehensive Loss.

#### **Gates Foundation**

In 2011, we entered into a collaboration agreement with the Bill & Melinda Gates Foundation, primarily for research services related to developing vaccines targeted at developing markets. We received an up-front fee of \$1.0 million under this agreement, which we recognized as revenue through December 2017. We are not performing any services under this collaboration agreement and do not expect to recognize any further revenue under the agreement.

#### **Components of Statements of Operations**

##### **Revenue**

Our revenue is primarily derived from collaborating and licensing our proprietary PRINT technology to pharmaceutical companies. In the future, we also expect to derive our revenue from our own pharmaceutical products. Up until the fourth quarter of 2018, we managed, reported and evaluated our business in the following two segments: Pharmaceutical Products and Partnering and Licensing. These reportable operating segments were determined in accordance with our internal management structure, which was organized based on operating activities, the manner in which we organized segments for making operating decisions and assessing performance and the availability of separate financial results.

In the fourth quarter of 2018, due to significantly diminished activities pursuant to collaborations, we changed the way we manage and operate the reporting entity and modified our information system to produce financial information for the chief operating decision maker, or CODM, to support the new structure. The changes required us to revise our segment reporting. Management reorganized our operations and reporting structure and began to manage our operations under our new segment structure, resulting in a single reportable segment. The financial statements were adjusted to reflect this change in segment reporting for all periods presented.

All long-lived assets are domiciled within the United States and all revenues were earned within the United States.

##### **Cost of Sales**

Cost of sales consists of the amortization of license fees owed to UNC upon our receipt of licensing revenues. See "Business — Our Collaboration and Licensing Agreements — The University of North Carolina at Chapel Hill" for further details. The amortization period is the same as the period and in the same manner in which the related revenue is recognized.

##### **Research and Development Expenses**

Research and development expense consists of expenses incurred in connection with the development of our product candidates. We expense research and development costs as incurred. These expenses include:

- § expenses incurred under agreements with CROs as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- § manufacturing process development and scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- § outsourced professional scientific development services;
- § employee-related expenses, which include salaries, benefits and stock-based compensation for personnel in research and development functions;
- § expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- § laboratory materials and supplies used to support our research activities; and
- § allocated expenses for utilities and other facility-related costs.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our ongoing Phase 3 clinical trial and other development work for LIQ861, continue the development of LIQ865, conduct additional clinical trials, continue manufacturing process development and scale up and prepare for regulatory filings for our product candidates and regulatory inspection of facilities utilizing our PRINT manufacturing process.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- § the number of clinical sites included in the trials;
- § the length of time required to enroll suitable patients;
- § the number of patients that ultimately participate in the trials;
- § the number of doses patients receive;
- § the duration of patient follow-up; and
- § the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, or our ability to manufacture and supply product, we could be required to expend significant additional financial resources and time on the completion of clinical development. Drug commercialization will take several years and millions of dollars in development costs.

#### **General and Administrative Expenses**

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for marketing, legal, auditing and tax services and insurance costs.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company. We anticipate the additional costs for these services will increase our general and administrative expenses by approximately \$1.5 million to \$2.0 million on an annual basis. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

**Other Income (Expense)**

Other income (expense) is comprised primarily of interest income and expense and derivative and warrant fair value adjustments. Interest income consists of interest earned on our cash deposits. Interest expense consists of interest charges on capital leases and debt. These charges include monthly recurring interest on such obligations in addition to non-cash charges. Non-cash charges include the accrual of interest expense at the end of each reporting period in addition to the expensing of debt issuance costs and amortization of discounts on long-term debt to interest expense. Derivative and warrant fair value adjustments consist of the unrealized gains and losses as a result of marking these financial instruments to fair market value at the end of each reporting period.

**Critical Accounting Policies and Estimates**

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to long-lived assets, derivatives, stock-based compensation and accrued expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this prospectus, we believe the following accounting policies to be the most critical to the judgments and estimates used in the preparation of our financial statements.

**Going Concern**

Our financial statements have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. We closed our initial public offering in July and August 2018 resulting in total net proceeds of \$47.3 million, after underwriting discounts and the payment of other offering expenses.

Our operations have consisted primarily of developing our technology, developing products, prosecuting our intellectual property and securing financing. We have incurred recurring losses and cash outflows from operations, have an accumulated deficit, and have debt maturing within twelve months. We expect to continue to incur losses in the foreseeable future and will require additional financial resources to continue to advance our products and intellectual property, in addition to repaying our maturing debt and other obligations.

These circumstances raise substantial doubt about our ability to continue as a going concern. Management's plans with regard to this matter include continuing attempts to obtain additional financing to sustain our operations. However, there is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us, and the failure to obtain sufficient funds on acceptable terms, when needed, could have a material adverse effect on our business, results of operations and financial condition. If sufficient financings are not obtained, this may necessitate other actions by us. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Revenue Recognition**

Our revenues are generated through license, collaboration and other similar research and development agreements. These agreements include up-front fees, payments for achievement of specified development, regulatory and sales milestones and provision for billing for research and development services like particle formulations and manufacturing, all of which comprise our revenues. In addition, such agreements provide

for royalties on product sales after commercial launch of the related products. We record any amounts received in advance of services performed as deferred revenue and recognize them as revenue over the estimated period of our substantive performance obligations.

In May 2014, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, or Topic 606. The FASB issued Topic 606 to clarify the principles for recognizing revenue and to develop a common revenue standard for GAAP. The standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. Topic 606 also includes Subtopic 340-40, *Other Assets and Deferred Costs — Contracts with Customers*, which requires the deferral of incremental costs of obtaining a contract with a customer and certain contract fulfillment costs. We adopted this standard and all the related amendments, or the new revenue standard, on January 1, 2018, applying the modified retrospective transition method. The modified retrospective transition method is applied on a prospective basis from the adoption date and does not recast historical financial statement periods. Any contracts with customers that were not complete as of the adoption date are reviewed and we recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of accumulated deficit as of January 1, 2018. Financial information in comparative periods have not been restated and continue to be reported under the accounting methods in effect for that period.

This adoption primarily affected the recognition of non-refundable up-front fees and milestone payments. We previously recognized non-refundable up-front fees as deferred revenue which was recognized into revenue on a straight-line basis over the estimated period of our substantive performance obligations, as a component of a multiple element arrangement. Milestone payments were previously accounted for under ASC 605 28-50-2(e), which had required recognition of a milestone payment when the applicable event was considered to be both substantive and achieved. The adoption of the new revenue standard generally requires licenses that are not considered distinct performance obligations from other goods or services within a contract to be bundled with those goods or services as a combined performance obligation. Revenue associated with the combined performance obligation is recognized over time as those goods or services are delivered.

The adoption of the new revenue standard also impacted the deferral of sublicense payments related to the milestone payments, which were previously expensed when the milestone payments were recognized, and the timing of recognition of deferred sublicense payments related to up-front license payments. Under the new revenue standard, the incremental sublicense payments related to milestone payments will be deferred as contract fulfillment costs and amortized over time, consistent with the method of recognition for the related revenues.

The cumulative effect of the changes made to the January 1, 2018 balance of accumulated deficit on our balance sheet for the adoption of Topic 606 was an increase to the accumulated deficit of \$0.5 million.

#### **Stock-Based Compensation**

We account for stock-based compensation under ASC Topic 718, *Compensation — Stock Compensation*, or ASC 718. Determining the amount of stock-based compensation to be recorded requires us to determine estimates of fair values of stock options as of the grant date.

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes option-pricing model, or the Black-Scholes Model. The Black-Scholes Model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of

grant, among other inputs. The risk-free interest rate was determined with the implied yield currently available for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options.

All stock-based awards granted to non-employees are accounted for at their fair value in accordance with ASC 505, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, or ASC 505, under which compensation expense is generally recognized over the vesting period of the award.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change.

#### **Convertible Instruments**

We have utilized various types of financing to fund our business needs, including convertible debt and convertible preferred stock, in some cases with corresponding warrants. We considered guidance within FASB ASC 470-20, *Debt with Conversion and Other Options*, or ASC 470-20, ASC 480, *Distinguishing Liabilities from Equity*, or ASC 480, and ASC 815, *Derivatives and Hedging*, or ASC 815, when accounting for the issuance of convertible securities. Additionally, we review the instruments to determine whether they are freestanding or contain an embedded derivative and, if so, whether they should be classified in permanent equity, mezzanine equity or as a liability at each reporting period until the amount is settled and reclassified into equity.

When multiple instruments are issued in a single transaction, we allocate total proceeds from the transaction among the individual freestanding instruments identified. The allocation is made after identifying all the freestanding instruments and the subsequent measurement basis for those instruments. The subsequent measurement basis determines how the proceeds are allocated. Generally, proceeds are allocated based on one of the following methods:

- § Fair value method — The instrument being analyzed is allocated a portion of the proceeds equal to its fair value, with the remaining proceeds allocated to the other instruments as appropriate.
- § Relative fair value method — The instrument being analyzed is allocated a portion of the proceeds based on the proportion of its fair value to the sum of the fair values of all the instruments covered in the allocation.
- § Residual value method — The instrument being analyzed is allocated the remaining proceeds after an allocation is made to all other instruments covered in the allocation.

Generally, when there are multiple instruments issued in a single transaction that have different subsequent measurement bases, the proceeds from the transaction are first allocated to the instrument that is subsequently measured at fair value (i.e., instruments accounted for as a derivative liabilities) at its issuance date fair value, with the residual proceeds allocated to the instrument not subsequently measured at fair value. In the event both instruments in the transaction are not subsequently measured at fair value (i.e., equity-classified instruments), the proceeds from the transaction are allocated to the freestanding instruments based on their respective fair values, using the relative fair value method.

After the proceeds are allocated to the freestanding instruments, resulting in an initial discount on the host contract, those instruments are further evaluated for embedded features (i.e., conversion options) that require bifurcation and separate accounting as a derivative financial instrument pursuant to ASC 815. Embedded derivative financial instruments are initially and subsequently measured at fair value. Under ASC 815, a portion of the proceeds received upon the issuance of the hybrid contract is allocated to the fair value of the derivative.

We account for convertible instruments in which it is determined that the embedded conversion options should not be bifurcated from their host instruments in accordance with ASC 470-20. Under ASC 470-20, we record, when necessary, discounts to convertible notes or convertible preferred stock for the intrinsic value of conversion options embedded in the convertible instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the transaction and the effective conversion price embedded in the convertible instrument, unless limited by the proceeds allocated to such instrument.

#### ***Warrant Liabilities***

We have historically classified warrants to purchase shares of preferred stock as liabilities on our Balance Sheets as these warrants were freestanding financial instruments that will require us to issue convertible securities upon exercise. The warrants were initially recorded at fair value on date of grant, and were subsequently remeasured to fair value at each reporting period. Changes in fair value of the warrants are recognized as a component of other income (expense) in our Statements of Operations and Comprehensive Loss. In conjunction with our initial public offering, the warrants were converted to warrants for common stock. Following that conversion, these warrants no longer meet the criteria to be presented as a liability and have been reclassified to additional paid-in capital. We will no longer include the warrants as liabilities or recognize changes in their fair value on the Statements of Operations and Comprehensive Loss.

We used the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the preferred stock warrants. We assessed these assumptions and estimates on a quarterly basis as additional information impacting the assumptions was obtained. Estimates and assumptions impacting the fair value measurement included the fair value per share of the underlying preferred stock, the remaining contractual term of the warrant, the risk-free interest rate, the expected dividend yield and the expected volatility of the price of the underlying preferred stock. We determined the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of our convertible preferred stock, results obtained from third-party valuations and additional factors that were deemed relevant. We estimated our expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. Expected dividend yield was based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

#### ***Embedded Derivatives***

Embedded derivatives that are required to be bifurcated from the underlying instrument are accounted for and valued as a separate financial instrument. In conjunction with our convertible notes, embedded derivatives existed associated with the future consummation of a qualified financing event, as defined in the notes, and a subsequent discounted conversion of the instrument to capital stock. The embedded derivatives were bifurcated and classified as derivative liabilities on the Balance Sheets and separately adjusted to their fair values at the end of each reporting period. Changes in fair values of the derivative liabilities were recognized as a component of other income (expense) in the Statements of Operations and Comprehensive Loss. These embedded derivatives were eliminated upon conversion of the underlying convertible notes into Series D preferred stock.

#### ***Issuance Costs Related to Equity and Debt***

We allocate issuance costs between the individual freestanding instruments identified on the same basis as proceeds were allocated. Issuance costs associated with the issuance of stock or equity contracts (i.e., equity-classified warrants and convertible preferred stock) are recorded as a charge against the gross proceeds of the offering. Any issuance costs associated with the issuance of liability-classified warrants are expensed as incurred. Issuance costs associated with the issuance of debt (i.e., convertible debt) are recorded as a direct reduction of the carrying amount of the debt liability, but limited to the notional value of the debt. We account for debt as liabilities measured at amortized cost and amortize the resulting debt discount to interest expense using the straight-line method over the expected term of the notes pursuant to

ASC 835, *Interest* (ASC 835). To the extent that the reduction from issuance costs of the carrying amount of the debt liability would reduce the carrying amount below zero, such excess is recorded as interest expense.

#### **Deferred Offering Costs**

We capitalize certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such equity financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering.

#### **Income Taxes**

We file U.S. Federal income tax returns and North Carolina State income tax returns. Our deferred tax assets primarily consist of Federal and State tax net operating losses and tax credit carryforwards and are recorded using enacted tax rates expected to be in effect in the years in which these temporary differences are expected to be utilized. At December 31, 2018, we had federal and state income tax loss carryforwards of \$97.3 million and \$132.4 million, respectively, which begin to expire in 2024 for federal purposes and in 2019 for state purposes. At December 31, 2018, we had federal and state income tax loss carryforwards of \$34.2 million and \$0.3 million, respectively, which carryforward indefinitely. The utilization of the loss carryforwards to reduce future income taxes will depend on our ability to generate sufficient taxable income prior to the expiration of the loss carryforwards. We may be subject to the net operating loss utilization provisions of Section 382 of the Code. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carryforwards attributable to periods before the change. The amount of the annual limitation depends upon our value immediately before the ownership change, changes to our capital during a specified period prior to the change and the Federal published interest rate. Our management estimates and records a valuation allowance against deferred tax assets when realization of the tax benefit is uncertain. A valuation allowance is recorded, if necessary, to reduce net deferred taxes to their realizable values if our management does not believe it is more likely than not that the net deferred tax assets will be realized.

On December 22, 2017, the Tax Cuts and Jobs Act, 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 revenues 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 have completed our accounting for the TCJA during the fourth quarter of 2018. No changes to the provisional amounts as of December 31, 2017 were recorded.

#### **Research and Development Expenses**

When preparing our financial statements, we are required to estimate our research and development expenses. This process involves reviewing open contracts and communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with parties depend on factors, such as successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. When accruing clinical expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services

based only on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated research and development expenses have approximated actual expenses incurred.

#### Fair Value of Financial Instruments

The carrying values of cash, accounts receivable and accounts payable at December 31, 2017 and 2018 approximated fair value due to the short maturity of these instruments.

Our valuation of financial instruments is based on a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- § Level 1 — Quoted prices in active markets for identical assets or liabilities;
- § Level 2 — Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly; and
- § Level 3 — Unobservable inputs for the asset and liability used to measure fair value, to the extent that observable inputs are not available.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

#### Year ended December 31, 2018 Compared to Year ended December 31, 2017

The following table summarizes our results of operations:

	Year ended December 31,	
	2017	2018
	(in thousands)	
Revenues	\$ 7,258	\$ 2,707
Costs and expenses:		
Cost of sales	320	121
Research and development	24,754	28,700
General and administrative	10,213	8,754
Total costs and expenses	35,287	37,575
Loss from operations	(28,029)	(34,868)
Other income (expense):		
Interest income	—	305
Interest expense	(13,010)	(18,989)
Gain on early extinguishment of long-term debt	—	138
Derivative and warrant fair value adjustments	11,884	278
Total other income (expense)	(1,126)	(18,268)
Net loss	\$ (29,155)	\$ (53,136)

#### Revenues

Revenues were \$2.7 million for the year ended December 31, 2018, compared to \$7.3 million for the year ended December 31, 2017. The decrease of \$4.6 million, or 63.0%, was due to lower research and development services performed, coupled with the adoption of ASC 606. Our revenues attributable to the GSK ICO Agreement were \$0.4 million and \$6.1 million during the years ended December 31, 2018 and December 31, 2017, respectively. Under the GSK ICO Agreement, we received an up-front payment of

\$15.0 million in 2015, which was being recognized into revenue on a straight-line basis over a period of approximately seven years under ASC 605, *Revenue Recognition*. Effective January 1, 2018 we adopted ASC 606. In addition, management revised the estimated performance periods under our collaboration agreements to reflect the current circumstances such that the weighted average time period over which management was recognizing revenue related to certain up-front and milestone payments was initially increased from approximately 29 months to approximately 96 months. Revenue related to up-front payments is recognized under a proportional performance model during 2018 to the extent that research and development services are performed. These changes were partially offset by the full acceleration of revenue recognition of \$0.9 million related to the mutual termination of the G&W Labs Agreement in April 2018. The combined effect of adoption of ASC 606 and acceleration of revenue recognition related to the G&W Labs Agreement was a decrease in revenue recognized from non-refundable up-front payments for the year ended December 31, 2018 by \$2.1 million as compared to the year ended December 31, 2017. In addition, we performed research and development services resulting in revenues of \$1.5 million for such services during the year ended December 31, 2018 as compared to \$3.9 million during the year ended December 31, 2017.

#### *Cost of Sales*

Our cost of sales was \$0.1 million for the year ended December 31, 2018, compared to \$0.3 million for the year ended December 31, 2017. The decrease in cost of sales is directly related to the decrease in revenues for the same period. Cost of sales represents sub-licensing fees paid to UNC when licensing revenue is recognized from the use of the intellectual property that we in-licensed from UNC.

#### *Research and Development Expenses*

Our research and development expenses were \$28.7 million for the year ended December 31, 2018, compared to \$24.8 million for the year ended December 31, 2017. The increase of \$3.9 million, or 15.7%, was due to the commencement of the Phase 3 clinical trial of LIQ861 in late December 2017. Research and development expenses consisted of \$19.6 million and \$0.7 million which were attributable to our ongoing development of LIQ861 and LIQ865, respectively, and \$8.4 million from general research and development that was not directly related to either LIQ861 or LIQ865.

#### *General and Administrative Expenses*

Our general and administrative expenses were \$8.8 million for the year ended December 31, 2018, compared to \$10.2 million for the year ended December 31, 2017. The decrease of \$1.4 million, or 13.7%, was primarily due to the deferral and realization of equity offering costs during the year ended December 31, 2018 as compared to similar costs being expensed during the year ended December 31, 2017 for an abandoned equity offering. General and administrative expense are mainly the result of personnel expenses, including stock-based compensation, as well as legal and consulting fees and non-income tax expense.

#### *Loss from Operations*

We recorded a loss from operations of \$34.9 million for the year ended December 31, 2018, compared to \$28.0 million for the year ended December 31, 2017. The increase of \$6.9 million, or 24.6%, was primarily due to a decrease in revenues and an increase in research and development expenses, partially offset by a decrease in general and administrative expenses during the year ended December 31, 2018 as compared to the year ended December 31, 2017.

#### *Other Income (Expense)*

Interest income was \$0.3 million for the year ended December 31, 2018 compared to \$0 for the year ended December 31, 2017. The increase in interest income was primarily due to the increase in cash deposits in interest-bearing accounts.

Interest expense was \$19.0 million for the year ended December 31, 2018, compared to \$13.0 million for the year ended December 31, 2017. The increase in interest expense of \$6.0 million, or 46.2%, was primarily due to amortization of discounts on convertible notes of \$17.6 million during the year ended

December 31, 2018 as compared to \$9.8 million during the year ended December 31, 2017. The unamortized discounts on convertible notes was being amortized through the maturity date of the notes, which was December 31, 2018. The amortization was accelerated by the early conversion of the notes into Series D preferred stock in February 2018. This increase was partially offset by debt issuance costs of \$1.4 million that were charged to interest expense for the year ended December 31, 2017.

During 2018, our debt refinancing resulted in a non-cash gain of \$0.1 million in accordance with ASC 470-50, *Debt — Modifications and Extinguishments*.

Derivative and warrant fair value adjustments resulted in income of \$0.3 million for the year ended December 31, 2018, compared to \$11.9 million for the year ended December 31, 2017. The decrease of \$11.6 million, or 97.5%, was primarily due to an overall decline in value of the warrant liabilities and the conversion of the warrants to warrants for common stock at the time of the initial public offering.

## **Liquidity and Capital Resources**

### **Overview**

We have financed our growth and operations through a combination of funds generated from our licensing revenues, the issuance of convertible preferred stock and common stock, capital leases, bank borrowings and the issuance of convertible notes. Our principal uses of cash have been for working capital requirements and capital expenditures. As of December 31, 2018, we have no outstanding material commitments for capital expenditures. We monitor our net operating cash flow and maintain a level of cash deemed adequate by our management for working capital purposes.

As of December 31, 2018, we had stockholders' equity of \$18.7 million and an accumulated deficit of \$167.1 million. Our cash balance was \$39.5 million as of December 31, 2018.

### **Sources of Liquidity**

We have financed a portion of our working capital through debt instruments. We maintained a \$10.0 million term loan facility with Pacific Western Bank, or PWB, for working capital purposes pursuant to a loan and security agreement, or the LSA. Immediately prior to entry into the A&R LSA (as defined below) we had fully utilized our \$10.0 million term loan facility with PWB with a remaining outstanding balance of \$8.0 million. The facility was collateralized by all of our assets other than intellectual property. We could not encumber our intellectual property without the consent of PWB. The outstanding principal amount under the loan facility bore interest at 5.0% per annum.

On October 26, 2018, we and PWB entered into an Amended and Restated Loan and Security Agreement, or the A&R LSA, in which we received an initial tranche of \$11.0 million to extinguish our then-current debt of \$8.0 million under the LSA, repay in full the outstanding indebtedness under the UNC Promissory Note (as described below) and for general corporate purposes. The indebtedness under the A&R LSA bears interest at the greater of the Prime rate or 5% and has a four-year term and maturity. The A&R LSA provides for access to a second tranche of up to \$5.0 million available to be drawn at our option through June 30, 2019 upon the full enrollment of the Phase 3 clinical trial of LIQ861, provided that we have not observed any materially adverse data through the two-week safety endpoint. Both tranches require payments of interest-only through December 31, 2019, which interest-only period can be extended by six months if we close on at least \$40.0 million in new financing from either equity sales or licensing activities by October 31, 2019, or if we close on at least \$40.0 million in new financing from either equity sales or licensing activities by October 31, 2019, or the Financing Condition. The A&R LSA carries a one-time success fee tiered by tranche totaling between \$187,000 and \$375,000 depending on whether the Financing Condition is met, and a prepayment penalty of 1% to 2% for the first 24 months of the drawn tranche. The minimum cash covenant is \$8.5 million, which can be reduced to \$6.0 million in the event the Financing Condition is met and we publicly disclose our safety data analysis for LIQ861 with no materially adverse data observed.

The A&R LSA contains restrictions that limit our flexibility in operating our business. We may not, among other things, 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, as defined, 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 the Board, which results in the failure of at least one partner of either New Enterprise Associates or Canaan Partners or their respective affiliates to serve as a voting member, in each case without having used best efforts to deliver at least 15 days' prior written notification to PWB. PWB maintains a blanket lien on all assets excluding intellectual property, for which it has been provided a negative pledge. We have, in the past, breached multiple covenants in our loan and security agreement related to cash levels and reporting requirements. PWB has provided waivers in relation to all such prior breaches.

During most of the year ended December 31, 2018, we had outstanding a promissory note to UNC, or the UNC Promissory Note. The UNC Promissory Note was unsecured and bore interest at a rate equal to one-year LIBOR plus 3%, compounded annually. The UNC Promissory Note was due and payable in full on December 31, 2018. Following the completion of the initial public offering of our common stock in July 2018, on August 2, 2018 we made a payment to UNC of \$600,000. We repaid the entire balance outstanding under the UNC Promissory Note, plus accrued interest pursuant to the closing of the A&R LSA with PWB on October 26, 2018.

In a series of closings from January 9, 2017 to November 29, 2017, we issued and sold an aggregate of \$27.4 million underlying a total of 27 unsecured subordinated convertible promissory notes, each accruing simple interest at a rate of 8.0% per annum.

In February 2018, we issued and sold an aggregate of 91,147,482 shares of Series D preferred stock at a price per share equal to \$0.59808. Of the 31 investors that participated in this offering, 10 investors purchased an aggregate of 42,863,825 shares of Series D preferred stock for an aggregate purchase price of \$25.6 million and 26 holders of outstanding convertible notes, in the aggregate amount of \$28.9 million, converted their notes into an aggregate of 48,283,657 shares of Series D preferred stock.

In the third quarter of 2018, we closed the initial public offering of 4,833,099 shares of common stock, including the underwriters' partial exercise of their over-allotment option in connection therewith, which resulted in aggregate net proceeds of \$47.3 million, after underwriting discounts and the payment of other offering expenses.

The total amount of outstanding principal and accrued interest on our unsecured subordinated convertible promissory notes was \$28.6 million as of December 31, 2017 and \$0 as of December 31, 2018. On February 2, 2018, the outstanding principal and accrued interest underlying each of the notes converted into shares of Series D preferred stock.

**Cash Flows**

The following table summarizes our sources and uses of cash for the periods indicated:

	Year ended December 31,	
	2017	2018
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (24,290)	\$ (31,830)
Investing activities	(2,544)	(871)
Financing activities	28,815	68,817
Net increase in cash	<u>\$ 1,981</u>	<u>\$ 36,116</u>

**Operating Activities**

Net cash used in operating activities increased \$7.5 million, from \$24.3 million for the year ended December 31, 2017 to \$31.8 million for the year ended December 31, 2018. The increase was mainly due to the increase in net loss. The primary drivers of operating cash requirements were our research and development and general and administrative activities in each period. For the year ended December 31, 2018, the net cash used in operating activities of \$31.8 million was comprised of operating cash outflows before working capital changes of \$32.1 million and net working capital outflows of \$0.3 million.

**Investing Activities**

Net cash used in investing activities decreased \$1.6 million from \$2.5 million for the year ended December 31, 2017 to \$0.9 million for the year ended December 31, 2018. The decrease was due to decreased purchases of property, plant and equipment.

**Financing activities**

Net cash provided by financing activities increased \$40.0 million from \$28.8 million for the year ended December 31, 2017 to \$68.8 million for the year ended December 31, 2018. This increase was primarily due to net proceeds for the year ended December 31, 2018 from the sale of Series D preferred stock of \$25.1 million, net proceeds from the initial public offering of \$47.3 million, a refund of principal payments of \$0.6 million and proceeds from the exercise of stock options and warrants of \$0.3 million, as compared to proceeds from the issuance of convertible notes of \$27.4 million and net proceeds from long-term debt of \$2.7 million for the year ended December 31, 2017. The 2018 inflows were partially offset by net principal payments on capital leases and debt of \$2.0 million and financing costs of \$2.5 million as compared to financing costs of \$1.4 million for the year ended December 31, 2017.

**Funding Requirements**

We plan to focus in the near term on the development, regulatory approval and potential commercialization of LIQ861 and LIQ865. We anticipate we will incur net losses for the next several years as we complete clinical development of these product candidates and continue research and development of additional product candidates. In addition, we plan to continue to invest in discovery efforts to explore additional product candidates, potentially build commercial capabilities and expand our corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our product candidates arising out of our current clinical trials when we expect, or at all.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, manufacturing process development, external research and development services, laboratory and related supplies, legal and other regulatory expenses, administrative and overhead costs and debt

service. Our future funding requirements will be heavily determined by the resources needed to support development of our product candidates.

As a publicly traded company we will incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules adopted by the SEC and Nasdaq Stock Market LLC, requires public companies to implement specified corporate governance practices that previously were inapplicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe that our existing cash position together with additional funding from the A&R LSA will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2019, including the completion of our ongoing Phase 3 clinical trial and other development work for LIQ861 and the initiation of our Phase 2-enabling toxicology studies in March 2019 for LIQ865 which we anticipate will result in LIQ865 being Phase 2-ready by the end of 2019. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional capital to commercialize our product candidates, if we receive regulatory approval, and to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for LIQ861 or LIQ865, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are unable to raise sufficient additional capital, we may need to substantially curtail our planned operations and the pursuit of our growth strategy.

We may raise additional capital through the sale of equity or convertible debt securities. In such an event, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- § the number and characteristics of the product candidates we pursue;
- § the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- § the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- § the cost of manufacturing our product candidates and any product we successfully commercialize;
- § our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- § the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- § the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

See "Risk Factors" for additional risks associated with our substantial capital requirements.

#### **Going Concern**

Our financial statements have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. We closed our initial public offering in July and August 2018 resulting in total net proceeds of \$47.3 million, after underwriting discounts and the payment of other offering expenses.

Our operations have consisted primarily of developing our technology, developing products, prosecuting our intellectual property and securing financing. We have incurred recurring losses and cash outflows from operations, have an accumulated deficit, and have debt maturing within twelve months. We expect to continue to incur losses in the foreseeable future and will require additional financial resources to continue to advance our products and intellectual property, in addition to repaying our maturing debt and other obligations.

These circumstances raise substantial doubt about our ability to continue as a going concern. Management's plans with regard to this matter include continuing attempts to obtain additional financing to sustain our operations. However, there is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us, and the failure to obtain sufficient funds on acceptable terms, when needed, could have a material adverse effect on our business, results of operations and financial condition. If sufficient financings are not obtained, this may necessitate other actions by us. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **JOBS Act**

As an "emerging growth company" under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Subject to certain conditions, as an emerging growth company, we intend to rely on certain of these exemptions, including without limitation:

- § only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- § reduced disclosure about our executive compensation arrangements;
- § no advisory votes on executive compensation or golden parachute arrangements; and
- § exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues 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. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

#### **Off-Balance Sheet Arrangements**

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

## BUSINESS

### Overview

We are a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using 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. 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. Our lead product candidate, LIQ861, is being evaluated in an open-label Phase 3 clinical trial. LIQ861 is an inhaled dry powder formulation of treprostinil designed to improve the therapeutic profile of treprostinil by enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies. We have applied our PRINT technology to enable us to deliver LIQ861 through a convenient, disposable dry powder inhaler, or DPI. We have also applied our PRINT technology to our second product candidate, LIQ865, for which we have completed two Phase 1 clinical trials. LIQ865 is designed to deliver sustained-release particles of bupivacaine, a non-opioid anesthetic, to treat local post-operative pain for three to five days through a single administration.

Our lead product candidate, LIQ861, is being evaluated for the treatment of PAH, a chronic, progressive disease caused by the hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death. Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function that is deficient in patients with PAH. PAH is a rare disease, with an estimated prevalence in the United States expected to be approximately 30,000 patients by 2020. Decision Resources Group, an independent industry research firm, estimated that in 2017 products containing treprostinil across its three routes of administration (oral, inhaled and parenteral infusion) generated revenue that represented about one-quarter of the approximately \$3.7 billion U.S. market for PAH drug therapies. The inhaled route of administration, in which medication is inhaled directly into the lungs, helps minimize the off-tissue adverse side effects of systemic delivery by delivering the drug directly where it is needed. Tyvaso® (treprostinil, inhaled solution), or Tyvaso, the inhaled form of treprostinil marketed by United Therapeutics Corporation, or United Therapeutics, in the United States, is the standard of care among the inhaled therapies, with more than 80% of inhaled prostacyclin sales in the United States. Current inhaled therapies, including Tyvaso, are delivered by a nebulizer, a device that converts a liquid formulation into mist, and require between four and nine doses per day. Nebulizers require regular care and maintenance, including daily cleaning and access to additional parts and supplies, such as distilled water and a power source, all of which compromise the portability of the device and the quality of life of patients.

We believe LIQ861, if approved, will be the first-to-market inhaled dry powder treprostinil that can be delivered using a convenient, palm-sized, disposable DPI. We believe LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs. Based on our *in vitro* studies we believe that the precise size, trefoil-like shape and uniformity of each LIQ861 particle may provide deep-lung delivery of treprostinil and may reduce deposition in the upper airway where irritation and pain have been observed with nebulized treprostinil. In March 2017, we completed a Phase 1 trial of LIQ861 in 57 healthy volunteers in which LIQ861 was well-tolerated at all doses tested up to 150 mcg (treprostinil capsule strength or capsule treprostinil fill weight), which we estimate is equivalent to approximately twice the maximum recommended dosage of Tyvaso, and showed a proportional dose-response in pharmacokinetics. We estimate that the capsule strength of 75 mcg of LIQ861, delivered in one to two breaths, is approximately equivalent to the maximum recommended dosage of Tyvaso (54 mcg, delivered in nine breaths). After consultation with the U.S. Food and Drug Administration, or the FDA, we advanced from this Phase 1 trial into our current pivotal Phase 3 trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil. We will seek approval of LIQ861 under

the 505(b)(2) pathway, which would allow 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 continuous infusion (parenteral), inhaled and oral routes. In January 2018, we announced the initiation of INSPIRE evaluating LIQ861 for the treatment of PAH in the United States. If approved, we believe LIQ861 will have the potential to increase the number of patients using the inhaled route of treatment for PAH by providing the benefits of inhaled prostacyclin therapy earlier in a patient's disease progression as well as delaying the burden of starting continuously infused products. As reported on March 11, 2019, we completed enrollment and met the primary endpoint in our open-label Phase 3 trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil. LIQ861 was observed to be well-tolerated in 109 patients, with 101 patients (93%) completing at least two months of treatment. During the two-month period, LIQ861 was evaluated at doses up to 150 mcg capsule strength with no study-drug related serious adverse events. Reported treatment-emergent adverse events, or TEAEs, were mild to moderate. The most common TEAEs in 34% of patients were: cough (33%), headache (18%), throat irritation (14%), dizziness (10%), diarrhea (8%), oropharyngeal pain (6%), nausea (6%), dyspnea (6%), flushing (6%) and chest discomfort (5%). These observations are consistent with the safety data at the two-week timepoint we reported on January 7, 2019. Of the TEAEs observed, most were reported during the first two weeks of initial exposure and occurred in patients previously naïve to prostacyclin-based therapy in which LIQ861 was added to oral therapy. The INSPIRE study is designed to evaluate patients who have either been under stable treatment with nebulizer-delivered treprostinil for at least three months and are transitioned to LIQ861 under the protocol or who have been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and have their treatment regimen supplemented with LIQ861 under the protocol. The primary objective of the study is to evaluate the long-term safety and tolerability of LIQ861. We also completed enrollment of our one-directional crossover sub-study to compare bioavailability and pharmacokinetics of treprostinil as the sub-study patients transitioned from Tyvaso to LIQ861. We expect to report pharmacokinetics results in the second quarter of 2019. We intend to conduct additional clinical work in support of our marketing and commercial activities in advance of our U.S. launch for LIQ861, including maintaining patients on LIQ861 up to our U.S. launch and collecting data relating to the effects of LIQ861 on hemodynamic measurements. We are targeting a New Drug Application, or NDA, submission to the FDA for LIQ861 in late 2019 which submission will include the two-week safety data, the available two-month safety and tolerability data and our bioavailability and pharmacokinetics results. We expect the NDA to also include additional data generated from our clinical studies on LIQ861 and any further safety data available at that time.

Our second product candidate, LIQ865, is an injectable, sustained-release formulation of bupivacaine for the management of local post-operative pain for three to five days after a procedure. We believe LIQ865, if approved, has the potential to provide significantly longer local post-operative pain relief compared to currently marketed formulations of bupivacaine. We estimate that there were over 40 million surgeries in our target market, which consists of orthopedic and soft tissue surgeries, performed in the United States in 2016. According to IMS Health, an independent market research firm, the global market for local anesthetics was approximately \$761.1 million in 2017. Despite current pain-management protocols, post-operative pain is still undermanaged, with studies showing that approximately 50% of patients self-report inadequate pain relief. Post-operative pain management is becoming more important as surgeries increase in volume and complexity and hospitals seek treatments that support faster recovery and time to discharge. Concurrently, the risk of opioid abuse and diversion has led physicians, payors and the U.S. federal government to prioritize pain management strategies that minimize reliance on opioids. Local anesthetics, such as bupivacaine, provide a well-established, non-opioid option for post-operative pain management, but their duration of efficacy has been limited to eight hours or less. The FDA has approved one long-acting local anesthetic, liposomal bupivacaine, but pain relief typically lasts only 24 to 36 hours, according to physicians, and its use in combination with other local anesthetics can result in an unsafe release of drug. In LIQ865, we have engineered the size and composition of the LIQ865 PRINT particles to release bupivacaine over three to five days through a single administration. We completed a Phase 1a

clinical trial of LIQ865 in Denmark and a Phase 1b clinical trial in the United States. We commenced preparation for Phase 2-enabling toxicology studies in the fourth quarter of 2018 and expect to initiate these studies in March 2019, complete these studies by the end of 2019 and commence initial Phase 2 proof of concept clinical trials in 2020.

Both LIQ861 and LIQ865 are being developed using our proprietary PRINT particle engineering technology, which allows us to engineer and manufacture highly uniform drug particles with independent control over their size, three-dimensional geometric shape and chemical composition. By controlling these physical and chemical parameters of particles, PRINT enables us to target and design desirable pharmacological benefits into product candidates, including prolonged duration of drug release, increased drug loading, a more convenient method of administration, novel combination products, enhanced storage and stability and the potential to reduce adverse side effects. We have scaled PRINT manufacturing to meet the demands of clinical development and, we believe, commercial production. Our approach enables us to design and produce custom micro- and nano-particles containing existing or new small molecule drugs or biologics. For example, we have engineered LIQ861 so that each particle has an ideal aerodynamic size and shape for deep-lung delivery. Our PRINT particle engineering technology also allows us to design the chemical composition of particles to control drug release ranging from minutes, days, weeks or months as needed to meet a target profile, such as LIQ865's three to five day release of bupivacaine.

Initially, our internal pipeline is focused on the development of improved and differentiated drug products containing FDA-approved active pharmaceutical ingredients, or APIs, with established efficacy and safety profiles, which we believe are eligible for the 505(b)(2) regulatory pathway to seek marketing approval in the United States. The 505(b)(2) regulatory pathway can be capital efficient and potentially enable a shorter time to approval. We intend to seek marketing approval in the United States for LIQ861 and LIQ865 under the 505(b)(2) regulatory pathway, which would allow us to rely in part on existing knowledge of the safety and efficacy of the reference listed drugs. The FDA has indicated that it considers LIQ861, which is delivered by a DPI, to be a drug-device combination product and, accordingly, the DPI will be evaluated as part of our NDA filing.

In addition to building our own internal pipeline, we have collaborated, and may consider collaborating, with pharmaceutical companies to develop their own product candidates, leveraging our PRINT technology across a wide range of therapeutic areas, molecule types and routes of administration. Through our collaboration arrangement with GlaxoSmithKline plc and its subsidiaries, collectively, GSK, we have applied PRINT technology to novel molecules. If our product candidates receive marketing approval, we plan to commercialize them in the United States by establishing our own sales force and commercial infrastructure. Outside of the United States, we intend to pursue the regulatory approval and commercialization of our product candidates with pharmaceutical companies with regional expertise. We intend to manufacture our product candidates using in-house capabilities. Where appropriate, we will rely on contract manufacturing organizations, or CMOs, to produce, package and distribute our approved drug products on a commercial scale.

**Product Pipeline**

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

Product	Indication	Formulation & Route	Phase 1	Phase 2	Phase 3	Next Key Milestone	Worldwide Commercial Rights
LIQ861 <sup>1</sup>	PAH	Dry powder inhalation				PK data 2Q:19	Liquidia
LIQ865	Local, post-operative pain	Sustained-release injectable				Ph2-enabling studies commencing March 2019	Liquidia

1. After consultation with the FDA, we advanced from a Phase 1 trial directly to a pivotal Phase 3 trial and will seek approval under the 505(b)(2) pathway. \_\_\_\_\_

**Our Strategy**

Our goal is to develop and commercialize medicines with improved and differentiated product profiles based on our PRINT particle engineering technology. To achieve this goal, we intend to execute the following key elements of our business strategy:

- § **Complete the NDA submission for our lead product candidate, LIQ861, in PAH.** We initiated INSPIRE, an open label Phase 3 trial, in patients with PAH and we have completed enrollment for the trial and met the primary endpoint. We believe, based on feedback from the FDA, that this clinical trial will support the NDA filing for our novel inhaled dry powder formulation of treprostinil to treat PAH. We reported positive interim two-week safety data in January 2019, and the completion of enrollment and achievement of our primary endpoint in March 2019. Moreover, we expect to report pharmacokinetics results in the second quarter of 2019. We intend to conduct additional clinical work in support of our marketing and commercial activities in advance of our U.S. launch for LIQ861, including maintaining patients on LIQ861 up to our U.S. launch and collecting data relating to the effects of LIQ861 on hemodynamic measurements. We are targeting an NDA submission to the FDA for LIQ861 in late 2019 which submission will include the two-week safety data, the available two-month safety and tolerability data and our bioavailability and pharmacokinetics results. We expect the NDA to also include additional data generated from our clinical studies on LIQ861 and any further safety data available at that time.
- § **Advance our local post-operative pain product candidate, LIQ865, through Phase 2-enabling toxicology studies into Phase 2 clinical trials.** We completed a Phase 1a clinical trial of LIQ865, our novel long-acting formulation of bupivacaine, in Denmark in March 2017, and a Phase 1b clinical trial in the United States in April 2018. We commenced preparation for Phase 2-enabling toxicology studies in the fourth quarter of 2018 and expect to initiate these initial studies in March 2019. We anticipate that the initial Phase 2-enabling toxicology studies will result in LIQ865 being Phase 2-ready by the end of 2019, that we will complete these studies by the end of 2019 and that we will commence initial Phase 2 proof of concept clinical trials in 2020.
- § **Secure regulatory approval and commercialize our internal product candidates independently in the United States and with pharmaceutical companies globally.** We hold worldwide commercialization rights to LIQ861 and LIQ865. Subject to receiving marketing approval which we intend to pursue in the United States via the 505(b)(2) regulatory pathway, we intend to independently pursue the commercialization of LIQ861 in the United States by establishing targeted sales and marketing teams. After reviewing the results of all of our Phase 2-enabling toxicology studies for LIQ865, and subject to the availability of sufficient funding, we will develop and commercialize LIQ865 independently, if it is ultimately approved, or seek to license this product candidate to one or more

third parties. Outside of the United States, we intend to pursue the regulatory approval and commercialization of LIQ861 and LIQ865 with pharmaceutical companies with regional expertise.

- § **Expand our internal pipeline leveraging our PRINT technology.** We intend to continue targeting diseases where we believe our PRINT technology can improve the efficacy, safety and patient experience of current treatments that have been impaired by suboptimal drug product formulation and delivery. We plan to focus initially on the development of improved and differentiated drug products containing FDA-approved APIs with proven efficacy and safety profiles eligible to use the 505(b)(2) regulatory pathway. In addition, we may expand our clinical development of LIQ861 and LIQ865, where appropriate, into broader indications or new applications.
- § **Pursue strategic collaborations to maximize the value of products enabled by PRINT technology.** In addition to advancing our own internal product candidates, we have collaborated, and may consider collaborating, with pharmaceutical companies to develop their own product candidates across a wide range of therapeutic areas, molecule types and routes of administration, leveraging our PRINT technology. We believe that collaborating with pharmaceutical companies helps advance new PRINT capabilities, while adding to our intellectual property portfolio.

#### Our Competitive Strengths

We believe that we have several key strengths that have contributed to the development of our business and that will help us to realize our goal of becoming a biopharmaceutical company across research, development and commercialization activities. Our competitive strengths include:

- § **Our PRINT technology gives us the capability to overcome the constraints of conventional formulation and production methods and can be applied broadly across therapeutic areas, molecule types and routes of administration.** Our PRINT technology allows us to precisely engineer drug particles in a wide variety of compositions, sizes and shapes and achieve a high level of control over the physical and chemical characteristics of drug particles, as compared to conventional formulation and production methods. PRINT particles can be designed to address specific pharmacological or therapeutic objectives, such as enhancing the route of administration, improving solubility, enhancing stability or extending therapeutic effects. Using our PRINT technology, we are able to engineer, among others, small molecule and biologic particles, single agent drug and combination drug particles and vaccine particles to improve efficacy, safety and convenience for patients. Our internal pipeline strategy is currently focused on developing proprietary innovations to currently approved drug products in order to minimize development risks and increase speed to market.

In particular, we have designed LIQ861 to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs using a convenient, palm-sized, disposable DPI. We believe that this may lead to a more attractive product profile with a more convenient method of administering the drug, as compared to the existing inhaled therapies that are currently available. We have also designed LIQ865 with the intention of providing patients with local post-operative analgesia for three to five days. We believe this would provide a longer period of pain relief than the existing local-acting pain drugs that are available, which could be a positive feature in light of interest in reducing the patient's reliance on opioids and non-steroidal anti-inflammatory drugs, or NSAIDs, for local post-operative pain management.

Our PRINT technology is broadly applicable — across therapeutic areas, molecule types and routes of administration — providing us with opportunities for future drug product development.

- § **We have scaled operations with rapid and cost-effective transition to clinical development and commercial production.** We believe our research and development operations and PRINT technology allow us to transition rapidly and cost-effectively from laboratory to clinical development and ultimately commercial-scale manufacture of drug particles. Utilizing well-established techniques from other roll-to-roll manufacturing processes, we have scaled PRINT technology to support the quality and quantity needs for clinical and, we believe, commercial production of our product candidates.

The physical equipment for the PRINT technology requires a relatively small footprint, low capital investment and minimal operating costs. We believe our manufacturing facilities comply with the FDA's current good manufacturing practices, or cGMP, requirements.

- § **We have a strong proprietary position through a combination of patents, trade secrets, proprietary know-how and licensing arrangements.** We protect our PRINT technology and the resulting engineered particles through a combination of patents, trade secrets, proprietary know-how and licensing arrangements. We have an active patent strategy that covers major geographic markets, including the United States, Europe and Japan. As of December 31, 2018, our patent portfolio, which includes patents and patent applications we own or co-own, as well as patents and patent applications we have licensed from third parties, such as the University of North Carolina at Chapel Hill, or UNC, comprises 112 issued patents and 51 pending patent applications worldwide. As we develop new product candidates, either independently or with collaborators, we will seek additional patent protection.
- § **We have strong capabilities in pharmaceutical research and clinical development.** Our research and development team includes 25 employees as of December 31, 2018, led by our senior management, and has extensive experience in clinical development and pharmaceutical research and development activities in our specific areas of research interest.
- § **We have a seasoned management team.** Our team includes industry veterans with significant experience in drug discovery, development and commercialization. Members of our leadership team have worked across different segments of the pharmaceutical industry, including branded and generic pharmaceuticals, medical devices and manufacturing services. Prior to joining us, our Chief Executive Officer and director, Neal Fowler, served as president of Centocor, Inc., a subsidiary of Johnson & Johnson that is focused on the development and commercialization of biomedicines used to treat chronic inflammatory diseases. Additionally, our Chief Operations Officer, Robert Lippe, previously served as executive vice president of operations and chief operations officer at Alexza Pharmaceuticals, Inc. Furthermore, our Senior Vice President, Product Development, Dr. Robert Roscigno, previously served as the executive vice president of Geno, LLC, where he led the clinical development team working on a novel nitric oxide delivery system, and before that he served as the president and chief operating officer of Lung Rx, Inc., where he was part of the team responsible for bringing Tyvaso through Phase 3 development, and he previously served in multiple leadership positions at United Therapeutics and its subsidiaries, contributing to the successful development and worldwide commercialization of Remodulin™, which is treprostinil administered through subcutaneous or intravenous infusion, for the treatment of PAH. We believe that their experience enables us to evaluate opportunities and build collaboration arrangements that match the breadth of the potential applications for our PRINT technology.

## Our Product Candidates

### LIQ861

Our lead product candidate, LIQ861, is an inhaled dry powder formulation of treprostinil designed using our PRINT technology to enhance deep-lung delivery using a convenient DPI for the treatment of PAH. We believe LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs. If approved, we believe LIQ861 will have the potential to increase the number of patients using the inhaled route of treatment for PAH by providing the benefits of inhaled prostacyclin therapy earlier in a patient's disease progression as well as delaying the burden of starting continuously infused products.

### Background on PAH

PAH is a chronic, progressive disease caused by the hardening and narrowing of pulmonary arteries that can lead to right heart failure and eventually death. Prostacyclin is a vasoactive mediator essential to normal lung function that is deficient in patients with PAH. With PAH, the elevated pressure in the pulmonary arteries strains the right side of the heart as it pumps blood to the lungs. The extra stress causes the heart

to enlarge and become less flexible, compromising its ability to push blood out of the heart through the lungs and into the rest of the body. PAH initially presents as exertional dyspnea, lethargy and fatigue and may be confused with other disease states with similar symptoms. PAH often goes undiagnosed or misdiagnosed until symptoms become severe, with the mean time from onset of symptoms to correct diagnosis being more than two years in the United States. As PAH progresses and right ventricular failure develops, exertional chest pain, or angina, exertional syncope and peripheral edema may develop. Following confirmation of diagnosis based on hemodynamic parameters, treatment is recommended to lower pulmonary pressures and treat the symptoms of PAH.

PAH is part of a larger classification of pulmonary hypertension, or PH, which is divided into five groups based on the criteria of the World Health Organization, or WHO, as defined at the 5th World Symposium on Pulmonary Hypertension in Nice, France. WHO Group I is comprised of individuals with PAH.

PAH is a rare disease, with an estimated prevalence in the United States expected to be approximately 30,000 patients by 2020. Today, the mean age of diagnosis is 50 years according to both French and U.S. registries, with more women being diagnosed with PAH than men. Patients may have idiopathic PAH, in which no underlying cause can be determined, or a heritable form of the disease. A large number of PAH patients also have associated comorbidities such as congenital heart disease, HIV, connective tissue diseases like scleroderma, liver diseases, systemic hypertension, obesity, clinical depression, non-PAH related obstructive airways, sleep apnea and diabetes.

Due to delayed diagnosis, many patients already have an advanced form of PAH, requiring aggressive treatment combining multiple classes of therapy. The severity of PAH may be classified according to the heart failure guidelines of the New York Heart Association, or NYHA, based on how much patients are limited during physical activity and described by the American Heart Association as follows:

- § NYHA Class I — No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea, which is shortness of breath.
- § NYHA Class II — Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation or dyspnea.
- § NYHA Class III — Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation or dyspnea.
- § NYHA Class IV — Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

As reported by Decision Resources Group, gross revenue in the U.S. market for PAH drug therapies in 2017 was estimated to be \$3.7 billion. Of such amount, \$2.1 billion was generated from patients in NYHA Class III, \$1.2 billion was generated from patients in NYHA Class II and an aggregate of \$0.4 billion was generated from patients in NYHA Classes I and IV.

As the disease progresses, these symptoms cause significant negative impact on the quality of life of patients, limiting their ability to do common daily activities, including work, travel and previous hobbies. Patients also describe the emotional toll of PAH, including fear, frustration, embarrassment and stigma. The burden of care associated with currently available treatments can add further logistical and emotional burden to the patients.

#### *Current Therapies and Their Limitations*

There is currently no cure for PAH. The goals of existing treatments are to alleviate symptoms, maintain or improve NYHA functional class, delay disease progression and improve quality of life. Inhaled therapies are generally prescribed for, but not limited to, patients in NYHA Class II and Class III. Approved drugs target three distinct molecular pathways that have been implicated in the disease process: the prostacyclin pathway, the nitric oxide pathway and the endothelin pathway. Drugs targeting each of these pathways are used alone or in combination with each other to treat patients with PAH. Prostacyclin deficiency in the lung is a central dysfunction in PAH, but can be supplemented with prostacyclin analogs. Prostacyclin deficiency

can also be managed with a recently approved selective IP prostacyclin receptor agonist, selexipag. Nitric oxide deficiency can be treated with phosphodiesterase-5, or PDE5, inhibitors, which target a specific enzyme, increasing vasodilation. Endothelin overexpression in PAH patients causes vasoconstriction of pulmonary vasculature, but can be treated with endothelin receptor antagonists, or ERAs. Many physicians start their PAH patients on oral PDE5 inhibitors, oral ERAs or both. Drugs targeted to the prostacyclin pathway are usually added to these oral therapies, but can be used alone.

Drugs targeting the prostacyclin pathway are central to PAH therapy. Prostacyclin is essential to normal lung function. In healthy people, prostacyclin, which is a vasoactive mediator, is continually released by lungs into arterial circulation to bind different receptors for different effects to regulate vessel tone, including direct vasodilation of pulmonary arteries, inhibition of the proliferation of smooth muscle cells within arteries and inhibition of platelet aggregation. To supplement the deficiency of prostacyclin in patients with PAH, several prostacyclin analogs have been developed including epoprostenol, which is administered intravenously; treprostinil, which can be administered intravenously, subcutaneously or in nebulized or oral formulations; and iloprost, which can be administered intravenously or in nebulized form. A new class of drugs called selective IP prostacyclin receptor agonists help stimulate some of the mechanisms that would otherwise be promoted by prostacyclin or an analog. Selexipag is an oral drug and the only approved molecule in this new class.

The goal of treatment targeting the prostacyclin pathway is to maximize a patient's exposure to the highest tolerable level of drug. Prostacyclin analogs, like treprostinil, have been developed for continuous infusion, either intravenously or subcutaneously, inhalation using a nebulizer and oral administration in the form of tablets. The maximal efficacy benefit of any one drug in the prostacyclin pathway is partially limited by its specific safety profile. Drugs treating the prostacyclin pathway, including oral treprostinil and IP prostacyclin receptor agonists such as selexipag, are limited by side effects from binding of the drug to receptors in non-targeted tissues, such as the gut and nerves, which can cause diarrhea, nausea and jaw pain. Nebulized solutions can have side effects including cough and upper airway irritation and pain caused by their topical irritant properties, which limits the amount of drug that can be given to the patient. As the disease progresses, patients will require continuous prostacyclin infusion to maximize drug exposure. Infusion pumps present unique risks related to infusion site pain and the risk of blood stream infections, and increase significant limitations on the quality of life of patients.

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

Decision Resources Group reported that more than 80% of PAH patients on inhaled therapy in the United States used Tyvaso in 2017. United Therapeutics reported approximately \$373 million in total sales of Tyvaso in the United States. Tyvaso is approved in the United States and Israel but is not approved in Europe and Japan. Tyvaso is indicated for the treatment of PAH to improve exercise ability. The maximum recommended dose of Tyvaso is 54 mcg, delivered four times daily from a proprietary nebulizer, requiring nine breaths for each dose. In a long-term open-label extension study of Tyvaso, patients continued treatment for a mean duration of 2.3 years, with 89% of patients achieving the target dose of 54 mcg, delivered in nine breaths, and 42% achieving a dose of 72 mcg, delivered in 12 breaths.

Ventavis is approved in the United States, Europe and Japan. Ventavis is nebulized six to nine times a day during waking hours, no more than once every two hours, and takes six to ten minutes to administer per use. Ventavis is a synthetic analog of prostacyclin indicated for the treatment of PAH to improve a composite endpoint consisting of exercise tolerance, symptoms and lack of deterioration.

Tyvaso and Ventavis require the use of proprietary nebulizers. Patients must follow specific instructions to set up and operate the device, clean the device daily, locate a power source or use a battery to operate the device, and carry the device and its associated accessories around in a large carrying case, along with distilled water, to administer the treatment throughout the day. As a result, the use of these approved inhaled prostacyclin therapies is typically limited to patients who have not responded to oral medications that target the three pathways. The current medical practice is to administer both an inhaled drug product and the patient's existing oral ERA and/or PDE5 drug product concurrently, instead of withdrawing the administration of the oral drug product upon initiation of the inhaled drug product.

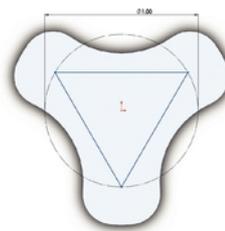
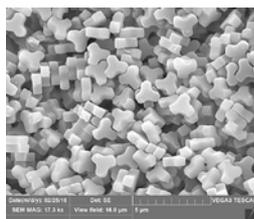
*Potential Benefits of Our Approach*

We believe LIQ861 can overcome the limitations of current nebulized therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs using a convenient, palm-sized, disposable DPI. In our Phase 1 trial, LIQ861 was well-tolerated at doses approximately twice as high as the maximum recommended dosage of Tyvaso. These higher doses of inhaled dry powder treprostinil can also be administered in fewer breaths. Each dose of LIQ861 can be administered in one to four breaths, compared to nine breaths for the maximum recommended dosage of Tyvaso. Additionally, we believe LIQ861 may have the potential to improve overall patient adherence and quality of life by offering the convenience of a discrete, palm-sized, disposable DPI. In our market research, patients expressed a preference for a DPI product, noting that it can fit easily into a purse, minimize hassle while traveling and reduce the breaths and time associated with their current nebulized treatments.

The advantages of the LIQ861 product profile are enabled by the PRINT technology. Each LIQ861 particle is designed to enhance delivery and deep-lung penetration. LIQ861 particles are a precise size and highly uniform since particles are formed from mold cavities that exactly match each other. Competing technologies, such as spray-drying, create particles that have a broader variation in shape and size. As a result, particles farther from the mean target size would be too large or too small to reach the intended location in the deep-lung.

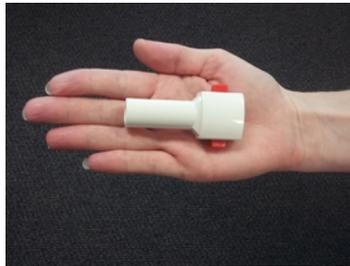
Inspired by a naturally occurring pollen, LIQ861 PRINT particles have a one micrometer trefoil-shape measured by an inscribed one micrometer circle as shown in the figure below. *In vitro* studies suggest that the uniformity of size and shape allow our inhaled particles to target delivery into the lungs while depositing less in the upper airways. Our independent control of the parameters of drug particles has enabled us to create the first clinically tested formulation that stabilizes treprostinil in an inhaled dry powder formulation.

The figures below depict LIQ861, with the figure on the left showing size and shape consistency among particles and the figure on the right showing their trefoil shape:



LIQ861 is administered using RS00 Model 8 DPI, a DPI manufactured by Plastiaple S.p.A. There are products approved in the United States and Europe containing this device. This device and its variants have been used in at least eight marketed products globally since 2001, including Novartis's Foradil Aerolizer®, for the treatment of asthma and chronic obstructive pulmonary disease, or COPD.

The picture below shows the DPI used to administer LIQ861:



#### *Clinical Development*

In March 2017, we completed a Phase 1 trial of LIQ861 in 57 healthy volunteers. In January 2018, we announced the initiation of INSPIRE, our pivotal open-label Phase 3 clinical trial, evaluating LIQ861 for the treatment of PAH in the United States. As reported on March 11, 2019, we completed enrollment and met the primary endpoint in our open-label Phase 3 trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil. LIQ861 was observed to be well-tolerated in 109 patients, with 101 patients (93%) completing at least two months of treatment. During the two-month period, LIQ861 was evaluated at doses up to 150 mcg capsule strength with no study-drug related serious adverse events. Of the TEAEs observed, most were reported during the first two weeks of initial exposure and occurred in patients previously naive to prostacyclin-based therapy in which LIQ861 was added to oral therapy. The INSPIRE study is designed to evaluate patients who have either been under stable treatment with nebulizer-delivered treprostinil for at least three months and are transitioned to LIQ861 under the protocol or who have been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and have their treatment regimen supplemented with LIQ861 under the protocol. Patients adding LIQ861 to current non-prostacyclin oral therapies started at a capsule strength of 25 mcg treprostinil and those transitioned from nebulizer-delivered treprostinil at a stable dose were initiated at a capsule strength of LIQ861 lower than their current stable treprostinil dose. In both cases, LIQ861 was uptitrated in 25 mcg treprostinil incremental capsule strengths to symptom relief or the limit of tolerance. The primary objective of the study is to evaluate the long-term safety and tolerability of LIQ861. We completed enrollment of our one-directional crossover sub-study to compare bioavailability and pharmacokinetics of treprostinil as the sub-study patients transitioned from Tyvaso to LIQ861. We reported positive interim two-week safety data in January 2019, and the completion of enrollment and achievement of our primary endpoint in March 2019. Moreover, we expect to report pharmacokinetics results in the second quarter of 2019. We intend to conduct additional clinical work in support of our marketing and commercial activities in advance of our U.S. launch for LIQ861, including maintaining patients on LIQ861 up to our U.S. launch and collecting data relating to the effects of LIQ861 on hemodynamic measurements. In the United States, we plan to seek approval of our NDA under the 505(b)(2) regulatory pathway, which would allow us to rely, in part, on the FDA's prior conclusions of efficacy and safety for Tyvaso and the active ingredient treprostinil, which has been approved in four different products administered through the continuous infusion, inhaled and oral routes. We are targeting an NDA submission to the FDA for LIQ861 in late 2019 which submission will include the two-week safety data, the available two-month safety and tolerability data and our bioavailability and pharmacokinetics results. We expect the NDA to also include additional data generated from our clinical studies on LIQ861 and any further safety data available at that time.

#### *Results of Phase 1 Trial*

We conducted a randomized, placebo-controlled, double-blind, Phase 1 trial in 57 healthy volunteer subjects to assess safety, tolerability and pharmacokinetics following a single administration of LIQ861 at

treprostinil capsule strengths between 25 mcg and 150 mcg. The subjects were enrolled into six dose cohorts. Within each dose cohort, subjects were randomized to receive LIQ861 or a placebo.

#### Dose Selection

For the first-in-human study, the initial dose for LIQ861 was chosen based on the indicated dosing for the reference listed drug, Tyvaso. Independent investigations of particle emission using the RS00 Model 8 DPI and simulated inspiration of the bulk powder from a nebulizer led to a projection that a 25 mcg treprostinil strength of LIQ861 dry powder inhalation would result in approximately similar treprostinil administration as three breaths of Tyvaso, or 18 mcg of treprostinil, the lowest approved dose through nebulization. The following table shows LIQ861's doses tested along with our estimate of the equivalent Tyvaso dose.

Capsule (LIQ861 fill wt.)	Estimated TRE Dose from LIQ861			Estimated TRE Dose from Tyvaso	
	Approx. Capsule (TRE fill wt.)	Approx. Emitted Dose	Breaths <sup>1</sup>	Approx. Emitted Dose	Breaths <sup>2</sup>
5 mg	25 mcg	20 mcg	1-2	18 mcg	3
10 mg	50 mcg	40 mcg	1-2	36 mcg	6
15 mg	75 mcg	60 mcg	1-2	54 mcg	9
20 mg	100 mcg	80 mcg	1-2	Above maximum recommended dose	
(10 mg + 15 mg)	125 mcg <sup>1</sup>	100 mcg	2-4	Above maximum recommended dose	
(15 mg + 15 mg)	150 mcg <sup>1</sup>	120 mcg	2-4	Above maximum recommended dose	

<sup>(1)</sup> LIQ861 capsule treprostinil doses between 25 mcg and 100 mcg are single capsules. LIQ861 capsule treprostinil strength doses 125 mcg and 150 mcg are two capsules but if approved, they could be developed as single capsules and therefore only require one to two breaths.

<sup>(2)</sup> Tyvaso (treprostinil) full prescribing information: initial dosage: 3 breaths (18 mcg); maximum recommended dosage: 9 breaths (54 mcg)

Our conclusion from this study is that the capsule strength of 75 mcg of LIQ861 is approximately equivalent to the maximum recommended dose of 54 mcg, or nine breaths, of Tyvaso, and the capsule strength of 150 mcg of LIQ861 is approximately double the maximum recommended dose of Tyvaso.

#### Safety and Tolerability

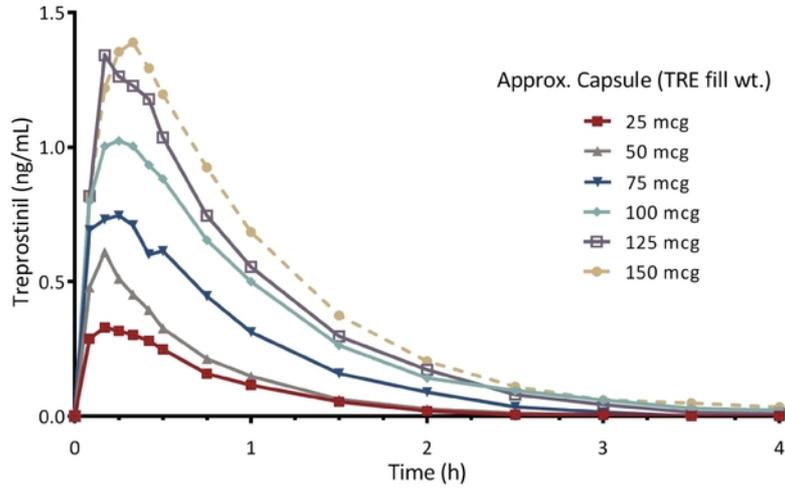
In the Phase 1 clinical trial, we escalated the treprostinil capsule strength of LIQ861 progressively from 25 mcg to 150 mcg. There were no dose-limiting toxicities at the highest dose evaluated. We noted no serious adverse events or deaths and all reported treatment-emergent adverse events, or TEAEs, related to the treatment were mild. The most frequent adverse event reported by subjects on LIQ861 was mild cough and throat irritation.

We did not observe a proportional increase of adverse events as the treprostinil capsule strengths were escalated from 25 mcg to 100 mcg. No adverse events were observed in subjects who received the placebo PRINT particles that contained only excipients.

#### Pharmacokinetics

In the Phase 1 trial, the LIQ861 plasma levels increased proportionally as the dosage of LIQ861 increased, as shown in the graph below. At higher doses, 50% of subjects receiving LIQ861 had measurable treprostinil after four hours, which could indicate the potential to minimize symptoms between dosing cycles.

LIQ861 Mean Concentration Over Time



The pharmacokinetic parameters in the table below were estimated from plasma samples. Nominal elapsed time from dosing was used to estimate all individual pharmacokinetic parameters, including:

- §  $C_{max}$  Maximum observed plasma concentration;
- §  $T_{max}$  Time of maximum concentration;
- §  $T_{1/2}$  Terminal-phase half-life; and
- §  $AUC_{inf}$  Area under the plasma concentration-time curve.

LIQ861 Pharmacokinetic Results

	Approx. Capsule (TRE fill wt.)					
	25 mcg	50 mcg	75 mcg	100 mcg	125 mcg	150 mcg
$C_{max}$ (ng/mL)	0.329	0.572	0.728	1.08	1.19	1.33
$T_{max}$ (h)	0.21	0.18	0.25	0.29	0.24	0.31
$T_{1/2}$ (h)	0.507	0.434	0.617	0.722	0.523	0.648
$AUC_{inf}$ (h*ng/mL)	0.285	0.428	0.766	1.22	1.16	1.50

The LIQ861 blood levels, as determined by the area under the curve, which is a pharmacokinetic measurement of drug exposure in blood plasma over time, and the maximum concentration were similar to the data used in connection with the approval of Tyvaso, as reported in the FDA Summary Basis of Approval for Tyvaso. LIQ861 also had half-life in the blood similar to such data. These results suggest that our formulation has not changed the pharmacokinetic profile of inhaled treprostinil.

*Results of Non-Clinical Studies*

The pharmacology, pharmacokinetics and toxicology of treprostinil are well understood, having previously been characterized to support approval of Remodulin, which is treprostinil administered through subcutaneous or intravenous infusion, Orenitram®, which is treprostinil administered through extended-release tablets, and Tyvaso, which is treprostinil inhaled through a proprietary nebulizer. We plan to rely in part on the data used in support of FDA approval of these treatments, in addition to our own toxicity studies, to support the development and approval of LIQ861.

In October 2016, we completed a 14-day, repeat dose, inhalation toxicity study in rats to support the Phase 1 trial. In August 2017, we completed a 26-week toxicology study in rats. In rats, pharmacokinetic profiles at the end of 14 days of LIQ861 treatment were generally similar to inhaled nebulized treprostinil delivered at similar treprostinil dose levels. Following 26 weeks of daily dosing, treprostinil exposure was slightly higher in LIQ861-treated rats. The results from this study support chronic outpatient dosing of LIQ861 in patients with PAH in our Phase 3 trial.

*Phase 3 Trial*

In January 2018, we announced the initiation of INSPIRE, our pivotal Phase 3 trial evaluating LIQ861 at treprostinil capsule strengths between 25 mcg and 150 mcg for the treatment of PAH in the United States. INSPIRE is an open-label trial enrolling over 100 patients with PAH across multiple sites in the United States. Primary endpoints are long-term safety and tolerability of LIQ861. Patients enrolled have been on stable doses of Tyvaso for at least three months or have been taking no more than two approved non-prostacyclin oral PAH therapies.

As reported on March 11, 2019, we completed enrollment and met the primary endpoint in our open-label Phase 3 trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil. LIQ861 was observed to be well-tolerated in 109 patients, with 101 patients (93%) completing at least two-months of treatment. During the two-month period, LIQ861 was evaluated at doses up to 150 mcg capsule strength with no study-drug related serious adverse events. Reported TEAEs were mild to moderate. The most common TEAEs in 34% of patients were: cough (33%), headache (18%), throat irritation (14%), dizziness (10%), diarrhea (8%), oropharyngeal pain (6%), nausea (6%), dyspnea (6%), flushing (6%) and chest discomfort (5%). These observations are consistent with the safety data at the two-week timepoint we reported on January 7, 2019. Of the TEAEs observed, most were reported during the first two weeks of initial exposure and occurred in patients previously naïve to prostacyclin-based therapy in which LIQ861 was added to oral therapy. Patients have continued to receive treatment with the first patient dosed in March 2018. Additionally, we have one center dosing a patient above the 150 mcg treprostinil capsule strength. We also completed enrollment of our one-directional crossover sub-study of at least 18 patients to compare bioavailability and pharmacokinetics of treprostinil as the patients transition from Tyvaso to LIQ861. We reported positive interim two-week safety data in January 2019, completion of enrollment and achievement of our primary endpoint in March 2019, and expect to report our bioavailability and pharmacokinetics results in the second quarter of 2019. We are targeting an NDA submission to the FDA for LIQ861 in late 2019 which submission will include the two-week safety data, the available two-month safety and tolerability data and our bioavailability and pharmacokinetics results. We expect the NDA to also include additional data generated from our clinical studies on LIQ861 and any further safety data available at that time.

*Additional Clinical Trials*

We also intend to conduct an additional clinical trial in Europe that explores the hemodynamic effects of LIQ861 in PAH patients. Although the FDA has not requested that we undertake this clinical trial, the data may help assess the effects of LIQ861 on acute and chronic hemodynamic measurements and right heart function. Data from this clinical trial would also add to our understanding of safety, tolerability and pharmacokinetics of LIQ861.

We intend to conduct additional clinical work in support of our marketing and commercial activities in advance of our U.S. launch for LIQ861, including maintaining patients on LIQ861 up to our U.S. launch.

Commercial Opportunity

Decision Resources Group estimated that sales for all major PAH drugs in 2017 were more than \$3.7 billion in the United States. Products approved to treat PAH through the prostacyclin deficient pathway generated approximately \$1.4 billion in sales in 2017, of which the prostacyclin analog treprostinil generated the majority from products formulated for continuous infusion, inhalation using a nebulizer and oral delivery, estimated to be approximately \$915 million.

If approved, we believe LIQ861 would be the first inhaled dry powder formulation of treprostinil delivered using a convenient, palm-sized, disposable DPI. The dosing regimens and patient experience for the two approved inhaled therapies compared to the expected product profile of LIQ861 are shown in the following table.

	<u>Ventavis (iloprost) inhalation solution</u>	<u>Tyvaso (treprostinil) inhalation solution</u>	<u>LIQ861 (treprostinil) dry powder for inhalation (expected)</u>
<b>Regulatory status</b>	FDA approved, 2004	FDA approved, 2009	Enrolling pharmacokinetics sub-study
<b>Method of administration</b>	Proprietary nebulizer	Proprietary nebulizer	Dry powder inhaler
<b>Frequency</b>	6 to 9 times daily	4 times daily	4 times daily
<b>Dose range</b>	2.5 to 5 mcg	18 to 72 mcg; (max recommended is 54 mcg)	25 to 150 mcg capsule strength
<b>Time or breaths per dose</b>	4 to 10 minutes depending on breathing pattern	9 breaths (54 mcg)	1-2 breaths per capsule, with 1 or 2 capsules per dose
<b>Supplies required</b>	<ul style="list-style-type: none"> <li>§ Ventavis Inhalation System</li> <li>§ Power supply</li> <li>§ Distilled water</li> <li>§ 2 medication chamber assemblies</li> <li>§ Washing basket</li> <li>§ Battery charger</li> <li>§ I-neb pouch</li> <li>§ Carry bag</li> <li>§ Power cord for charger</li> <li>§ 2 Spare discs</li> </ul>	<ul style="list-style-type: none"> <li>§ Tyvaso Inhalation System</li> <li>§ Rechargeable battery</li> <li>§ 12V DC adapter</li> <li>§ AC wall plug</li> <li>§ 16 Medicine cups</li> <li>§ Filter membranes</li> <li>§ Plugs</li> <li>§ Filter shell</li> <li>§ Dome assembly with baffle plate</li> <li>§ Inhalation piece</li> <li>§ Mouthpiece</li> <li>§ Water level cup</li> <li>§ Carrying case</li> <li>§ Distilled water carrier</li> </ul>	<ul style="list-style-type: none"> <li>§ Dry powder inhaler</li> <li>§ Carrying pouch</li> <li>§ Daily blister pack</li> <li>§ Small cleaning brush</li> </ul>

Picture



*Preferred choice within inhaled options.* As reported in our market research, physicians and patients expressed a clear preference for the expected product profile of LIQ861 over current nebulized therapies, primarily due to the ease and convenience of administration of LIQ861. Nebulized therapies require more time and breaths than LIQ861, as well as daily and weekly assembly, disassembly and cleaning.

*Attractive switch from orals.* The ease and range of dosing LIQ861 may be attractive to patients who are in earlier stages of the disease, but poorly managed on oral prostacyclin products. Local delivery of treprostinil to the lung offers fewer systemic side effects. However, we believe some of these patients are hesitant to switch to more burdensome nebulized options.

*Delay transition to continuous infusion.* We are investigating a wide range of LIQ861 doses in order to maximize patient exposure to treprostinil, a key factor in the efficacy of prostacyclin analogs. In our Phase 1 trial, LIQ861 was well-tolerated at levels that we estimate are approximately twice the maximum recommended dose of Tyvaso. We believe the dose range enabled by LIQ861 would allow patients to titrate to higher levels of treprostinil and potentially extend the time on inhaled therapy, delaying the eventual transition to continuous infusion.

*Expand inhaled options outside the United States.* We intend to develop and seek regulatory approval for LIQ861 for markets outside of the United States in order to provide an attractive choice that leverages the benefits of local delivery to the lung. Tyvaso is approved in the United States and Israel but is not approved in Europe and Japan. Ventavis is approved in the United States, Europe and Japan, but its use has been limited due to its delivery regimen. Decision Resources Group estimated that fewer than 10% of PAH patients in the United Kingdom, Germany, France, Italy and Spain, which we collectively refer to herein as the 5EU, use Ventavis. In Japan, Ventavis was approved in May 2016 as the first inhaled PAH treatment. The combined population of diagnosed prevalent PAH patients in the 5EU markets and Japan was estimated to be approximately 25,000 patients in 2017.

*Expand beyond WHO Group I patients (PAH).* Prostacyclin based therapies have only been approved for WHO Group I patients. However, prostacyclin analogs may have utility in the treatment of PH in other categories, as suggested by current off-label use in WHO Group III, which includes individuals with pulmonary hypertension secondary to lung diseases or hypoxemia, and WHO Group IV, which includes individuals with chronic thromboembolic pulmonary hypertension. Although we have no current plans to study LIQ861 in PH patients outside of WHO Group I, we will continue to monitor the investigations conducted by other companies and independent investigators of prostacyclin analogs, especially Tyvaso. If Tyvaso is approved for additional indications, the path for seeking approval of LIQ861 in the same indications should be made clear and could quickly follow. For example, United Therapeutics is actively studying Tyvaso in a Phase 3 trial of a subpopulation of WHO Group III subjects with pre-capillary PH with interstitial lung disease, including combined pulmonary fibrosis and emphysema, with an estimated prevalence of 27,500 patients globally in this subpopulation. By 2025, the diagnosed prevalence of all WHO Group III sub-types is expected to grow to over 250,000 patients in the United States, 5EU markets and Japan. WHO Group IV includes patients diagnosed with chronic thromboembolic pulmonary hypertension, or CTEPH. While considered underdiagnosed and undertreated, the current estimates for diagnosed prevalence of CTEPH are between 2,000 and 6,500 patients in the United States and more than 10,000 patients in the 5EU markets and Japan.

#### *Competition in PAH*

If approved, LIQ861 would be one of several prostacyclin based products that can be used to manage a patient's disease. Initially, it would be positioned between the use of oral options and the continuous infusion of prostacyclin analogs.

In the inhaled category, the primary competitor for LIQ861 would be Tyvaso, the nebulized inhaled treprostinil. Tyvaso is administered by a proprietary nebulizer device four times per day. In addition to Tyvaso, LIQ861 would compete with inhaled iloprost, which is marketed as Ventavis in the United States by

Actelion Pharmaceuticals Ltd, a subsidiary of Johnson & Johnson, and in Europe by Bayer Schering Pharma AG. Ventavis is administered by a proprietary nebulizer device six to nine times per day.

There would be additional competition from oral products in the prostacyclin pathway, including oral treprostinil, marketed as Orenitram by United Therapeutics, selexipag, marketed as Upravi by Actelion Pharmaceuticals Ltd., and ralinepag, an oral treprostinil product for the treatment of patients suffering from PAH being studied in a Phase 3 clinical trial by Arena Pharmaceuticals, Inc., or Arena. These oral options may be used by a patient earlier in the disease cycle than LIQ861. However, we believe that LIQ861 could offer an attractive option for patients who are in earlier stages of the disease, but poorly managed on oral prostacyclin products. On January 24, 2019, Arena and United Therapeutics closed on a global license agreement for ralinepag. Under the agreement, United Therapeutics is now responsible for the development, manufacture and commercialization of ralinepag.

Continuously infused prostacyclins include epoprostenol, marketed by multiple companies as generic and branded products, and treprostinil, marketed as Remodulin by United Therapeutics. These options are considered to offer the greatest efficacy and are usually prescribed to patients later in the disease. Infusion pumps present unique risks related to infusion site pain and the risk of blood stream infections, creating major limitations on the quality of life of patients.

We are aware that MannKind has recently filed an IND and completed a Phase 1 trial evaluating an inhaled dry powder treprostinil product for the treatment of PAH. On October 15, 2018, United Therapeutics and MannKind closed their worldwide exclusive licensing and collaboration agreement for the development and commercialization of a dry powder formulation of treprostinil, an investigational product currently being evaluated in clinical trials for the treatment of PAH. Under the agreement, United Therapeutics will be 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. We also expect generic equivalents of Tyvaso may eventually enter the market following the expiry or invalidity of Tyvaso's patents.

#### **LIQ865**

Our second product candidate, LIQ865, which is designed using PRINT technology, is an injectable, sustained-release formulation of bupivacaine for the management of local post-operative pain for three to five days after a procedure, which we believe, if approved, would have the potential to provide significantly longer post-operative pain relief compared to currently marketed formulations of bupivacaine.

#### *Background on Post-Operative Pain*

The treatment of post-operative pain typically involves multi-modal therapy including the administration of local anesthetics after surgery. Although local anesthetics provide a well-established, safe and efficacious option for post-operative pain management, the duration of efficacy for conventional local anesthetics, including bupivacaine and lidocaine, is limited, with the pain relief typically lasting for eight hours or less. Because post-operative pain may continue to be severe for several days following the surgery, additional therapies are required. These therapies include morphine and other opioids administered through intravenous systems or orally, as well as various non-opioids, including acetaminophen and NSAIDs, like ibuprofen and ketorolac.

#### *Current Therapies and Their Limitations*

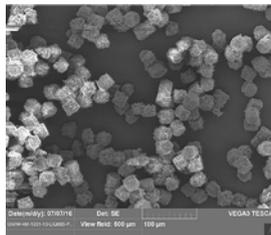
Opioids are the mainstay of post-operative pain management, but they are associated with a variety of unwanted and potentially serious or life-threatening side effects such as sedation, nausea, constipation, cognitive impairment, respiratory depression and death. In addition, opioids may be administered through patient-controlled analgesia systems, which may interfere with or delay patient ambulation and require significant hospital resources to implement and monitor. Furthermore, exposure to opioids for as little as four days can lead to increased risk of chronic opioid use. The risk of opioid abuse and diversion has led physicians, payors and the U.S. federal government to prioritize pain management strategies that minimize the use of opioids.

NSAIDs and other non-opioids for pain relief in the post-operative period are also associated with various undesirable side effects. Bleeding and gastrointestinal and renal complications may result from NSAID use. Acetaminophen can cause liver injury or failure with excessive dosing. As a result, we believe there is demand from healthcare providers and patients for post-operative pain relief therapies that can help prevent these issues.

Local anesthetics such as bupivacaine hydrochloride, or Marcaine, and lidocaine have been safely used for post-operative pain for decades, but have a duration of effect limited to less than eight hours. Approved in 2011, EXPAREL is a long-acting local anesthetic that involves an injection of bupivacaine in a multivesicular liposome carrier at the surgical site and is marketed in the United States by Pacira Pharmaceuticals, Inc. Physicians report that EXPAREL typically provides postsurgical analgesia for only 24 to 36 hours in practice, and market research we conducted suggests that physicians desire longer duration of effect to better manage local post-operative pain. In addition, because the interactions between the liposomal formulation of EXPAREL and co-administered local anesthetics can result in rapid release of bupivacaine, co-administration of other local anesthetics is inadvisable.

#### *Potential Benefits of Our Approach*

Using our PRINT technology, we have developed a particle formulation of bupivacaine that, if approved for marketing, will be used to manage local post-operative pain. We engineered the size and composition of LIQ865 particles to slowly release bupivacaine with the goal of providing patients with local pain relief for three to five days through a single administration, which we believe would provide significantly longer post-operative pain relief compared to currently marketed formulations of bupivacaine. The figure below depicts LIQ865, showing size consistency among particles.



LIQ865 is administered as a suspension and is easily injected at the surgical site. Because the molded drug particles are highly stable, we believe the potential for dose dumping, the unintended rapid drug release of bupivacaine from the carrier, would be minimized with LIQ865. In a non-clinical study, co-administration of LIQ865 with lidocaine did not cause early release of bupivacaine or otherwise negatively affect the pharmacokinetic profile of LIQ865. LIQ865 was engineered to be rapidly reconstituted and administered by injection. Unlike other sustained-release formulations, we do not expect LIQ865 will be constrained by a specific ratio of drug to diluting agent so its reconstitution volume can be adjusted based on the volume needs of a particular procedure. Furthermore, because particle-to-particle uniformity in size and composition is key to determining drug release rates, the particle-to-particle and batch-to-batch uniformity of our LIQ865 particles creates consistent release rates.

#### *Results of Non-Clinical Studies*

We commissioned an animal efficacy study of two formulations of LIQ865 in a rat perineural sciatic model, which was completed in January 2016. LIQ865 showed an extended pharmacokinetic profile and duration of nerve sensory block and the potential for extended post-operative pain management. Additionally, we evaluated the safety and tolerability of LIQ865 in a rat toxicology study in 2016. The results of this study supported advancing LIQ865 to human clinical trials. We commenced preparation for Phase 2-enabling toxicology studies in the fourth quarter of 2018 and expect to initiate the initial Phase 2-enabling toxicology studies in March 2019.

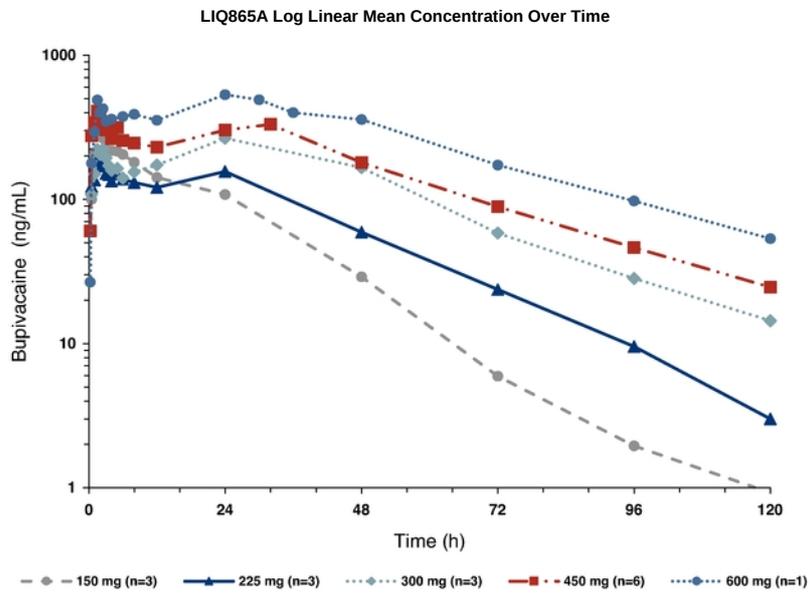
*Clinical Development*

In March 2017, we completed our Phase 1a trial in Denmark to evaluate the safety and tolerability profile of two different PRINT formulations of bupivacaine: LIQ865A, consisting of particles combining bupivacaine and polylactic-glycolic acid, a polymer widely used in sustained-release drug products and surgical sutures; and LIQ865B, consisting of particles of bupivacaine alone, in a proprietary diluting agent. We observed a dose-response relationship in this trial, and all doses were well-tolerated. The results from the Phase 1a trial helped inform our selection of LIQ865A for further investigation in the United States. We filed an IND application in the United States in June 2017 and initiated a Phase 1b trial in the United States in September 2017 using an experimental pain model in healthy adults with quantitative sensory testing. We completed the U.S. Phase 1b trial in April 2018. We commenced preparation for Phase 2-enabling toxicology studies in the fourth quarter of 2018 and expect to initiate these initial studies in March 2019, we expect to complete these studies by the end of 2019 and we expect to commence initial Phase 2 proof of concept clinical trials in 2020. In the United States, we plan to rely in part on the 505(b)(2) regulatory pathway for our NDA submission to the FDA for LIQ865, which would allow us to rely on the FDA's prior determinations of safety and efficacy for other products containing bupivacaine, such as Marcaine and EXPAREL.

*Results of Phase 1 Trials*

Our Phase 1a trial was a randomized, double-blind, controlled, single ascending dose, safety, pharmacokinetic and pharmacodynamic trial of LIQ865A and LIQ865B in 28 healthy male volunteers at a single site in Copenhagen, Denmark. The study design included dosing multiple cohorts, or groups, each receiving increasing bupivacaine doses as either LIQ865A or LIQ865B: 150 mg, 225 mg, 300 mg, 450 mg or 600 mg. The LIQ865 formulation was injected into the upper calf in one leg, and the other leg received the diluting agent without LIQ865 particles. The primary objective of this Phase 1a clinical trial was to evaluate the safety and tolerability profile of the two formulations of LIQ865. We also assessed bupivacaine pharmacokinetic and pharmacodynamic responses.

Based on the results of the Phase 1a trial, we selected the LIQ865A formulation for further development, and all of our references to LIQ865 are to this formulation. Results for 16 volunteers who received LIQ865A in this Phase 1a trial are shown below. The graph shows the mean plasma concentration of bupivacaine over 120 hours comparing the 150 mg, 225 mg, 300 mg, 450 mg and 600 mg dose cohorts of LIQ865A formulation, expressed on a logarithmic, or log, scale.



A dose-response relationship was observed, with the plasma levels increasing as the dosage level of LIQ865 increased. Doses of LIQ865 up to 600 mg of bupivacaine were well-tolerated in the trial. All adverse events were mild to moderate in severity, and most adverse events were limited locally at the site of injection, with most related to sensory block of underlying sensory branches of the saphenous nerve in the leg.

At the 450 mg dose of LIQ865, all subjects had maximum concentration values below 800 ng/ml, which is well below the reported thresholds for neurotoxicity and cardiac toxicity of 2000 and 4000 ng/mL, respectively. The pharmacokinetic and pharmacodynamic profile for this dose suggested a sustained duration of effect, with nearly all subjects receiving this dose reporting at least three days of sensory blunting in response to quantitative sensory testing. LIQ865 also showed rapid onset of action at the one-hour time point in all subjects, even at the lowest dose of 150 mg. Additionally, we observed a sensory block of distal sensory branches of the saphenous nerve below the knee in eight of nine subjects who received 450 mg doses of LIQ865. This sensory block lasted at least three days, which we believe further supports the duration profile of LIQ865.

In March 2017, we met with the FDA at a pre-IND meeting and verified that the current Chemical Manufacturing and Control, or CMC, and preclinical package were "phase-appropriate" and sufficient to support our initial U.S. Phase 1 trial.

Following our submission of the IND for LIQ865, we initiated our U.S. Phase 1b clinical trial in September 2017, which was completed in April 2018. This trial used an experimental pain model in healthy male and female subjects with quantitative sensory testing after an injection of LIQ865 at doses of 150 mg, 300 mg and 450 mg. The experimental pain model was designed to simulate post-operative pain for up to five days through a combination of localized ultraviolet B burn and mini-incision. Additionally, the trial included a cross-over design to compare LIQ865 to EXPAREL. We observed that LIQ865 was well-tolerated across the dose ranges. All adverse events were mild to moderate, and no dose-limiting toxicities were noted. The

pharmacokinetic profiles were similar to what was seen in the Phase 1a trial. Pharmacodynamic effects were highly variable and inconclusive, which we associated with the experimental design of the pain model used in the Phase 1b trial.

#### *Plans for Phase 2 Development*

At our pre-IND meeting in March 2017, the FDA requested additional toxicology studies prior to the initiation of Phase 2 trials and we commenced preparation for our initial Phase 2-enabling toxicology studies in the fourth quarter of 2018 which we expect to initiate in March 2019. We anticipate completing these initial studies by the end of 2019. After reviewing the results of all of our Phase 2-enabling toxicology studies for LIQ865, and subject to the availability of sufficient funding, we will develop and commercialize LIQ865 independently, if it is ultimately approved, or seek to license this product candidate to one or more third parties. We are targeting to commence initial Phase 2 proof of concept clinical trials in 2020. We will seek to identify, in our Phase 2 trials, the minimum and optimal effective dose of LIQ865 to achieve three or more days of pain relief. We expect that this dose would be carried forward into Phase 3 development.

#### *Competition*

The primary competitor for LIQ865, if approved, would be liposomal bupivacaine, marketed as EXPAREL by Pacira Pharmaceuticals, Inc. We are aware of other long-acting local anesthetic products in clinical development from DURECT Corporation, Innocoll Holdings plc and Heron Therapeutics, Inc., or Heron, as well as generic equivalents of EXPAREL, which may enter the market following the expiry of EXPAREL's patent in 2018. In October 2018, 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 and a PDUFA date of April 30, 2019. In addition to long-acting local anesthetics, there are a number of indirect competitors in development, including clinical-stage opioids and development-stage molecules that pursue the treatment of pain through alternative pathways.

#### **Our PRINT Technology**

Both LIQ861 and LIQ865 are being developed using our proprietary PRINT particle engineering technology, which allows us to engineer and manufacture highly uniform drug particles with independent control over the size, three-dimensional geometric shape and chemical composition of the particles. By controlling these physical and chemical parameters of particles, PRINT enables us to engineer desirable pharmacological benefits into product candidates, including prolonged duration of drug release, increased drug loading, more convenient routes of administration, the ability to create novel combination products, enhanced storage and stability and the potential to reduce adverse side effects. Controlling three-dimensional geometric shape and chemical composition of drug particles enables us to research, identify and pursue the improvement of existing therapies and creation of new therapies from existing drugs or new chemical entities, including small molecules and biologics.

Our ability to design and control these features of drug particles has the potential to provide significant benefits across the breadth of pharmaceutical applications. Product characteristics and features can be tuned depending on the need of a particular application, drug substance, delivery route and other such considerations. Based on our research to date, we anticipate the ability to: (i) enhance inhaled delivery through the highly uniform geometric shape of each drug particle; (ii) design desired drug release profiles ranging from minutes post-delivery to days, weeks or months depending on need of a target therapy, by controlling the chemical composition of the drug particles and the surface area-to-volume ratio of the particles; (iii) enable combination products where one or more of the chemical constituents can destabilize or interact by encapsulating the desired constituent in a particle to shield it from another constituent during packaging and storage; and (iv) enhance the deposition and retention of topically delivered products by designing particles with a desired charge and/or Young's modulus.

Besides using our PRINT technology to develop our two product candidates, LIQ861 and LIQ865, we have exclusively licensed our PRINT technology to (i) GSK, a market leader in respiratory therapies, for applications broadly across inhaled delivery of their small molecule and biologic chemical entities, although we retained the ability to develop LIQ861; and (ii) Aerie Pharmaceuticals, Inc., which acquired most of the assets of Envisia Therapeutics, Inc. in 2017, for broad usage in the design and commercialization of small molecule and biologic ophthalmic therapies.

Our molding approach, which we branded as "PRINT" or Particle Replication In Non-wetting Templates, combines the precision of the semi-conductor industry with the high throughput of roll-to-roll manufacturing to make highly uniform micro- and nano-particles at a commercially viable scale. Our manufacturing equipment and materials used in the production of our drug particles are proprietary and protected by our patent portfolio and trade secret know-how. Our PRINT equipment is also modular, scalable and cost-effective.

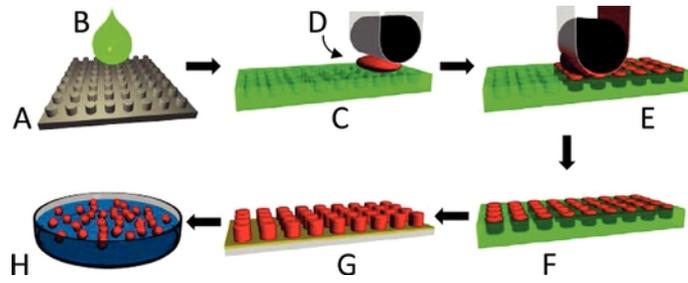
#### *Our PRINT Process*

We begin our particle design by procuring a custom designed master template etched with three-dimensional structures, or posts, that will become the eventual shape and size of our drug particles. These three-dimensional structures are then replicated in negative form, through our proprietary processing into flexible rolls of polymeric PRINT molds. Our PRINT molds consist of thousands of linear feet of thin flexible molds up to twenty-four inches wide. We then design and formulate our desired drug particle composition and apply that to our PRINT molds in our high-throughput roll-to-roll processing equipment, with each particle mimicking the shape of the mold cavity from which it was molded, thus taking the shape of the original master template structures.

The general components and steps of our PRINT molding are as follows:

- § Etch a master template with the three-dimensional geometric structures of the desired particle size and shape (step A in the diagram below);
- § Apply our proprietary polymeric mold material over the master template (step B) and cure the polymeric material to form our PRINT molds with discrete molding cavities that replicate the structures of the master template (step C);
- § Design the chemical composition of the drug particle of interest (step D);
- § Apply the drug particle composition to the cavities in the mold to fill the cavities (step E);
- § Form the drug particles in the cavities of the mold that mimic the size and shape of the mold cavities (step F);
- § Remove the drug particles from the mold cavities on a harvesting film (step G); and
- § Remove the particles from the harvesting film for further functionalization, purification or packaging to be included in the final drug particle product (step H).

The diagram below shows the general steps involved in producing drug particles using our PRINT technology:



We have translated the PRINT process into a continuous, roll-to-roll manufacturing process that we believe is compliant with cGMP and scaled to support clinical and commercial production, when required. One of our current manufacturing lines is shown below:



#### Manufacturing and Supply

Our facilities occupy approximately 45,000 square feet and are located in Morrisville, North Carolina. Within these premises, there are office space, research and development laboratories and equipment, analytical development and quality control laboratories, research, development and mold production facilities, research and development particle fabrication equipment, including two operational PRINT particle fabrication lines, both of which we believe are cGMP-compliant, as well as appropriate staging, storage and stability facilities. These two operational PRINT particle fabrication lines are located within class ISO7 clean rooms that operate under applicable ISO and cGMP air quality and environmental requirements.

We currently produce in this facility the product candidates for our and our collaborators' preclinical studies and clinical trials. Our current operational PRINT particle fabrication lines are scaled and capable of producing the necessary materials to support our ongoing operations and planned studies and clinical trials and, we believe, ultimately our initial commercial scale manufacturing. The production capacity for each PRINT particle fabrication line within our production facility varies depending on the drug particle that is being produced.

We are expanding our production facility, including the installation of an additional PRINT particle fabrication line in early 2018 and mold template production, which is intended to further increase our production capacity and capability in anticipation of the commercial production of LIQ861 and LIQ865, if and when we receive marketing approval for them. The capital expenditures for leasehold improvements in our facility related to this additional fabrication line were partially financed through reimbursement allowances provided by the landlord. In November 2018, we amended our primary lease with our landlord to expand into contiguous space for more optimized business operations and simultaneously terminated the lease to our second facility for non-contiguous space.

If and when we receive marketing approval for our product candidates, we may, from time to time, rely on third-party CMOs to produce, package and distribute some or all of our approved drug products on a commercial scale.

We also depend on third-party suppliers for clinical supplies, including active pharmaceutical ingredients which are used in our product candidates. For example, we currently rely on a sole supplier, LGM Pharma, LLC for treprostinil, the active pharmaceutical ingredient of LIQ861, and we currently rely on a sole supplier, Plastiape S.p.A., for RS00 Model 8 DPI, the DPI used to administer LIQ861. We also rely on a sole supplier, Xcellience LLC (now a Lonza Group Ltd company), for encapsulation and packaging services.

#### **Our Collaboration and Licensing Agreements**

In addition to advancing our own product candidates, we have collaborated, and may consider collaborating, with pharmaceutical companies to develop their own product candidates across a wide range of therapeutic areas, molecule types and routes of administration, leveraging our PRINT technology. These collaborations are intended to help advance new PRINT capabilities and build upon our competitive advantage in the pharmaceutical industry, while adding to our intellectual property portfolio.

##### ***GlaxoSmithKline***

We have actively collaborated with GSK on the use of our PRINT technology in respiratory disease. In June 2012, we entered into an Inhaled Collaboration and Option Agreement, or the GSK ICO Agreement, with GSK to collaborate on research regarding the application of our PRINT technology to specified inhaled therapies. Pursuant to the GSK ICO Agreement, we granted GSK exclusive options and licenses to further develop and commercialize such inhaled therapies using our PRINT technology. In partial consideration of the rights granted to GSK under the GSK ICO Agreement, we received a one-time up-front payment of \$4.0 million. We also entered into a stock purchase agreement with GSK pursuant to which GSK purchased 4,765,248 shares of our Series C-1 convertible preferred stock for an aggregate of \$3.8 million. In September 2015, GSK exercised its option to obtain an exclusive, worldwide license to certain of our know-how and patents relating to our PRINT technology, for the purpose of, among others, preclinical studies of inhaled therapeutics developed, manufactured or otherwise produced using our PRINT technology. In connection with the grant of this license, we received a one-time option exercise fee of \$15.0 million. Under the terms of the GSK ICO Agreement, we are also entitled to continued research and development funding, certain milestone payments aggregating up to \$158 million upon the achievement of specified milestone events for new non-rescue therapeutic products. Rescue therapeutic products are therapeutics that GSK develops with our PRINT technology that had previously been discontinued from development. We are also entitled to tiered royalties on the worldwide sales of the licensed products at percentages ranging from the mid-single digits to low-single digits depending on the total number of

products developed and other royalty step-down events with a fixed low-single digit royalty floor under the GSK ICO Agreement. In February 2016, we received a \$3.0 million payment from GSK upon the achievement of a clinical development milestone.

GSK has the right to terminate the GSK ICO Agreement in its entirety or on a product-by-product basis upon a specified period of prior written notice. Upon termination of the GSK ICO Agreement, each party will continue to have the right to practice and/or license its interest in any know-how developed during the collaboration without seeking the consent of, or accounting to, the other party.

Through this collaboration, we have worked together with GSK to advance inhaled therapeutic products toward clinical studies. In June 2018, GSK notified us of its intention to review continuation of development of an inhaled antiviral for viral exacerbations in chronic obstructive pulmonary disease, or COPD, candidate that was formulated as an inhaled, dry powder using the PRINT technology, part of the GSK ICO Agreement, after completion of its related Phase 1 clinical trial. On July 20, 2018, GSK confirmed that it will not continue the COPD program. As of December 31, 2018, GSK was in the reporting phase of the Phase 1 trial of the COPD program. We do not expect to incur additional expenses directly associated with the COPD program. GSK continues to express an interest in using PRINT technology for new inhaled programs, though no specific assets or activities have been identified at this time.

***The University of North Carolina at Chapel Hill***

In December 2008, we entered into the Amended and Restated License Agreement with UNC for the use of certain patent rights and technology relating to initial innovations of our PRINT technology, or the UNC License. Under the terms of the UNC License, we have an exclusive license to such patent rights and technology for our drug products. The UNC License grants us the right to grant sublicenses to the technology as well as control the litigation of any infringement claim instituted by or against us in respect of the licensed patent rights. We are also responsible for the costs of all expenses associated with the prosecution and maintenance of the patents and patent applications. Such filings and prosecution will be carried out by UNC and in UNC's name but under our control.

Under the UNC License, we are required to pay UNC royalties equal to a low single digit percentage of all net sales of our drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC License, as well as tiered royalty percentages ranging in the low single digits of sales by our sublicensees for any product covered by rights under a sublicense agreement granted pursuant to the UNC License. Under the UNC License, we are also required to pay UNC 20% of all fees other than royalties that we collect and are attributable to UNC sublicensed intellectual property. As consideration for the UNC License, we paid UNC a license issue fee in the form of 196,469 shares of our Class B non-voting common stock in 2004. During the term of the UNC License, we have also paid approximately \$2.9 million in the aggregate to UNC pursuant to a Supported Research Agreement, or the SRA. In connection therewith, we may exclusively license resulting inventions under the SRA for a \$5,000 up-front license fee per invention. We have also paid aggregate consideration of \$5.7 million in sublicense fees to UNC pursuant to the UNC License, for our sublicenses of our PRINT technology to GSK and G&W Labs, as described above. We also reimburse UNC for its costs of procuring and maintaining the patents we license from UNC. Such reimbursements amounted to \$129,778 for the year ended December 31, 2018. Effective November 2017, we satisfied all substantive milestones associated with our UNC License other than semi-annual and annual reporting-based milestones that continue through the term of the UNC License. The UNC License expires (i) on the expiration of the last to expire patent included in the patent rights or (ii) if no patents mature from such patent rights, in December 2028.

We have the right to terminate the UNC License upon a specified period of prior written notice. UNC may terminate the UNC License in certain circumstances, including if we fail to pay royalty or other payments on time or if we fail to sublicense in accordance with the terms of the UNC License. Upon termination of the UNC License, we must pay any royalty obligations due upon termination.

## Intellectual Property

The proprietary nature and protection of our product candidates, their methods of use and our platform technology that enables our product candidates are an important part of our business strategy of rapidly developing and commercializing new medicines that address areas of significant unmet medical needs.

Our policy is to seek patent protection of our proprietary product candidates and technology by filing U.S., international and certain foreign patent applications covering certain of our proprietary technology, inventions, improvements and product candidates that are important to the growth and protection of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to patent protection or where we do not consider patent protection to be adequate or applicable.

Our success depends, in part, on our ability to obtain and maintain patent and other protection for our product candidates, enabling technology, inventions and know-how and our ability to defend and enforce these patents, preserve the proprietary nature of our trade secrets and operate our business without infringing valid and enforceable patent and other proprietary rights of third parties. We pursue both composition-of-matter patents and method-of-use patents for our product candidates. We are also pursuing patents covering our proprietary PRINT micro- and nano-particle fabrication technology.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest filing date of a non-provisional patent application to which the patent claims priority in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, or PTA, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Act, permits a patent term extension, or PTE, of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to each regulatory review period may be extended. Further, only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended and the extension only applies to the approved drug, method for using it or method for manufacturing it for which the extension was obtained. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

We are the owner or exclusive licensee of patents and applications relating to our proprietary technology platform and our product candidates, and are pursuing additional patent protection for these and for our other product candidates and technology developments.

We have a total of 163 patents and pending patent applications in our patent portfolio. As of December 31, 2018, we were the sole owner of 14 patents in the United States and 26 patents in foreign jurisdictions, as well as approximately 21 additional pending patent applications, including provisional patent applications, in the United States, Europe, Japan and other jurisdictions. In addition to the patents and patent applications owned solely by us, our patent portfolio also includes 72 patents and 30 patent applications licensed from third parties. As of December 31, 2018, we had an exclusive, worldwide license from UNC to 17 U.S. patents and 54 foreign patents, as well as 11 additional patent applications in the United States or selected foreign jurisdictions. Seven of the patents and two of the patent applications in the portfolio licensed from UNC are jointly owned by us.

With regard to our LIQ861 product candidate, as of December 31, 2018 our owned or in-licensed patents and patent applications that are directed to aspects of the PRINT technology utilized in LIQ861 include:

- § U.S. Patent No. 8,263,129, which includes claims directed to methods of forming substantially uniform particles and is expected to expire on January 14, 2029, including 1486 days of PTA and assuming payment of all maintenance fees;
- § U.S. Patent No. 8,420,124, which includes claims directed to a plurality of monodisperse particles and is expected to expire on August 19, 2028, including 1338 days of PTA and assuming payment of all maintenance fees;
- § U.S. Patent No. 9,877,920, which includes claims directed to a plurality of particles and is expected to expire on December 20, 2024, assuming payment of all maintenance fees;
- § U.S. Patent No. 8,439,666, which includes claims directed to laminate molds and is expected to expire on December 4, 2026, assuming payment of all maintenance fees;
- § U.S. Patent No. 8,662,878, which includes claims directed to molds and mold systems and is expected to expire on December 4, 2026, assuming payment of all maintenance fees;
- § U.S. Patent Nos. 8,945,441 and 9,662,809, which include claims directed to methods of making laminate molds and are each expected to expire on December 4, 2026, assuming payment of all maintenance fees;
- § U.S. Patent No. 7,976,759, which includes claims directed to methods of forming nanoparticles and is expected to expire on October 13, 2028, assuming payment of all maintenance fees;
- § U.S. Patent No. 9,545,737, which includes claims directed to methods of forming pharmaceutical particles and is expected to expire on April 22, 2029, including 191 days of PTA and assuming payment of all maintenance fees;
- § U.S. Patent No. 8,444,907, which includes claims directed to methods for fabricating a substantially seamless pattern and is expected to expire on June 28, 2031, including 572 days of PTA and assuming payment of all maintenance fees; and
- § U.S. Patent No. 9,744,715, which includes claims directed to methods for fabricating a substantially seamless pattern and is expected to expire on December 3, 2029, assuming payment of all maintenance fees.

As of December 31, 2018, we were sole owner of one international patent application, PCT/US17/31301, specifically directed to our LIQ861 product candidate, which has been entered into the national/regional stage in Australia, Canada, Europe, Israel, Japan and the United States. PCT/US17/31301 includes claims directed to dry powder inhalation compositions, methods of using such compositions treating a patient with PAH and methods of making such compositions. Any patents that may issue from PCT/US17/31301 are expected to expire on May 5, 2037, absent any terminal disclaimers, patent term adjustments or extensions and assuming payment of all maintenance fees.

With regard to our LIQ865 product candidate, as of December 31, 2018, our owned or in-licensed patents and patent applications that cover aspects of the PRINT technology utilized in LIQ865 include:

- § U.S. Patent No. 8,263,129, which includes claims directed to methods of forming substantially uniform particles and is expected to expire on January 14, 2029, including 1,486 days of PTA and assuming payment of all maintenance fees;
- § U.S. Patent No. 8,420,124, which includes claims directed to a plurality of monodisperse particles and is expected to expire on August 19, 2028, including 1,338 days of PTA and assuming payment of all maintenance fees;
- § U.S. Patent No. 9,877,920, which includes claims directed to a plurality of particles and is expected to expire on December 20, 2024, assuming payment of all maintenance fees;
- § U.S. Patent No. 8,662,878, which includes claims directed to molds and mold systems and is expected to expire on December 4, 2026, assuming payment of all maintenance fees;

- § U.S. Patent Nos. 8,945,441 and 9,662,809, which include claims directed to methods of making laminate molds and are each expected to expire on December 4, 2026, assuming payment of all maintenance fees;
- § U.S. Patent No. 7,976,759, which includes claims directed to methods of forming nanoparticles and is expected to expire on October 13, 2028, assuming payment of all maintenance fees;
- § U.S. Patent No. 9,545,737, which includes claims directed to methods of forming pharmaceutical particles and is expected to expire on April 22, 2029, including 191 days of PTA and assuming payment of all maintenance fees;
- § U.S. Patent No. 8,444,907, which includes claims directed to methods for fabricating a substantially seamless pattern and is expected to expire on June 28, 2031, including 572 days of PTA and assuming payment of all maintenance fees; and
- § U.S. Patent No. 9,744,715, which includes claims directed to methods for fabricating a substantially seamless pattern and is expected to expire on December 3, 2029, assuming payment of all maintenance fees.

As of December 31, 2018, we were sole owner of one international patent application, PCT/US17/31397, specifically directed to our LIQ865 product candidate, which has been entered into the national/regional stage in Europe, Japan and the United States. PCT/US17/31397 includes claims directed to particulate compositions comprising an amino amide anesthetic and Poly(lactide-co-glycolide) polymer, formulations comprising such compositions, methods of using such compositions for inducing extended analgesia and methods of forming such compositions. Any patents that may issue from PCT/US17/31397 are expected to expire on May 5, 2037, absent any patent term adjustments or extensions and assuming payment of all maintenance fees.

#### **Sales and Marketing**

We have retained worldwide commercial rights for our internal product candidates. If our product candidates receive marketing approval, we plan to commercialize them in the United States by building and utilizing our own commercial infrastructure. Outside of the United States, we intend to pursue regulatory approval of our product candidates in collaboration with others, while leveraging the regional expertise of a commercialization partner. In addition, we plan to establish collaborations with pharmaceutical companies to commercialize our products in foreign markets. Considering our stage of development, we have not yet established a commercial organization or distribution capabilities.

With regard to our lead product candidate, LIQ861, we intend to focus our commercial efforts initially on the U.S. market, which we believe represents the largest market opportunity. Within the United States, we believe that we can effectively commercialize LIQ861, if approved, with an initial specialty field team of approximately 50 individuals. We intend to initially pursue a highly concentrated target market of PAH centers of excellence and high prescribers of PAH therapies. Our physician call points within these sites of care will include cardiologists, pulmonologists and their supporting staff. We expect to supplement our field team with medical science liaisons and reimbursement specialists to support the proper training and utilization of LIQ861. As part of our commercialization strategy, we plan to educate physician specialists, healthcare practitioners, patients and caregivers of the benefits of LIQ861 and its proper use. We plan to work with national associations, such as the Pulmonary Hypertension Association, and patient advocacy groups to update treatment guidelines to include LIQ861, a new, convenient, novel product with a wide range of dosing flexibility.

#### **Competition**

The pharmaceutical industry is intensely competitive, subject to rapid and significant technological change and places emphasis on the value of proprietary products. While we believe that our technologies and experience provide us with a competitive advantage, our competitors include organizations such as major

multinational pharmaceutical companies, established biotechnology companies, biopharmaceutical companies and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, technologies and drug products that are more effective or less costly than products that we are currently selling through collaborators or developing or that we may develop, which could render our products obsolete and non-competitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payors. We also expect to face competition in our efforts in recruiting and retaining qualified personnel and establishing clinical trial sites, patient enrollment in clinical trials and in identifying appropriate collaborators to help commercialize any approved products in our target commercial markets.

## **Government Regulation**

### ***Government Regulation and Product Approval***

Government authorities in the United States at the federal, state and local level and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, (including manufacturing changes), quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

### ***U.S. Drug Development Process***

In the United States, the FDA regulates drugs under the United States Federal Food, Drug, and Cosmetic Act, or the FDCA, and the FDA's implementing regulations.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- § completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- § submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- § approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- § performance of adequate and well-controlled human clinical studies according to Good Clinical Practice, or GCP, regulations, to establish the safety and efficacy of the proposed drug for its intended use;
- § preparation and submission to the FDA of an NDA, containing the results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical

tests conducted on the drug product, proposed labeling and other relevant information, to request approval to market the drug product;

- § satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug product, or components thereof, are produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- § satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of clinical data;
- § FDA review and approval of the NDA;
- § payment of fees, including annual program fees for each drug product on the market; and
- § ongoing compliance with any post-approval requirements, including risk evaluation and mitigation strategy, or REMS, and post-approval studies required by the FDA.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. When a sponsor wants to proceed to test the product candidate in humans, it must submit an IND in order to conduct clinical trials.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical study lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical study and places the study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance, and may be imposed on all product candidates within a certain pharmaceutical class. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical studies of a certain duration or for a certain dose.

All clinical studies must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical study. Further, an IRB must review and approve the plan for any clinical study before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical study are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- § *Phase 1.* The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- § *Phase 2.* Involves clinical studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- § *Phase 3.* Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

There are FDA-imposed limitations on communications about investigational drugs. The FDA prohibits companies from making promotional claims of safety or effectiveness of the drug for a use for which it is under investigation, and from "commercialization" of the drug before it is approved for commercial distribution.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### ***U.S. Review and Approval Processes***

Assuming successful completion of the required clinical testing, the results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

The submission of an NDA is subject to the payment of a substantial application user fee although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review. The sponsor of an approved NDA is also subject to annual program user fees.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, an NDA application (or a supplement to an application) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support

dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the applicant has obtained a waiver or deferral.

A sponsor who is planning to submit a marketing application for a drug product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within 60 days of an End-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical studies or other clinical development program.

The FDA also may require submission of a REMS to mitigate any identified or suspected serious risks. The REMS could include medication guides, physician communication plans, assessment plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. There are numerous FDA personnel assigned to review different aspects of an NDA, exercising judgment, discretion, and interpretation of data relative to the review process.

The FDA may approve an NDA only if the methods used in, and the facilities and controls used for, the manufacture processing, packing and testing of the product are adequate to ensure and preserve its identity, strength, quality and purity.

Before approving an NDA, the FDA often will inspect the facility or facilities where the product is or will be manufactured.

The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts, including clinicians and other scientific experts, who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making decisions.

Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure clinical data supporting the submission were developed in compliance with GCP.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied, or may require additional preclinical, clinical or CMC data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than an applicant interprets the same data.

After the FDA's evaluation of an application, the FDA may issue an approval letter or a complete response letter to indicate that the review cycle is complete and that the application is not ready for approval. A complete response letter generally contains a statement of specific conditions that must be met to secure final approval of the application and may require additional clinical or preclinical testing for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the application, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

Even with submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical studies, to further assess safety and effectiveness after approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

#### *New Drug Applications*

Most drug products obtain FDA marketing approval pursuant to an NDA (described above) for innovator products, or an abbreviated new drug application, or ANDA, for generic products. Relevant to ANDAs, the Hatch-Waxman Act amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are also referred to as listed drugs). Because the safety and efficacy of listed drugs have already been established by the brand company (sometimes referred to as the innovator), the FDA does not require a demonstration of safety and efficacy of generic products. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the active pharmaceutical ingredient is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. For some drugs, including locally acting drugs such as topical anti-fungals, other means of demonstrating bioequivalence may be required by the FDA, especially where rate and/or extent of absorption are difficult or impossible to measure. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling and stability data.

A third alternative is a special type of NDA, commonly referred to as a 505(b)(2) NDA, enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing product, or published literature, in support of its application. 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings with respect to certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new

product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below. Thus approval of a 505(b)(2) NDA or ANDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

#### **Combination Products**

Medical products containing a combination of new drugs, biological products, or medical devices are regulated as "combination products" in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories, such as drug/device, device/biologic or drug/biologic. The term combination product includes: (i) a product comprised of two or more regulated components (i.e., drug/device, biologic/device, drug/biologic or drug/device/biologic, that are physically, chemically or otherwise combined or mixed and produced as a single entity); (ii) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products or biological and drug products; (iii) a drug, device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, such as to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (iv) any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication or effect.

Each constituent part of a combination product is subject to the requirements established by the FDA for that type of constituent part, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the

pre-market review and regulation of the overall product based upon a determination by FDA of the primary mode of action of the combination product, and typically one application, such as for a drug/device combination product assigned to the FDA's Center for Drug Evaluation and Research, or CDER, an NDA, will be made.

A device with the primary purpose of delivering or aiding in the delivery of a drug and distributed containing a drug (i.e., a "prefilled delivery system") is typically evaluated by CDER using drug authorities and device authorities, as necessary.

A device with the primary purpose of delivering or aiding in the delivery of a drug and that is distributed without the drug (i.e., unfilled) is typically evaluated by the FDA's Center for Devices and Radiological Health and CDER, respectively, unless the intended use of the two products, through labeling, creates a combination product.

The FDA has indicated that dry powder inhalers, such as our lead product candidate, LIQ861, are drug/device combination products.

#### **Post-Approval Requirements**

Drugs manufactured or distributed pursuant to FDA approvals are subject to extensive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping (including certain electronic record and signature requirements), periodic reporting, product sampling and distribution, advertising and promotion and reporting of certain adverse experiences, deviations and other problems with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and certain other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release. Combination products are subject to FDA regulation to ensure the quality of both the constituent parts and the finished product.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

The FDA may impose a number of post-approval requirements as a condition of approval of an application. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, problems with manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on the product or even complete withdrawal of the product from the market.

Potential implications include required revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. As a compliance best practice and risk mitigation measure, pharmaceutical companies typically train their sales force regarding the limitations on promotion of products relative to their approved indications for use and concerns regarding potential "off-label promotion." However, a physician may use products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Recent court decisions have impacted FDA's enforcement activity regarding off-label promotion in the light of First Amendment considerations; however, there are still significant risks in this area in part due to the potential for False Claims Act exposure.

The distribution of prescription drugs is subject to the Drug Supply Chain Security Act, or DSCSA, which regulates the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain and regulation of manufacturers and repackagers, wholesale distributors, third-party logistics providers, and dispensers. The DSCSA preempts previously enacted state pedigree laws and upon taking effect superseded the pedigree requirements of the Prescription Drug Marketing Act, or PDMA. Trading partners within the drug supply chain must now ensure certain product tracing requirements are met, and are required to exchange transaction information, transaction history, and transaction statements. Further, the DSCSA limits the distribution of prescription pharmaceutical products and imposes requirements to ensure overall accountability and security in the drug supply chain. The distribution of product samples continues to be regulated under the PDMA.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

#### **Patent Term Restoration**

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited PTE under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term effectively lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that

application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension. Extensions are not granted as a matter of right and the extension must be applied for prior to expiration of the patent and within a sixty day period from the date the product is first approved for commercial marketing. The USPTO, in consultation with the FDA, reviews and approves the application for any PTE or restoration. In the future, we may apply for PTEs, defined as the length of the regulatory review of products covered by our granted patents, for some of our currently owned or licensed applications and patents to add patent life beyond their current expiration dates. Such extensions will depend on the length of the regulatory review; however, there can be no assurance that any such extension will be granted to us.

#### **Marketing Exclusivity**

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The specific scope varies, but fundamentally the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving applications for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical studies necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to the term of any existing regulatory exclusivity, including the non-patent exclusivity periods described above. This six-month exclusivity may be granted based on the voluntary completion of a pediatric clinical study in accordance with an FDA-issued "Written Request" for such a clinical study.

#### **Pharmaceutical Coverage, Pricing and Reimbursement**

In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. Some of the additional requirements and restrictions on coverage and reimbursement levels imposed by third-party payors influence the purchase of healthcare services and products. Third-party payors may limit coverage to specific drugs on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication, or place drugs at certain formulary levels that result in lower reimbursement levels. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, one payor's determination to provide coverage does not assure that other payors will also provide coverage and reimbursement for the product.

and the level of coverage and reimbursement may differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors.

Reimbursement may also impact the demand for drug products that obtain marketing approval. If coverage for a drug product is obtained by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Prescribing physicians are unlikely to use or prescribe drug products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of those drug products. If reimbursement is not available, or is available only to limited levels, a drug product which has obtained marketing approval may not be successfully commercialized.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

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

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

#### **Other Healthcare Laws and Compliance Requirements**

Healthcare providers, physicians and third-party payors often play a primary role in the recommendation and prescription of any currently marketed products and product candidates 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 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 the following:

- § The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities including pharmaceutical manufacturers from 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 reimbursable, in whole or in part, under a federal healthcare

program, 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 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. 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. In addition, federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may also implicate the False Claims Act. Although the False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes.
- § 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.

Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

- § HIPAA, as amended by 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, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, and business associates. Among other things, HITECH made certain aspects of HIPAA's rules (notably the Security Rule) directly applicable to business associates — independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and 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 Department of Health and Human Services, or HHS, Office of 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, with one recent penalty exceeding \$5 million.
- § 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, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.
- § The federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under 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, and its implementing regulations, 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 & 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, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. On October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act." This law, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine"), extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act, to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments and transfers of value 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 which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts (for example, California recently enacted legislation — the California Consumer Privacy Act, or CCPA — which goes into effect 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 certain disclosures 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; legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations, and 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 it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted).

- § 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.

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 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.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws 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 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.

#### **Healthcare Reform**

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. By way of example, in March 2010, the ACA as amended was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are the following:

- § The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the HHS as a condition of Medicare Part B and Medicaid coverage of the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid

rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, establishing new methodologies by which AMP is calculated and rebates owed by manufacturers under the Medicaid Drug Rebate Program are collected for drugs that are inhaled, infused, instilled, implanted or injected, adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended-release formulations) of solid oral dosage forms of branded products, expanding the universe of Medicaid utilization subject to drug rebates to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, and expanding the population potentially eligible for Medicaid drug benefits.

- § 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. Effective in 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Recent proposed guidance from the HHS Health Resources and Services Administration, if adopted in its current form, may affect manufacturers' rights and liabilities in conducting audits and resolving disputes under the 340B program.
- § Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133.0% of the federal poverty level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability.
- § 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) in order for Part D coverage to be available for the manufacturer's covered Part D drugs.
- § The ACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs with aggregate branded prescription drug sales over \$5 million to certain government healthcare programs or pursuant to coverage under such programs, 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 federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act", which under 2018 legislation will be extended to cover 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 and transfers of value made in 2021).
- § The ACA established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products by influencing decisions relating to coverage and reimbursement rates.
- § The ACA established the Center for Medicare and Medicaid Innovation, or Innovation Center, within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. The Innovation Center has been funded through 2019, and funding will be automatically renewed for each 10-year budget window thereafter.
- § The ACA established a licensure framework for follow-on biologic products.

- § 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 requires annual reporting of drug samples that manufacturers and distributors provide to physicians.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. President Trump has 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. Concurrently, Congress has considered legislation that would repeal or replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or TCJA, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. While the decision has been stayed pending outcome of an appeal to the Fifth Circuit Court of Appeals, so the ruling does not have immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA. It is also unclear how regulatory and subregulatory policy, which fluctuate continually, may affect interpretation and implementation of the ACA and its practical effects on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, then-President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent 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. Recent 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. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS is soliciting feedback on some of these measures and, has begun implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019; in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product and in early 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although some of these, and other, proposals may require additional authorization to become effective, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs, including by addressing the role of pharmacy benefit managers in the supply chain. 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for patients to access certain investigational new drug products that have completed a Phase I clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

#### ***Foreign Regulation of Drugs***

In order to market any product outside of the United States, we will need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding development, approval, commercial sales and distribution of our products, and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products, if approved. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

**Employees**

As of December 31, 2018, we had 63 full-time employees, including seven employees in management (including our executive officers), 25 employees in research and development, 15 employees in manufacturing and technical operations, six employees in regulatory and quality and ten employees in general and administration. All of our full-time employees are employed in the United States.

**Facilities**

Our corporate headquarters are located in Morrisville, North Carolina, and consist of 45,095 square feet of space under a lease that expires on October 31, 2026 and includes an option for us to renew for an additional five years through October 31, 2031, as amended. The primary use of this location is general office, laboratory, research and development and light manufacturing. In November 2018, we amended this primary lease to include an additional 8,264 square feet of contiguous space and, in conjunction therewith, we terminated our additional lease in Morrisville, North Carolina consisting of 4,401 square feet of space that was not contiguous. We believe that our facilities are adequate for our current needs and for the foreseeable future; however, we will continue to seek additional space as needed to accommodate our growth.

**Legal Proceedings**

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or other body pending or, to the knowledge of our executive officers, threatened against or affecting us, our common stock or any of our officers or directors in their capacities as such, in which an adverse decision could have a materially adverse effect on our financial condition or results of operations.

**MANAGEMENT****Executive Officers and Directors**

The following table sets forth the name, age as of March 4, 2019 and position of each of our executive officers and directors. On March 1, 2019, Kevin Gordon retired as our President and Chief Financial Officer and accepted a consulting role with us which expires on March 31, 2019. On March 4, 2019, our Board appointed Timothy Albury, our Senior Vice President, Chief Accounting Officer, as Interim Chief Financial Officer. The following also includes certain information regarding our directors' and executive officers' individual experience, qualifications, attributes and skills and brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors. Unless otherwise stated, the business address for all of our executive officers and members of our Board is c/o Liquidia Technologies, Inc., 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560.

Name	Age	Position
<b>Executive Officers</b>		
Neal Fowler	57	Chief Executive Officer and Director
Timothy Albury	50	Interim Chief Financial Officer
Robert Lippe	54	Chief Operations Officer
Dr. Robert Roscigno	52	Senior Vice President, Product Development
Dr. Benjamin Maynor	44	Senior Vice President, Research and Development
Jeri Thomas	57	Senior Vice President, Commercial
<b>Non-Employee Directors</b>		
Dr. Stephen Bloch <sup>(1)(3)</sup>	56	Chairman of the Board and Director
Dr. Seth Rudnick <sup>(2)(3)(4)</sup>	70	Director
Edward Mathers <sup>(2)(3)</sup>	58	Director
Dr. Ralph Snyderman <sup>(2)(4)</sup>	78	Director
Arthur Kirsch <sup>(1)</sup>	67	Director
Raman Singh <sup>(1)(2)</sup>	48	Director

<sup>(1)</sup> Member of our Audit Committee.

<sup>(2)</sup> Member of our Nominating and Corporate Governance Committee.

<sup>(3)</sup> Member of our Compensation Committee.

<sup>(4)</sup> Member of our Research and Development Committee.

**Executive Officers**

**Neal Fowler** has been our Chief Executive Officer and a member of our Board since March 2008. Mr. Fowler also served as a director of Envisia Therapeutics Inc. from November 2013 until November 2017. From June 2006 to March 2008, Mr. Fowler served as president of Centocor, Inc., a subsidiary of Johnson & Johnson, which focused on the development and commercialization of industry-leading biomedicines used to treat chronic inflammatory diseases. From July 2004 to June 2006, Mr. Fowler was the president of Ortho-McNeil Neurologics, Inc. and from October 2001 to July 2004, the vice president of the central nervous system business of Ortho-McNeil-Janssen Pharmaceuticals, Inc. From June 1988 to October 2001, Mr. Fowler held a variety of sales, marketing and business development roles at Eli Lilly and Company in the pharmaceutical and medical device divisions. Mr. Fowler served as a director of Aralez Pharmaceuticals, Inc. (Nasdaq: ARLZ) from June 2010 until August 2018. Mr. Fowler graduated from UNC with a Bachelor of Science in Pharmacy and holds a Master of Business Administration from UNC. We believe Mr. Fowler is qualified to serve on our Board due to his extensive and broad range of experience in

business and healthcare product development, including previous experience growing companies in the pharmaceutical industry.

**Timothy Albury** has been our Interim Chief Financial Officer since March 2019. From January 2018 through February 2019, Mr. Albury served as our Senior Vice President, Chief Accounting Officer. From June 2013 until January 2018, Mr. Albury served as our Chief Financial Officer. From September 2009 to June 2013, Mr. Albury served as the chief financial officer of Osmotica Pharmaceutical Corp., a multinational specialty pharmaceutical company in the field of osmotic drug delivery, and prior to that had served as the chief financial officer of KBI BioPharma, Inc., a biopharma contract development and manufacturing organization. Mr. Albury graduated from Liberty University with a Bachelor of Science and completed a Master of Professional Accounting program at the University of Miami. He is also a Certified Public Accountant with the North Carolina State Board of Certified Public Accountant Examiners and the State of Florida Board of Accountancy as well as a member of the American Institute of Certified Public Accountants.

**Robert Lippe** has been our Chief Operations Officer since June 2015. From February 2014 to June 2015, Mr. Lippe served as executive vice president of operations and chief operations officer at Alexza Pharmaceuticals, Inc. From January 2011 to February 2014, Mr. Lippe worked as the head of global operations at Ironwood Pharmaceuticals, Inc., and from March 2002 to January 2011, he was the head of manufacturing for one of Genentech, Inc.'s Vacaville operating facilities. From May 1992 to May 2002, Mr. Lippe worked at Lawrence Livermore National Laboratory as an assurance and facility manager. Mr. Lippe graduated with a Bachelor of Science in Marine Engineering from the United States Coast Guard Academy. Mr. Lippe holds a Master of Business Administration and Public Health from the University of California, Berkeley.

**Dr. Robert Roscigno** has been our Senior Vice President, Product Development since December 2017. He served as our Senior Vice President, Research and Development from March 2016 until December 2017 and our Vice President, Research and Development from September 2015 until March 2016. From January 2009 to September 2015, Dr. Roscigno served as the executive vice president, global clinical affairs of GeNO, LLC, a pharmaceutical company in the field of inhaled nitric oxide drug products. From July 2007 to January 2009, Dr. Roscigno provided scientific consulting for various companies in the pharmaceutical industry and also worked as a subject matter expert in PAH. From March 2005 to July 2007, Dr. Roscigno was the president and chief operations officer of Lung Rx, Inc., a subsidiary of United Therapeutics Corporation. Prior to Lung Rx, Inc., Dr. Roscigno served in multiple leadership positions at United Therapeutics Corporation. Dr. Roscigno graduated from Trinity College with a Bachelor of Science in Biology. He also holds a Doctor of Philosophy in Cell and Molecular Biology from Duke University.

**Dr. Benjamin Maynor** has been our Senior Vice President, Research and Development since January 2016. He served as our Vice President, Research and Development from March 2015 to January 2016. He joined us as a scientist in September 2005 and is a co-inventor of our PRINT technology. Dr. Maynor was seconded by us to Envisia Therapeutics Inc. from January 2013 to March 2015 where he served as Envisia's vice president, research. Dr. Maynor was also our Vice President, Research from January 2012 to January 2013, our Executive Director of Research from November 2011 to January 2012, our Director of Research from January 2010 to November 2011, our Principal Scientist from October 2009 to January 2010 and a Scientist of the Company from September 2005 to October 2009. Prior to joining us, Dr. Maynor was a postdoctoral associate at UNC from May 2004 to September 2005. He was also a scientist at Polestar Technologies, Inc. from September 1996 to June 1999. Dr. Maynor graduated from Harvard University with a Bachelor of Arts in Chemistry. He also holds a Doctor of Philosophy in Chemistry from Duke University. He is also a member of both the American Chemical Society and the American Association of Pharmaceutical Scientists. Dr. Maynor was honored with the Kathryn C. Hach Award for Entrepreneurial Success in 2014 by the American Chemical Society.

**Jeri Thomas** has been our Senior Vice President, Commercial since May 2018. From June 2017 to March 2018, Ms. Thomas was senior vice president, strategic group planning at Harrison and Star, a healthcare marketing agency. From July 2016 to June 2017, Ms. Thomas was the managing director at JFB

Consulting, a marketing consulting firm. From October 2014 to July 2016, Ms. Thomas served as senior vice president of the Surgical & Perioperative Care Business Unit at The Medicines Company. Prior to The Medicines Company, Ms. Thomas was at Janssen Pharmaceuticals (a Johnson & Johnson company) from December 2001 to October 2014, where she held various senior leadership positions, including vice president, market strategy & access for Latin America, vice president, new business and new product planning, and director of marketing, analgesic franchise. Ms. Thomas obtained her Master of Business Administration in a dual program from the McDonough School of Business at Georgetown University and ESADE Business School in Barcelona, Spain. She holds a Bachelor of Science in Health Planning and Administration from Pennsylvania State University.

#### **Directors**

**Dr. Stephen Bloch** has been the Chairman of our Board since October 2018 and has been a member of our Board since July 2009, a member of our Audit Committee since its formation in August 2016 and the Chairman of our Compensation Committee since its formation in August 2016. Dr. Bloch is currently a director of a number of private life sciences companies and served as a director of Marinus Pharmaceuticals, Inc. (Nasdaq: MRNS) from September 2005 until April 2016. Dr. Bloch has been a general partner at Canaan Partners, a global venture capital firm, since November 2007. From August 2003 to November 2007, Dr. Bloch was a principal at Canaan Partners. From January 1995 to June 2002, Dr. Bloch was the founder and chief executive officer of Radiology Management Sciences, LLC, a specialty medical management company. Dr. Bloch graduated from Dartmouth College with a Bachelor of Arts. Dr. Bloch also holds a Doctor of Medicine from the University of Rochester and a Master of Arts in the History of Science and Public Policy from Harvard University. We believe Dr. Bloch is qualified to serve on our Board due to his financial expertise, experience as a venture capitalist and his experience of serving on the board of directors for several public and private pharmaceutical and life sciences companies.

**Dr. Seth Rudnick** has been a member of our Board since March 2008, a member of our Compensation Committee since its formation in August 2016, a member of our Nominating and Corporate Governance Committee since its formation in July 2018 and the Vice Chairman of our Research and Development Committee since its formation in May 2017. Dr. Rudnick served as the Chairman of our Board from March 2008 until October 2018. Dr. Rudnick is currently a director of G1 Therapeutics, Inc. (Nasdaq: GTHX) and served as a director of Aralez Pharmaceuticals, Inc. (Nasdaq: ARLZ) from June 2011 until August 2018. Dr. Rudnick previously served as a partner at Canaan Partners, a global venture capital firm, from January 1998 to December 2013. From January 1991 to January 1998, Dr. Rudnick was the chief executive officer and chairman of CytoTherapeutics, Inc. From July 1986 to January 1991, Dr. Rudnick worked at Ortho Biotech, Inc., a subsidiary of Johnson & Johnson, where he served as vice president, head of research and development. Dr. Rudnick also previously held directorships at Square 1 Bank, LQ3 Pharmaceuticals, Inc. and Spine Wave, Inc. Dr. Rudnick graduated from the University of Pennsylvania with a Bachelor of Arts in History. He also holds a Doctor of Medicine from the University of Virginia and a Diplomate in the Specialty of Internal Medicine from the American Board of Internal Medicine. We believe Dr. Rudnick is qualified to serve on our Board due to his industry experience, experience as a venture capitalist and senior executive and his experience of serving on the board of directors for several public and private pharmaceutical and life sciences companies.

**Edward Mathers** has been a member of our Board since July 2009, a member of our Compensation Committee since its formation in August 2016 and a member of our Nominating and Corporate Governance Committee since its formation in July 2018. Mr. Mathers, a current Class I director whose term of office will expire at the 2019 annual meeting of stockholders, or the 2019 Annual Meeting, is not seeking re-election and will resign as a director and as a member of the Compensation Committee and Nominating and Corporate Governance Committee immediately prior to the conclusion of the 2019 Annual Meeting. Mr. Mathers is currently a partner at New Enterprise Associates, Inc., a global venture capital firm that invests in technology and healthcare companies. Mr. Mathers is currently a director of ObsEva SA (Nasdaq: OBSV), Ra Pharmaceuticals, Inc. (Nasdaq: RARX), Rhythm Pharmaceuticals, Inc. (Nasdaq: RYTM), Synlogic, Inc. (Nasdaq: SYBX) and a number of private life sciences companies. From July

2002 to August 2008, Mr. Mathers was the executive vice president, corporate development and venture of MedImmune, Inc. From August 2000 to July 2002, he was the vice president, marketing and corporate licensing and acquisitions, of Nektar Therapeutics, Inc. Prior to this, Mr. Mathers worked at Glaxo Wellcome, Inc. from July 1997 to August 2000, where he last held the role of vice president, e-business. Mr. Mathers graduated from the North Carolina State University with a Bachelor of Science in Chemistry. We believe Mr. Mathers is qualified to serve on our Board due to his experience as a venture capitalist, his experience as an executive and in business development and his experience in serving on the board of directors for several public and private pharmaceutical and life sciences companies.

**Dr. Ralph Snyderman** has been a member of our Board since February 2007, the Chairman of our Nominating and Corporate Governance Committee since its formation in July 2018 and the Chairman of our Research and Development Committee since its formation in May 2017. Dr. Snyderman is currently a director of CareDx, Inc. (Nasdaq: CDNA), iRhythm Technologies, Inc. (Nasdaq: IRTC) and a number of private life sciences companies. Dr. Snyderman also served as a director of Argos Therapeutics, Inc. (Nasdaq: ARGX) from December 2016 until March 2017. Dr. Snyderman is currently Chancellor Emeritus of Duke University, the James B. Duke Professor of Medicine, as well as a director of the Duke Center for Research on Personalized Health Care. From January 1989 to July 2004, he served as Chancellor for Health Affairs and Dean of the Duke University School of Medicine. From July 1998 to July 2004, Dr. Snyderman also oversaw the development of the Duke University Health System as its first president and chief executive officer. From January 1987 to June 1989, Dr. Snyderman served as senior vice president, medical research and development at Genentech, Inc. From February 1972 to June 1987, he was a Professor of Medicine at the Duke University. From July 1970 to February 1972, Dr. Snyderman started his career at the National Institutes of Health as a senior investigator. Dr. Snyderman previously served as a venture partner at New Enterprise Associates, Inc., a venture capital firm, from January 2006 to November 2009. Dr. Snyderman graduated from Washington College with a Bachelor of Science and from the State University of New York Downstate Medical Center with a Doctor of Medicine. Dr. Snyderman holds an honorary Doctor of Science from the State University of New York and an honorary Doctor of Science from Washington College. He currently holds memberships in the American Academy of Arts & Sciences, the National Academy of Medicine as well as the Association of American Physicians. Dr. Snyderman is also a recipient of several awards, including the Pioneer Award by the Personalized Medicine World Congress in 2016, as well as the North American Healthcare Lifetime Achievement Award by Frost & Sullivan in 2008 for his leadership in the field of personalized health care. We believe Dr. Snyderman is qualified to serve on our Board due to his extensive industry experience and knowledge and his experience serving on the board of directors of several public and private biotechnology and life sciences companies.

**Arthur Kirsch** has been a member of our Board since September 2016 and the Chairman of our Audit Committee since its formation in August 2016. Mr. Kirsch is currently a director of Aralez Pharmaceuticals, Inc. (Nasdaq: ARLZ until October 2018). From August 2015 until October 2016, Mr. Kirsch served as a director of Immunomedics, Inc. (Nasdaq: IMMU). Since June 2005, Mr. Kirsch has served as the managing director and senior advisor, as well as global head of medical devices and diagnostics, of GCA Global, LLC, a global investment banking firm. From May 1994 to May 2004, he served as executive vice president, head of research at Vector Securities, LLC. From February 1990 to May 1993, Mr. Kirsch served as president of Natwest Securities Limited. From June 1979 to February 1990, Mr. Kirsch worked at Drexel Burnham Lambert, Inc., an investment banking firm, where he held the position of executive vice president, head of equity division. Mr. Kirsch graduated from the University of Rhode Island with a Bachelor of Science and also holds a Master of Business Administration from The City University of New York. We believe Mr. Kirsch is qualified to serve on our Board due to his business and financial expertise and his experience serving on the boards of directors of several public pharmaceutical and life sciences companies.

**Raman Singh** has been a member of our Board since February 2018, a member of our Audit Committee since July 2018 and a member of our Nominating and Corporate Governance Committee since its formation in July 2018. Since October 2011, Mr. Singh has served as the chief executive officer of Mundipharma Pte

Limited, which is part of a network of independent associated companies active in the fields of analgesia, oncology, ophthalmology, respiratory, specialty care and consumer health. Mr. Singh graduated from Osmania University with a Bachelors in Mechanical Engineering in 1992. He also holds Masters in International Management from Thunderbird School of Global Management and in Business Administration from Assumption University. We believe Mr. Singh is qualified to serve on our Board due to his vast industry experience and knowledge as well as his business experience.

## **Corporate Governance**

### **Board Composition**

Our amended and restated bylaws provide that our Board shall consist of that number of directors to be determined from time to time by vote of our Board, provided that such authorized number shall be no fewer than three and no greater than 11 members, and is currently set at nine members. Currently our Board consists of Drs. Bloch, Rudnick and Snyderman, and Messrs. Fowler, Kirsch, Mathers and Singh. Mr. Mathers, a current Class I director whose term of office will expire at the 2019 Annual Meeting, is not seeking re-election and will resign as a director and as a member of the Compensation Committee and Nominating and Corporate Governance Committee immediately prior to the conclusion of the 2019 Annual Meeting. On March 10, 2019, the Board approved the reclassification of Dr. Bloch from a Class II director to a Class I director such that, upon Mr. Mathers' resignation, no one class of directors will have more than one director more than any other class of directors.

In accordance with our amended and restated bylaws and our amended and restated certificate of incorporation, our Board is divided into three classes with staggered three-year terms. At each annual meeting of stockholders after the initial classification, as amended on March 10, 2019, the successors to the directors whose terms will then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election. Our directors are divided among the three classes as follows:

- § the Class I directors are Mr. Mathers and Drs. Bloch and Snyderman, and their terms will expire at the 2019 Annual Meeting;
- § the Class II directors are Dr. Rudnick and Mr. Singh, and their terms will expire at the annual meeting of stockholders to be held in 2020; and
- § the Class III directors are Messrs. Fowler and Kirsch, and their terms will expire at the annual meeting of stockholders to be held in 2021.

Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our Board may have the effect of delaying or preventing changes in control of our company.

There are no contractual obligations or arrangements pursuant to which our directors serve on our Board.

### **Director Independence**

Our Board has determined that Drs. Bloch, Rudnick and Snyderman, and Messrs. Kirsch, Mathers and Singh are independent directors. In making this determination, our Board applied the standards set forth in the Nasdaq listing standards and in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In evaluating the independence of Drs. Bloch, Rudnick and Snyderman, and Messrs. Kirsch, Mathers and Singh, our Board considered their current and historical employment, any compensation we have given to them, any transactions we have entered into with them, their beneficial ownership of our capital stock, their ability to exert control over us, all other material relationships they have had with us and the same facts with respect to their immediate families. The Board also considered all other relevant facts and circumstances known to it in making this independence determination. In addition, Drs. Bloch, Rudnick and Snyderman, and Messrs. Kirsch, Mathers and Singh are non-employee directors, as defined in Rule 16b-3 of the Exchange Act.

### **Code of Conduct**

In October 2016, we adopted a code of conduct, which applies to all of our employees, officers and directors, including those officers responsible for financial reporting. In July 2018, we amended our code of conduct to qualify as a "code of ethics" as defined by the rules of the SEC. The code of conduct is available on our website at [www.liquidia.com](http://www.liquidia.com). We intend to disclose any amendments to the code of conduct, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus.

### **Board Committees**

#### *Audit Committee*

The Audit Committee of our Board oversees the quality and integrity of our financial statements and other financial information, accounting and financial reporting processes, internal controls and procedures for financial reporting and internal audit function. It also oversees the audit and other services provided by our independent auditors and is directly responsible for the appointment, independence, qualifications, compensation and oversight of the independent auditor. In addition, our audit committee is responsible for reviewing our compliance with legal and regulatory requirements, and it assists the Board in an initial review of recommendations to the Board regarding proposed business transactions.

The current members of our Audit Committee are Dr. Bloch and Messrs. Kirsch and Singh, with Mr. Kirsch serving as Chairman. All members of our Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our Board has determined that Mr. Kirsch is an "audit committee financial expert" as defined under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of Nasdaq. Under the rules of the SEC, members of the audit committee must also meet heightened independence standards. Our Board has determined that each of Dr. Bloch and Messrs. Kirsch and Singh are independent under the heightened audit committee independence standards of the SEC and Nasdaq. The Audit Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

#### *Compensation Committee*

The Compensation Committee of our Board reviews and determines the compensation of all of our executive officers and establishes our compensation policies and programs. Specific responsibilities of our Compensation Committee include, among other things, evaluating the performance of our Chief Executive Officer and determining our Chief Executive Officer's compensation. It also determines the compensation of our other executive officers. In addition, our Compensation Committee administers all equity compensation plans and has the authority to grant equity awards subject to the terms and conditions of such equity compensation plans. Our Compensation Committee also reviews and approves various other compensation policies and matters, including establishing policies and making recommendations to our Board regarding director compensation. Our Compensation Committee may also review and discuss with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings, and it may prepare a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

The current members of our Compensation Committee are Drs. Bloch and Rudnick and Mr. Mathers, with Dr. Bloch serving as Chairman. On March 10, 2019, our Board, on the recommendation of the Nominating and Corporate Governance Committee, appointed Mr. Kirsch to serve as a member of the Compensation Committee effective upon Mr. Mathers' resignation as a member of the Board and committees of the Board immediately prior to the conclusion of the 2019 Annual Meeting. Each of the members of our Compensation Committee is independent under the applicable rules and regulations of Nasdaq, and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The Compensation Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

*Nominating and Corporate Governance Committee*

The Nominating and Corporate Governance Committee of our Board oversees the nomination of directors, including, among other things, identifying, evaluating and making recommendations of nominees to our Board, and evaluating the performance of our Board and individual members of our Board. When identifying nominees, the Nominating and Corporate Governance Committee considers, among other things, a nominee's character and integrity, level of education and business experience, financial literacy and commitment to represent long-term interests of our equity holders. Our Nominating and Corporate Governance Committee is also responsible for reviewing developments in corporate governance practices, evaluating the adequacy of our corporate governance practices and making recommendations to our Board concerning corporate governance matters.

The current members of our Nominating and Corporate Governance Committee are Drs. Snyderman and Rudnick and Messrs. Mathers and Singh, with Dr. Snyderman serving as the Chairman. Following Mr. Mathers' resignation as a member of the Board and committees of the Board immediately prior to the conclusion of the 2019 Annual Meeting, the Nominating and Corporate Governance Committee will consist of Drs. Snyderman and Rudnick and Mr. Singh, with Dr. Snyderman serving as the Chairman. The composition of our Nominating and Corporate Governance Committee meets the requirements for independence under the rules and regulations of the SEC and the listing standards of Nasdaq. The Nominating and Corporate Governance Committee operates under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

*Research and Development Committee*

The current members of our Research and Development Committee are Drs. Snyderman and Rudnick, who are, respectively, the Chairman and Vice Chairman of our Research and Development Committee. The role of our Research and Development Committee is to make recommendations to our Board regarding our research and development functions and programs, including our research and development strategies, priorities and opportunities.

**Director Compensation**

The following table presents the total compensation for each person who served as a non-employee member of our Board and received compensation for such service during the fiscal year ended December 31, 2018. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to or pay any other compensation to any of the non-employee members of our Board in 2018. We reimburse non-employee members of our Board for reasonable travel expenses. Mr. Fowler, a member of our Board who also serves as our Chief Executive Officer, does not receive any additional compensation for his service as a director. Mr. Fowler's compensation for service as an employee for 2018 is presented in "Executive Compensation — Summary Compensation Table."

	Fees Earned or Paid in Cash (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(2)</sup>	Total (\$)
Dr. Stephen Bloch <sup>(3)</sup>	26,041	210,056	236,097
Dr. Seth Rudnick	100,729	361,236	461,965
Edward Mathers <sup>(3)</sup>	18,230	210,056	228,286
Dr. Ralph Snyderman	74,791	178,674	253,465
Arthur Kirsch	49,995	130,661	180,656
Raman Singh	19,272	188,925	208,197

<sup>(1)</sup> Represents (i) prior to our initial public offering in July 2018, fees earned pursuant to a board service agreement by Drs. Rudnick and Snyderman and Mr. Kirsch, as further described below under "— Board Service Agreements" and (ii) following our initial public offering, fees earned pursuant to our non-employee director compensation policy described below.

(2) The value of option awards granted to directors is based upon the grant date fair value of awards calculated in accordance with ASC Topic 718. For information regarding our valuation of option awards, see "Stock-based Compensation" in Note 2 of our financial statements for the period ended December 31, 2017. For information regarding these grants, see "— 2018 Option Grant to Raman Singh" and "— Other 2018 Equity Awards to Non-Employee Directors and Neal Fowler".

(3) Investor-appointed directors did not receive fees or other compensation for their service on our Board.

The following table lists all outstanding option awards held by our non-employee directors as of December 31, 2018:

Name	Option Awards
Dr. Seth Rudnick	82,618
Dr. Stephen Bloch	26,986
Edward Mathers	26,986
Dr. Ralph Snyderman	32,830
Arthur Kirsch	26,986
Raman Singh	26,986

#### **Board Service Agreements**

Mr. Kirsch and Drs. Rudnick and Snyderman were each parties to individual board service agreements with us which terminated upon consummation of our initial public offering in July 2018. Each individual board service agreement is described below.

##### *Rudnick*

On April 1, 2015, we and Dr. Rudnick entered into a board service agreement whereby, in exchange for Dr. Rudnick serving as a non-employee member of the Board and providing periodic additional consulting or advisory services to us from time to time, we (i) paid Dr. Rudnick \$120,000 annually for serving on the Board and (ii) granted a nonstatutory stock option to Dr. Rudnick to purchase 12,182 shares of common stock, with an exercise price equal to \$4.71 per share and vesting over a four year period commencing July 1, 2016, pursuant to the Liquidia Technologies, Inc. Stock Option Plan, as amended, or the 2004 Plan.

##### *Snyderman*

On April 1, 2015, we and Dr. Snyderman entered into a board service agreement whereby, in exchange for Dr. Snyderman serving as a non-employee member of the Board and providing periodic additional consulting or advisory services to us from time to time, we (i) paid Dr. Snyderman \$60,000 annually and (ii) granted a nonstatutory stock option to Dr. Snyderman to purchase 5,942 shares of common stock, with an exercise price equal to \$4.71 per share and vesting over a four year period commencing April 1, 2015, pursuant to the 2004 Plan.

##### *Kirsch*

On December 7, 2016, we and Mr. Kirsch entered into a board service agreement whereby, in exchange for Mr. Kirsch acting as a non-employee member of the Board, acting as a non-employee chairman of the Audit Committee and providing periodic additional consulting or advisory services to us from time to time, we (i) paid Mr. Kirsch \$35,000 annually for serving on the Board, (ii) paid Mr. Kirsch \$15,000 annually for participating as the Chairman of the Audit Committee and (iii) granted a nonstatutory stock option to Mr. Kirsch to purchase 8,914 shares of common stock, with an exercise price equal to \$20.36 per share and vesting over a four year period commencing December 7, 2016, pursuant to the 2016 Plan.

#### **2018 Option Grant to Raman Singh**

In connection with his appointment to our Board, on March 7, 2018 we granted Mr. Singh an option to purchase 16,936 shares of common stock, or the Singh Option Shares, under our 2016 Plan, with an exercise price equal to \$9.31 per share, and with one-third of the Singh Option Shares vesting on March 7,

2019, and the remaining two-thirds of the Singh Option Shares vesting monthly thereafter over a period of two years.

**Other 2018 Equity Awards to Non-Employee Directors and Neal Fowler**

On March 7, 2018, we granted each of Mr. Kirsch and Drs. Rudnick and Snyderman options to purchase 8,022, 55,267 and 27,336 shares of common stock, respectively, under our 2016 Plan, with an exercise price equal to \$9.31 per share, with one-third of such option shares vesting on March 7, 2019 and the remaining two-thirds of such option shares vesting monthly thereafter over a period of two years.

On July 25, 2018, we granted, under the 2018 Plan, Dr. Bloch and Messrs. Kirsch, Mathers and Singh an aggregate of 74,072 shares of common stock issuable upon the exercise of stock options. These options have an exercise price equal to \$11.00, the initial public offering price, with such option shares vesting monthly over a period of three years.

On July 25, 2018, we also granted, under the 2018 Plan, Mr. Fowler an option to purchase 192,008 shares of common stock. This option has an exercise price equal to \$11.00, the initial public offering price, with 25% such option shares vesting on July 25, 2018 and the remaining shares vesting in 36 equal monthly installments thereafter, subject to Mr. Fowler's continuous service as of each such date.

On October 12, 2018, we granted, under the 2018 Plan, Mr. Fowler 11,238 restricted stock units, which shall be settled in common stock pursuant to the following vesting schedule: 25% of the restricted stock units shall vest on August 14, 2019, with the remaining 75% of such restricted stock units vesting in 36 equal monthly installments thereafter, subject to Mr. Fowler's continuous service as of each such date.

**Non-Employee Director Compensation Policy**

Our Board has adopted a non-employee director compensation policy that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee is paid cash compensation as set forth below:

	Member Annual Fee (\$)	Chairman Additional Annual Fee (\$)
Board of Directors	35,000	25,000
Audit Committee	7,500	15,000
Compensation Committee	5,000	10,000
Nominating and Corporate Governance Committee	3,750	7,500

Additionally, the Chairman of our Research and Development Committee is paid \$32,000 annually in cash compensation and the Vice-Chairman of our Research and Development Committee is paid \$15,000 annually in cash compensation.

Pursuant to the compensation policy adopted by the Compensation Committee in February 2019, (i) each individual who is first elected or appointed as a non-employee director shall be automatically granted, on the date of such initial election or appointment, a nonqualified stock option to purchase 15,000 shares of our common stock, and (ii) each director then serving on our Board shall be automatically granted, on an annual basis, a nonqualified stock option to purchase 7,500 shares of our common stock. Option grants to our non-employee directors vest in 36 equal monthly installments, becoming fully vested on the third anniversary of the date of grant. Each option granted to our non-employee directors shall terminate on the earlier of (i) the ten year anniversary of the date of grant and (ii) the one year anniversary of such director's ceasing to serve on the Board.

Other option grant awards to non-employee directors are determined by the Board in its sole, good faith discretion. Information regarding compensation for those of our directors who are also employees is set forth in the Executive Compensation — Summary Compensation Table below.

## EXECUTIVE COMPENSATION

The following section provides compensation information pursuant to the scaled disclosure rules applicable to "emerging growth companies" under the rules of the SEC.

### Named Executive Officers

Our named executive officers for the year ended December 31, 2018, which consisted of our principal executive officer and two other most highly compensated executives, were:

- § Neal Fowler;
- § Kevin Gordon; and
- § Robert Lippe.

Kevin Gordon began service as our President and Chief Financial Officer on January 22, 2018 and retired on March 1, 2019. On March 4, 2019, our Board appointed Timothy Albury, our Senior Vice President, Chief Accounting Officer, as Interim Chief Financial Officer.

On March 8, 2019, or the Albury Amendment Effective Date, we and Mr. Albury entered into an amendment, or the Albury Amendment, to that certain Amended and Restated Executive Employment Agreement, effective as of July 25, 2018, or the Albury Employment Agreement, providing for Mr. Albury's employment as Interim Chief Financial Officer. The Albury Amendment shall be in effect from the Albury Amendment Effective Date and continue until the earlier of (i) six months thereafter or (ii) the date on which our new Chief Financial Officer commences employment with us, or the Interim CFO Term. In the event Mr. Albury remains employed by us in a non-Chief Financial Officer role upon expiration of the Albury Amendment, then his employment shall be governed by the terms and conditions set forth in the Albury Employment Agreement. Pursuant to the Albury Amendment, if Mr. Albury remains employed with us in good standing and satisfactorily performs the role of Interim Chief Financial Officer, then (i) he shall earn a bonus in the total amount of \$100,000, less applicable withholdings and deductions, payable in a lump sum within 30 days after the end of the Interim CFO Term, or the Albury Bonus, and (ii) the vesting of the remaining unvested shares of common stock underlying that certain option granted to Mr. Albury on March 7, 2018, or 22,909 shares as of the Albury Amendment Effective Date, shall accelerate and become vested and exercisable as of the end of the Interim CFO Term. Additionally, pursuant to the Albury Amendment, in the event that Mr. Albury's employment is terminated by us during the Interim CFO Term for any reason other than poor performance, and subject to Mr. Albury's compliance with the obligations in the Albury Employment Agreement, then he shall be entitled to (i) the Albury Bonus, which will be payable in a lump sum by us within 30 days after the Release Effective Date (as defined in the Albury Employment Agreement), and (ii) the accelerated vesting described in the immediately preceding sentence.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Future compensation programs that we adopt may differ materially from the currently planned programs summarized in this discussion. See "Cautionary Note Regarding Forward-Looking Statements."

**Summary Compensation Table**

The following table sets forth certain information with respect to the total compensation paid to the named executive officers for the years ended December 31, 2017 and 2018:

<u>Name and principal position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Stock Awards (\$)<sup>(1)</sup></u>	<u>Option Awards (\$)<sup>(2)</sup></u>	<u>Non-equity incentive plan compensation (\$)</u>	<u>All other compensation (\$)<sup>(5)</sup></u>	<u>Total (\$)</u>
Neal Fowler	2018	478,692	324,441	3,009,434	235,200 <sup>(3)</sup>	13,310	4,061,077
Chief Executive Officer <sup>(6)</sup>	2017	411,769	—	—	164,800 <sup>(4)</sup>	10,800	587,369
Kevin Gordon	2018	415,385 <sup>(7)</sup>	1,726,138	1,153,616	176,400 <sup>(3)</sup>	12,633	3,484,172
Former President and Chief Financial Officer <sup>(7)</sup>							
Robert Lippe	2018	408,960	—	285,488	160,400 <sup>(3)</sup>	13,310	868,158
Chief Operations Officer <sup>(8)</sup>	2017	397,048	—	—	127,126 <sup>(4)</sup>	10,800	534,974

<sup>(1)</sup> In 2018, Messrs. Fowler and Gordon received grants of restricted stock units, as further described below under "2018 Equity Grants". The value of these grants has been calculated in accordance with ASC Topic 718.

<sup>(2)</sup> The value of option awards granted to our named executive officers is based upon the grant date fair value of awards calculated in accordance with ASC Topic 718. For information regarding our valuation of option awards, see "Stock-based Compensation" in Note 2 of our financial statements for the period ended December 31, 2017. For information regarding these grants, see "—2018 Option Grants".

<sup>(3)</sup> Represents cash bonuses paid by us to the named executive officers in early March 2019 in accordance with our payroll and reflects the achievement of 98% of our 2018 corporate goals, as determined by the Compensation Committee.

<sup>(4)</sup> Represents cash bonuses paid by us to the named executive officers in March 2018 in accordance with our payroll and reflects the achievement of 92% of our 2017 corporate goals, as determined by the Compensation Committee.

<sup>(5)</sup> Represents contributions to (i) our 401(k) plan on behalf of each of our named executive officers and (ii) our named executive officers' health savings accounts. Such 401(k) plan contributions for services performed in 2017 were paid in March 2018 and such 401(k) plan contributions for services performed in 2018 were paid in March 2019.

<sup>(6)</sup> Mr. Fowler has served as our Chief Executive Officer and a director since March 2008. On March 7, 2018, we granted, under the 2016 Plan, Mr. Fowler an option to purchase 231,765 shares of common stock. This option has an exercise price equal to \$9.31, with 25% of such option shares vesting on March 7, 2019 and the remaining shares vesting in 36 equal monthly installments thereafter, subject to Mr. Fowler's continuous service as of each such date. On July 25, 2018, we granted, under the 2018 Plan, Mr. Fowler an option to purchase 192,008 shares of common stock. This option has an exercise price equal to \$11.00, the initial public offering price, with 25% of such option shares vesting on July 25, 2019 and the remaining shares vesting in 36 equal monthly installments thereafter, subject to Mr. Fowler's continuous service as of each such date. On October 12, 2018, we granted, under the 2018 Plan, Mr. Fowler 11,238 restricted stock units, which shall be settled in common stock pursuant to the following vesting schedule: 25% of the restricted stock units shall vest on August 14, 2019, with the remaining 75% of such restricted stock units vesting in 36 equal monthly installments thereafter, subject to Mr. Fowler's continuous service as of each such date.

<sup>(7)</sup> Mr. Gordon was appointed as our President and Chief Financial Officer in January 2018. The salary information for 2018 reflects the pro-rated portion of Mr. Gordon's annual salary of \$450,000 attributable to the portion of the year during which he served as our President and Chief Financial Officer. Mr. Gordon retired as our President and Chief Financial Officer, effective March 1, 2019. See "—Narrative Disclosure to Summary Compensation Table — Fowler and Gordon Employment Agreements" for a discussion of grants made to Mr. Gordon.

<sup>(8)</sup> Mr. Lippe has served as our Chief Operations Officer since June 2015.

**Narrative Disclosure to Summary Compensation Table**

*Base Salary*

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

As a public company, base salaries for the named executive officers will be reviewed periodically by the Board and/or the Compensation Committee, with adjustments expected to be made generally in accordance with the applicable employment agreements, as well as financial and other business factors affecting our company, and to maintain a competitive compensation package for our executive officers.

*Performance-Based Compensation and Bonuses*

Our named executive officers are entitled to annual bonuses calculated as a target percentage of their annual base salary based upon our Compensation Committee's assessment of their performance and our attainment of targeted goals as set by the Compensation Committee in their sole discretion, and communicated to each named executive officer. Bonuses are based on the Compensation Committee's assessment of each named executive officer's and our performance.

*Other Compensation*

We contribute to our 401(k) plan on behalf of our named executive officers and we also contribute to our named executive officers' health savings accounts, but we have no pension benefits, nonqualified defined contribution or other nonqualified deferred compensation plans for our named executive officers.

*Fowler and Gordon Employment Agreements*

We entered into an amended and restated employment agreement with Mr. Fowler, our Chief Executive Officer, on January 31, 2018, and an employment agreement with Mr. Gordon, our former President and Chief Financial Officer, on January 22, 2018, together, the Executive Employment Agreements, and individually, an Executive Employment Agreement, pursuant to which Mr. Fowler is entitled to receive an annual base salary of \$480,000 and an annual target bonus equal to 50% of his annual base salary and Mr. Gordon was entitled to receive an annual base salary of \$450,000 and an annual target bonus equal to 40% of his annual base salary. The annual bonus amounts are and were based upon our Board's assessment of Messrs. Fowler and Gordon's respective performances and our attainment of targeted goals as set by the Board in its sole discretion. The Executive Employment Agreements also provide that executive has either signed or will sign a confidentiality, inventions assignment, non-competition and non-solicitation agreement, pursuant to which each of Messrs. Fowler and Gordon agree to refrain from disclosing our confidential information during or at any time following their employment with us and from competing with us or soliciting our employees or customers during their employment and for 12 months following termination of their employment.

Mr. Fowler's Executive Employment Agreement provides that, in the event that his employment is terminated by us without "cause" or by him for "good reason," subject to the execution and effectiveness of a separation agreement and release, he will be entitled to receive (i) an amount equal to (x) 12 months of base salary plus the amount of the bonus he would have earned had he remained employed pro-rated based on the number of days that he was employed with us during the applicable fiscal year, payable on our normal payroll cycle if such termination is not in connection with a "change in control" or (y) 18 months of base salary plus an amount equal to 1.5 times his target bonus and 100% vesting of the unvested portion of his equity if such termination is within the 12 month period following a "change in control," and (ii) payment of U.S. Consolidated Omnibus Budget Reconciliation Act of 1985, or COBRA, premiums for health benefit coverage for him and his immediate family in an amount equal to the monthly employer contribution that we would have made to provide health insurance to Mr. Fowler, had he remained employed with us for up to 12 months following termination if such termination is not in connection with a "change in control" or up to 18 months if in connection with a "change in control."

Under Mr. Fowler's Executive Employment Agreement, "cause" means that we have determined, in our sole discretion, that Mr. Fowler has engaged in any of the following: (a) any material breach of the terms of the Executive Employment Agreement, or a willful failure to diligently and properly perform material duties for us; (b) misappropriation or unauthorized use of our tangible or intangible property that causes or is likely to cause material harm to us or our reputation, or material breach of the confidentiality, inventions and non-competition agreement entered between him and our company or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation; (c) any material failure to comply with our policies or any other policies and/or directives of our Board; (d) use of illegal drugs or any illegal substance, or use of alcohol in any manner that materially interferes with the performance of employment duties; (e) any dishonest or illegal action, or any other action, whether or not dishonest or illegal, which is materially detrimental to our interest and well-being; (f) failure to disclose any material conflict of interest in a transaction being us and any third party which is materially detrimental to our interest and well-being; (g) any adverse action or omission which would be required to be disclosed pursuant to public securities laws or limit our ability, or the ability of any entity affiliated with us, to sell securities under any federal or state law which would disqualify us from any exemption otherwise available to us; or (h) any material violation of our policies prohibiting unlawful harassment, discrimination, retaliation or workplace violence; provided that, before we may terminate Mr. Fowler for cause, if the grounds for such cause are reasonably capable of cure by him, we will provide him with written notice of the grounds of cause and provide him with 10 business days in which to cure such cause.

Under Mr. Fowler's Executive Employment Agreement, "good reason" means the occurrence of any of the following without the Mr. Fowler's prior consent: (a) a material diminution in authority, duties or responsibility; (b) a material diminution in his base salary or bonus target; (c) a requirement that he report to an employee other than the Board; (d) his principal place of employment is relocated by more than 25 miles from our present location in Research Triangle Park, North Carolina; or (e) materially breach our obligations under his Executive Employment Agreement. In addition, for any of the above events to constitute good reason, Mr. Fowler must inform us of the existence of the event within 60 days of the initial existence of the event, after which date we shall have no less than 30 days to cure the event which otherwise would constitute good reason, and Mr. Fowler must terminate his employment with us for such good reason no later than 90 days after the initial existence of the event.

Pursuant to his Executive Employment Agreement, on March 7, 2018 Mr. Gordon was granted a stock option award to purchase shares of our common stock equal to 1% (127,576 shares) of our capital stock on a fully-diluted basis on the date of grant and a restricted stock unit award equal to approximately 1% (127,576 shares) of our capital stock on a fully-diluted basis on the date of grant, or the Sign-On Award. The option and restricted stock unit award vest as to 25% of the shares underlying the option and the award on the first anniversary of Mr. Gordon's start date and, as to the remainder, in 36 equal monthly installments, subject to Mr. Gordon's continued employment. Further, in connection with our initial public offering, Mr. Gordon was also awarded under the 2018 Plan (i) an additional stock option award under the 2018 Plan, on July 25, 2018, to purchase 41,084 shares of our common stock such that, when added to such number of shares of common stock underlying the option grant to Mr. Gordon on March 7, 2018, the aggregate number of shares of common stock underlying the option grants equaled 1% of our capital stock on a fully-diluted basis on the date of grant with an exercise price per share equal to \$11.00, the initial public offering price of our common stock, and (ii) 41,084 restricted stock units on July 26, 2018 such that, when added to such number of restricted stock units granted to Mr. Gordon on March 7, 2018, the aggregate number of restricted stock units equaled 1% of our capital stock on a fully-diluted basis on the date of grant. These additional awards were on the same terms as the Sign-On Award (except the vesting start date was as of the grant date). On October 12, 2018, as a result of the underwriters partially exercising their option to purchase additional shares on August 14, 2018, we granted Mr. Gordon an additional award of 5,870 restricted stock units, to maintain Mr. Gordon's aggregate 2% ownership of our capital stock on a fully-diluted basis as of August 14, 2018. On March 1, 2019, Mr. Gordon resigned from the positions of President and Chief Financial Officer and entered into a consulting agreement with us

through March 31, 2019. Following the expiration of the consulting period on March 31, 2019, Mr. Gordon will forfeit (i) all of the restricted stock units previously granted to him except for the 37,209 restricted stock units which settled in common stock before March 31, 2019 and (ii) all of the shares of common stock underlying stock option awards previously granted to him except for the 37,209 shares which vested before March 31, 2019. Per the terms of Mr. Gordon's Sign-On Award, he will have until July 1, 2019 to exercise the vested option shares.

#### *Lippe Employment Agreement*

In connection with our initial public offering, we entered into a new employment agreement with Mr. Lippe, or the Lippe Employment Agreement, which took effect as of July 25, 2018 and superseded Mr. Lippe's employment agreement entered into on April 1, 2017. The Lippe Employment Agreement reflects updated and enhanced severance terms which include certain change in control severance benefits.

Pursuant to the terms of Lippe Employment Agreement, Mr. Lippe is entitled to an annual base salary of \$409,189, which reflects Mr. Lippe current salary and is eligible to receive a discretionary annual cash bonus of up to 40% of his annualized base salary, which is consistent with his current agreement.

The base salary of Mr. Lippe may be increased from time to time by our Board, and, notwithstanding anything to the contrary, may also be reduced if our Board determines such reduction is necessary and justified by our financial condition and implements an equal percentage reduction in the base salaries of all of our executive officers, provided that such reduction will not be greater than 10% of his base salary.

In accordance with the employment practices in North Carolina, Mr. Lippe is employed by us on an at-will basis, meaning that either we or such executives may terminate their employment with us at any time without giving advance notice. The Lippe Employment Agreement shall be governed by the laws of North Carolina.

In the event we terminate Mr. Lippe's employment with us at any time without "cause" or Mr. Lippe resigns from his employment with us for "good reason", as such terms are defined in the Lippe Employment Agreement, then he will be entitled to receive, subject to his compliance with certain obligations:

- (a) salary continuation for nine months, or the Lippe Severance Period;
- (b) any unpaid bonus for any full performance period completed prior to the termination date; and
- (c) payment of the employer portion of the premiums required to continue his group healthcare coverage under the applicable provisions of the U.S. Consolidated Omnibus Budget Reconciliation Act of 1985, or COBRA, provided that he elects to continue and remains eligible for these benefits, until the earliest of (i) the close of the Lippe Severance Period, (ii) the expiration of his eligibility for the continuation coverage under COBRA or (iii) the date when he becomes eligible for substantially equivalent health insurance coverage in connection with new employment.

In the event Mr. Lippe's employment with us is terminated for cause or due to his death or "disability", as defined in the Lippe Employment Agreement or Mr. Lippe resigns from his employment with us for any reason other than a resignation for good reason, he will not receive any severance compensation or benefits.

Under the Lippe Employment Agreement, "cause" shall mean that we have determined, in our sole discretion, that he has engaged in any of the following: (a) any material breach of the terms of the Lippe Employment Agreement, or a willful failure to diligently and properly perform material duties for us; (b) misappropriation or unauthorized use of our tangible or intangible property that causes or is likely to cause material harm to us or our reputation, or material breach of the confidentiality, inventions and non-competition agreement entered between him and our company or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation; (c) any material failure to comply with our policies or any other policies and/or directives of our Board; (d) use of illegal drugs or any illegal substance, or use of alcohol in any manner that materially interferes with the performance of

employment duties; (e) any dishonest or illegal action, or any other action, whether or not dishonest or illegal, which is materially detrimental to our interest and well-being; (f) failure to disclose any material conflict of interest in a transaction between us and any third party which is materially detrimental to our interest and well-being; (g) any adverse action or omission which would be required to be disclosed pursuant to public securities laws or limit our ability, or the ability of any entity affiliated with us, to sell securities under any federal or state law which would disqualify us from any exemption otherwise available to us; (h) becoming prohibited by law or any order from any regulatory body or governmental body from being an employee or director of any company, firm or entity; provided that, before we may terminate Mr. Lippe for cause, if the grounds for such cause are reasonably capable of cure by him, we will provide him with written notice of the grounds of cause and provide him with 10 business days in which to cure such cause.

Under the Lippe Employment Agreement, "good reason" means the occurrence of any of the following without Mr. Lippe's prior consent: (a) a material diminution in his authority, duties or responsibility; (b) a material diminution in his base salary; (c) a requirement that he report to an employee other than the Chief Executive Officer; (d) his principal place of employment is relocated by more than 25 miles from our present location in Research Triangle Park, North Carolina; or (e) we materially breach our obligations under the Lippe Employment Agreement. In addition, for any of the above events to constitute good reason, Mr. Lippe must inform us of the existence of the event within 60 days of the initial existence of the event, after which date we shall have no less than 30 days to cure the event which otherwise would constitute good reason, and Mr. Lippe must terminate his employment with us for such good reason no later than 90 days after the initial existence of the event. Also, any action taken by us to accommodate a disability of Mr. Lippe or pursuant to the U.S. Family and Medical Leave Act of 1993 does not constitute good reason.

In the event we, or any surviving or acquiring corporation, terminate Mr. Lippe's employment without cause or he resigns for good reason within 12 months following the effective date of a "change in control", as defined in the 2018 Plan, then Mr. Lippe will be eligible to receive, subject to his compliance with certain obligations, the same severance benefits on the same conditions as if he had been terminated by us without cause; provided, however, that (a) the Lippe Severance Period shall be increased to 12 months, (b) Mr. Lippe will receive a bonus paid at the target amount, and (c) in the event that Mr. Lippe's outstanding equity as of the closing of the change in control is assumed or continued (in accordance with its terms) by the surviving entity in a change in control, then 100% of the unvested portion of such equity shall become vested.

**Outstanding Equity Awards at December 31, 2018**

The following table sets forth information concerning outstanding equity awards at December 31, 2018 for each of our named executive officers:

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price (\$/share)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#) <sup>(6)</sup>	Market Value of Shares or Units of Stock That Have Not Vested (\$) <sup>(10)</sup>
Neal Fowler	62,885	—	1.85	11/23/2020		
	24,069	—	3.87	11/21/2023		
	68,638	9,805 <sup>(1)</sup>	4.71	05/21/2025		
	—	231,765 <sup>(2)</sup>	9.31	03/06/2028		
	—	192,008 <sup>(4)</sup>	11.00	07/25/2028		
Kevin Gordon	—	127,576 <sup>(3)</sup>	9.31	03/06/2028	11,238 <sup>(7)</sup>	243,415
	—	41,084 <sup>(4)</sup>	11.00	07/25/2028		
					127,576 <sup>(8)</sup>	2,763,296
Robert Lippe	26,928	5,571 <sup>(5)</sup>	4.71	08/27/2025	41,084 <sup>(9)</sup>	889,879
	—	43,678 <sup>(2)</sup>	9.31	03/06/2028	5,870 <sup>(7)</sup>	127,144
					—	—

<sup>(1)</sup> 2.084% of the shares underlying the option vest monthly commencing August 1, 2015, becoming fully vested on July 1, 2019.

<sup>(2)</sup> 25% of the shares underlying the option vest on March 7, 2019, with 2.084% of the shares underlying the option vest monthly thereafter, becoming fully vested on March 7, 2022.

<sup>(3)</sup> 25% of the shares underlying the option vest on January 22, 2019, with 2.084% of the shares underlying the option vest monthly thereafter, becoming fully vested on January 22, 2022.

<sup>(4)</sup> 25% of the shares underlying the option vest on July 25, 2019, with 2.084% of the shares underlying the option vest monthly thereafter, becoming fully vested on July 25, 2022.

<sup>(5)</sup> 25% of the shares underlying the options vested on July 13, 2016, with 2.084% of the shares vesting monthly thereafter, becoming fully vested on July 13, 2019.

<sup>(6)</sup> Amount includes the unvested portion of restricted stock units granted on March 7, 2018, July 25, 2018 and October 12, 2018.

<sup>(7)</sup> The restricted stock units shall be settled in common stock pursuant to the following vesting schedule: 25% of the restricted stock units shall vest on August 14, 2019, with the remaining 75% of such restricted stock units vesting in 36 equal monthly installments thereafter, subject to the holder's continuous service as of each such date.

<sup>(8)</sup> The restricted stock units shall be settled in common stock pursuant to the following vesting schedule: 25% of the restricted stock units shall vest on January 22, 2019, with the remaining 75% of such restricted stock units vesting in 36 equal monthly installments thereafter, subject to Mr. Gordon's continuous service as of each such date.

<sup>(9)</sup> The restricted stock units shall be settled in common stock pursuant to the following vesting schedule: 25% of the restricted stock units shall vest on July 26, 2019, with the remaining 75% of such restricted stock units vesting in 36 equal monthly installments thereafter, subject to Mr. Gordon's continuous service as of each such date.

<sup>(10)</sup> Based on the \$21.66 per share closing price of our Common Stock on December 31, 2018, as reported by Nasdaq.

## **2018 Equity Grants**

On March 7, 2018, we granted incentive stock options to purchase shares of our common stock under the 2016 Plan, with an exercise price equal to \$9.31 per share, to each of the following officers: (i) Neal Fowler, our Chief Executive Officer, for 231,765 shares; (ii) Kevin Gordon, our former President and Chief Financial Officer, for 127,576 shares; and (iii) Timothy Albury, our Interim Chief Financial Officer, for 30,545 shares (iv) Robert Lippe, our Chief Operations Officer, for 43,678 shares; (v) Dr. Robert Roscigno, our Senior Vice President, Product Development, for 35,656 shares; and (vi) Dr. Benjamin Maynor, our Senior Vice President, Research and Development, for 41,598 shares. Such options, with the exception of the options granted to Mr. Albury, vest as to 25% on March 7, 2019, and, as to the remainder, in 36 equal monthly installments thereafter. The options granted to Mr. Albury vest as to 25% on March 7, 2019, and, as to the remainder, in 12 equal monthly installments thereafter.

On March 7, 2018, we granted Mr. Gordon a restricted stock unit award of 127,576 shares. The restricted stock unit award vests as to 25% of the shares underlying the award on January 22, 2019, and, as to the remainder, in 36 equal monthly installments thereafter, subject to Mr. Gordon's continued employment.

On July 25, 2018, we granted incentive stock options to purchase 192,008 and 41,084 shares of our common stock under the 2018 Plan, with an exercise price equal to \$11.00, the initial public offering price of our common stock, to Messrs. Fowler and Gordon, respectively. Such options vest as to 25% on July 25, 2019 and, as to the remainder, in 36 equal monthly installments thereafter.

On July 26, 2018, we granted Mr. Gordon a restricted stock unit award of 41,084 shares. The restricted stock unit award vests as to 25% of the shares underlying the award on July 26, 2019, and, as to the remainder, in 36 equal monthly installments thereafter, subject to Mr. Gordon's continued employment.

On October 12, 2018, we granted Messrs. Fowler and Gordon restricted stock unit awards of 11,238 and 5,870 shares, respectively. The restricted stock unit awards vest as to 25% of the shares underlying the award on August 14, 2019, and, as to the remainder, in 36 equal monthly installments thereafter, subject to continued employment.

On March 1, 2019, Mr. Gordon resigned from the positions of President and Chief Financial Officer and entered into a consulting agreement with us through March 31, 2019. Following the expiration of the consulting period on March 31, 2019, Mr. Gordon will forfeit (i) all of the restricted stock units previously granted to him except for the 37,209 restricted stock units which settled in common stock before March 31, 2019 and (ii) all of the shares of common stock underlying stock option awards previously granted to him except for the 37,209 shares which vested before March 31, 2019. Per the terms of Mr. Gordon's Sign-On Award, he will have until July 1, 2019 to exercise the vested option shares.

## **Equity and Other Incentive Compensation Plans**

### ***Employee Bonus Plan***

In July 2018, we adopted an employee bonus plan, or the Employee Bonus Plan, under which eligible employees are eligible to receive an annual cash bonus determined by the achievement of certain company and individual performance indicators that have been approved by our Compensation Committee and our Board for the relevant financial year.

Employees who are employed by us or our participating affiliates on the date the bonus payout is made are eligible to receive a cash bonus pursuant to and on the terms of our Employee Bonus Plan. Employees who do not work a full plan year may be paid bonuses on a pro rata basis, at the discretion of our management. All bonus eligibility is subject to the determination of our Compensation Committee.

The determination of the bonus (if any) payable to any eligible employee is solely and completely within the discretion of our Compensation Committee, and there is no obligation on our Compensation Committee to award any bonus to any employee.

### **Severance Plan**

In July 2018, we adopted an Executive Severance and Change in Control Plan, or the Severance Plan, under which eligible employees are entitled to receive certain severance benefits upon the termination of their employment with us, if such termination was (a) initiated by us and not for "cause" or "disability", each as defined under the Severance Plan, or because of death or (b) initiated by the employee for "good reason", as defined under the Severance Plan, or an Involuntary Termination.

Under the Severance Plan, in the event of an Involuntary Termination, we will pay and provide the following to the eligible employee: an amount equal to the employee's monthly salary as of the termination date multiplied by the applicable severance multiple, an amount equal to the excess of COBRA coverage over the monthly premium rate for our active employees multiplied by the applicable healthcare assistance multiple, and post-termination nonqualified deferred compensation benefits, equity awards and employee welfare benefits pursuant to the terms of the respective plans and policies under which such benefits are provided, if any. In connection with an Involuntary Termination following a "change in control", as defined under the Severance Plan, we will pay and provide the following to the eligible employee: an amount equal to the sum of the employee's monthly salary and one-twelfth of the employee's target annual incentive (such amounts shall be determined as of the date of termination) multiplied by the applicable severance multiple, an amount equal to the excess of COBRA coverage over the monthly premium rate for our active employees multiplied by the applicable healthcare assistance multiple, and post-termination nonqualified deferred compensation benefits, equity awards and employee welfare benefits pursuant to the terms of the respective plans and policies under which such benefits are provided, if any. As a condition to the receipt of certain of these benefits under the Severance Plan, the employee must execute and not revoke a valid release of claims in the form provided by us.

The severance multiple and healthcare assistance multiple under the Severance Plan is as follows: six months for a termination date prior to or absent a change in control and nine months for a termination date during the two-year period following a change in control.

Generally, employees holding a position of vice president or a more senior position are eligible to be selected by our Compensation Committee to participate in the Severance Plan, except that an individual who is (a) party to an employment agreement with us that provides for payments upon his termination of employment, whether before or after a change in control, or (b) entitled to "deferred compensation" under Section 409A of the Code payable in installments shall not be eligible.

### **Stock Option Plan (2004)**

The 2004 Plan was approved by our Board and our stockholders on November 6, 2004 and November 9, 2004, respectively. The 2004 Plan was most recently amended in September 2018 with the approval of our Board. Under the 2004 Plan, we have reserved for issuance an aggregate of 1,004,297 shares of our common stock. The number of shares of common stock reserved for issuance is subject to adjustment in the event of any stock dividend, stock split, reverse stock split, combination, reclassification or other similar change in our capital structure.

The shares of common stock underlying awards that expire or are terminated or cancelled without having been fully exercised under the 2004 Plan are added back to the shares of common stock available for issuance under the 2004 Plan.

Our Board has acted as administrator of the 2004 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2004 Plan. Persons eligible to participate in the 2004 Plan are our employees, officers, directors, consultants and advisors as selected from time to time by the administrator in its discretion.

The 2004 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code, or ISOs, and (2) non-statutory stock options, or NSOs. Subject to certain exceptions set forth therein, the per share option exercise price of each option will be determined by the administrator but may not be less than 100% of the fair market value of the common stock on the date of grant, provided that the per share option exercise price of each option granted to an optionee that owns more than 10% of the common stock may not be less than 110% of the fair market value of the common stock on the date of grant. The term of each option will be fixed by the administrator. The administrator will determine at what time or times each option may be exercised.

The 2004 Plan provides that upon the occurrence of a "Transfer of Control," as defined in the 2004 Plan, except as otherwise provided in a particular option agreement, any unexercisable portion of an outstanding option under the 2004 Plan that would have otherwise become exercisable within 12 months following the effective time of the Transfer of Control shall become immediately exercisable as of a date prior to the Transfer of Control, which date shall be determined by the Board. Upon the occurrence of a Transfer of Control, each outstanding option under the 2004 Plan, to the extent not exercised prior to the Transfer of Control, shall terminate as of the effective time of the Transfer of Control, unless such option is assumed by the successor corporation (or parent thereof) or replaced with a comparable option to purchase shares of the common stock of the successor corporation (or parent thereof).

The Board may amend, suspend or terminate the 2004 Plan or any portion thereof at any time, subject to stockholder approval where such approval is required by applicable law. The Board may also amend, modify or terminate any outstanding option award, provided that no amendment to an award may adversely affect a participant's rights without his or her consent, unless such amendment is required to enable an option designated as an incentive stock option to qualify as an incentive stock option.

All options underlying the 2004 Plan were required to be granted within 10 years from November 6, 2004, the date the 2004 Plan was adopted by the Board. On November 6, 2014, the expiration date of the 2004 Plan was extended to November 6, 2016. As of December 31, 2018, options to purchase 426,250 shares of common stock were outstanding under the 2004 Plan. No future grants will be made under the 2004 Plan.

#### **2016 Equity Incentive Plan**

The 2016 Plan was adopted by the Board on May 18, 2016 and our stockholders on August 10, 2016 to succeed the 2004 Plan. The 2016 Plan was most recently amended on February 2, 2018. As a result, all options granted under the 2004 Plan remained subject to the terms of the 2004 Plan, but any shares of common stock that otherwise remained available for future grants under the 2004 Plan as of the effective date of the 2016 Plan ceased to be available under the 2004 Plan at such time.

Under the 2016 Plan, we have reserved for issuance an aggregate of 1,355,610 shares of our common stock. The number of shares of common stock reserved for issuance is subject to adjustment in the event of a capitalization event in which we are not paid any consideration including a merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in ASC 718.

The shares of common stock underlying awards that expire or are terminated, surrendered or cancelled without having been fully exercised or are forfeited or repurchased or result in shares of common stock not being issued under the 2016 Plan are added back to the shares of common stock available for issuance under the 2016 Plan. In addition, shares of common stock tendered to us by a participant to exercise an award are added back to the shares available for grant under the 2016 Plan.

Our Board has acted as administrator of the 2016 Plan. The administrator has full power to, among other things, select, from among the individuals eligible for awards, the individuals to whom awards will be

granted, to accelerate the time at which a stock award may be exercised or vest, to amend the 2016 Plan and to determine the specific terms and conditions of each award, subject to the provisions of the 2016 Plan. Persons eligible to participate in the 2016 Plan are our employees, directors and consultants.

The 2016 Plan permits the granting of (1) options to purchase common stock intended to qualify as ISOs, (2) NSOs, (3) stock appreciation rights, (4) restricted stock awards, (5) restricted stock unit awards and (6) other stock awards. The per share option exercise price of each option will be determined by the administrator but may not be less than 100% of the fair market value of the common stock on the date of grant, provided that the per share option exercise price of each option granted to an optionee that owns more than 10% of the common stock may not be less than 110% of the fair market value of the common stock on the date of grant and such option grant may not be exercisable after the ten year anniversary of the date of grant. The term of each option will be fixed by the administrator. The administrator will determine at what time or times each option may be exercised.

The 2016 Plan provides that upon the occurrence of a "Corporate Transaction," as defined in the 2016 Plan, our Board may take one or more of the following actions as to some or all awards outstanding under the 2016 Plan: (i) provide that outstanding options awards will be assumed or substituted by the acquiring or successor corporation, (ii) arrange for the assignment of any reacquisition or repurchase rights held by us in respect of common stock issued pursuant to the stock award to the surviving corporation or acquiring corporation, (iii) accelerate the vesting, in whole or in part, of the stock award to a date prior to the effective time of such Corporate Transaction, (iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by us with respect to the stock award, (v) cancel or arrange for the cancellation of the stock award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration as the Board, in its sole discretion, may consider appropriate, or without the payment of consideration or (vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the participant would have received upon the exercise of the stock award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise.

The Board may amend or terminate the 2016 Plan at any time, subject to stockholder approval where such approval is required by applicable law. Board may also amend, modify or terminate any outstanding award, provided that no amendment to an award may adversely affect a participant's rights without his or her consent.

Unless terminated by the Board, the 2016 Plan will terminate automatically on May 17, 2026. No stock awards may be granted under the 2016 Plan while the 2016 Plan is suspended or after it is terminated.

As of December 31, 2018, options to purchase 883,383 shares of common stock were outstanding under the 2016 Plan and 127,576 restricted stock units were outstanding under the 2016 Plan. Our Board determined not to make any further awards under the 2016 Plan following our initial public offering, at which time the 2018 Plan became effective.

#### **2018 Long-Term Incentive Plan**

The Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan, or the 2018 Plan, was approved by our Board on July 12, 2018 and our stockholders on July 19, 2018 and became effective as of July 25, 2018, or the Effective Date. No "Awards", as defined below, will be made under the 2004 Plan or the 2016 Plan on or after the Effective Date.

The 2018 Plan is designed to:

- § promote the long-term financial interests and growth of our company and its subsidiaries by attracting and retaining directors and employees, which include management as well as other personnel;
- § motivate management by means of growth-related incentives to achieve long-range goals; and
- § further the alignment of the interests of participants and those of our stockholders, through opportunities for increased stock or stock-based ownership in our company.

The 2018 Plan will remain in effect, subject to the right of our Board or our Compensation Committee to amend or terminate the 2018 Plan at any time, until the earlier of (a) the earliest date as of which all Awards granted under the 2018 Plan have been satisfied in full or terminated and no shares of common stock approved for issuance under the 2018 Plan remain available to be granted under new Awards, or (b) July 18, 2028. No Awards will be granted under the 2018 Plan after such termination date. Subject to other applicable provisions of the 2018 Plan, all Awards made under the 2018 Plan on or before July 18, 2028, or such earlier termination of the 2018 Plan, shall remain in effect until such Awards have been satisfied or terminated in accordance with the 2018 Plan and the terms of such Awards.

#### **Participation in the 2018 Plan**

All of our officers, non-employee directors, employees and consultants are eligible to participate in the 2018 Plan.

##### *Participation by Non-Employee Directors*

Although our non-employee directors, including our independent directors, are not involved in the day-to-day running of our operations, they play an important role in furthering our business interests by contributing their experience and expertise. In particular, a number of our independent directors have substantial experience and expertise in pharmaceutical research and development and play an important role in helping us shape our business strategy. It is crucial for us to be able to attract, retain and incentivize such individuals.

It may not always be possible to quantify the services and contributions of our non-employee directors to our company, and accordingly, it may not always be possible to compensate them fully or appropriately by increasing their directors' fees or other cash payments. To that end, participation by non-employee directors in the 2018 Plan will allow us to acknowledge and reward their services and contributions to our company. In addition, we believe that opportunities for increased stock or stock-based ownership in our company will further align the interests of our non-employee directors with the interests of our stockholders.

##### *Administration Plan*

The 2018 Plan is administered by the "Administrator", as defined below, provided that no director shall participate in any deliberation or decision in respect of any stock option, stock appreciation right, stock award, stock unit, performance share, performance unit and/or other stock-based award, each, an Award, and collectively, the Awards, to be granted to him or held by him.

For the purposes of the 2018 Plan, "Administrator" means our Compensation Committee, or such other committee(s) of director(s) duly appointed by our Board or our Compensation Committee to administer the 2018 Plan or delegated limited authority to perform administrative actions under the 2018 Plan, and having such powers as shall be specified by our Board or our Compensation Committee, provided, however, that at any time our Board may serve as the Administrator in lieu of or in addition to our Compensation Committee or such other committee(s) of director(s) to whom administrative authority has been delegated. With respect to any Award to which Section 16 of the Exchange Act applies, the Administrator shall consist of either our Board or a committee of our Board, which committee shall consist of three or more directors, each of whom is intended to be, to the extent required by Rule 16b-3 of the Exchange Act, a "non-employee director" as defined in Rule 16b-3 of the Exchange Act and an "independent director" to

the extent required by the Nasdaq listing rules. Any member of the Administrator who does not meet the foregoing requirements shall abstain from any decision regarding an Award and shall not be considered a member of the Administrator to the extent required to comply with Rule 16b-3 of the Exchange Act.

The Administrator has the authority, in its sole and absolute discretion, to grant Awards under the 2018 Plan to eligible individuals, and to take all other actions necessary or desirable to carry out the purpose and intent of the 2018 Plan. Further, the Administrator has the authority, in its sole and absolute discretion, subject to the terms and conditions of the 2018 Plan, to, among other things:

- (a) determine the eligible individuals to whom, and the time or times at which, Awards shall be granted;
- (b) determine the type of Awards to be granted to any eligible individual;
- (c) determine the number of shares of common stock to be covered by or used for reference purposes for each Award or the value to be transferred pursuant to any Award; and
- (d) determine the terms, conditions and restrictions applicable to each Award and any shares of common stock acquired pursuant thereto, including, without limitation, (i) the purchase price of any shares of common stock, (ii) the method of payment for shares of common stock purchased pursuant to any Award, (iii) the method for satisfying any tax withholding obligation arising in connection with any Award, including by the withholding or delivery of shares of common stock, (iv) the timing, terms and conditions of the exercisability, vesting or payout of any Award or any shares of common stock acquired pursuant thereto, (v) the performance goals applicable to any Award and the extent to which such performance goals have been attained, (vi) the time of the expiration of an Award, (vii) the effect of a participant's Termination of Service, as defined in the 2018 Plan, on any of the foregoing and (viii) all other terms, conditions and restrictions applicable to any Award or shares of common stock acquired pursuant thereto as the Administrator considers to be appropriate and not inconsistent with the terms of the 2018 Plan.

#### *Size*

A total of 1,600,000 shares of our common stock were initially authorized and reserved for issuance under the 2018 Plan. This reserve automatically increased on January 1, 2019 by 620,778 shares and will automatically increase on each subsequent anniversary through 2028, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the Board. This reserve will not be increased to include any shares issuable upon exercise of options granted under our 2016 Plan that expire or terminate without having been exercised in full.

Appropriate adjustments will be made in the number of authorized shares and other numerical limits in the Equity Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards which expire or are cancelled or forfeited will again become available for issuance under the Equity Plan.

Subject to adjustment as provided in the provision of the 2018 Plan pertaining to the occurrence of certain corporate transactions, the maximum number of shares of common stock that may be issued pursuant to stock options granted under the 2018 Plan that are intended to qualify as ISOs is 5,000,000.

#### *Maximum Entitlements*

The Administrator may establish compensation for directors who are not employees of our company or any of our Affiliates, as defined in the 2018 Plan, or the Non-Employee Directors, from time to time, provided that the sum of any cash compensation and the grant date fair value of Awards granted under the 2018 Plan to a non-employee director as compensation for services as a non-employee director during any calendar year may not exceed \$500,000 for an annual grant, provided however that in a non-employee's director first year of service, compensation for services may not exceed \$1,000,000. The Administrator may

make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the Administrator may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other compensation decisions involving non-employee director.

#### *Awards*

Awards may be granted individually or in tandem with other types of Awards, concurrently with or with respect to outstanding Awards. Participants are not required to pay for the application or acceptance of Awards.

**Stock Options.** The Administrator may, from time to time, grant to eligible individuals Awards of stock options.

Such stock options shall be exercisable at such time or times and subject to such terms and conditions as shall be determined by the Administrator; provided, however, that, Awards of stock options may not have a term in excess of ten years unless otherwise required by applicable law.

The exercise price per share subject to a stock option granted under the 2018 Plan shall not be less than the fair market value of one share on the date of grant of the stock option, except as provided under applicable law or with respect to stock options that are granted in substitution of similar types of awards of a company acquired by our company or with which our company combines (whether in connection with a corporate transaction, such as a merger, combination, consolidation or acquisition of property or stock, or otherwise) to preserve the intrinsic value of such awards.

Except as provided in the applicable award agreement or otherwise determined by the Administrator, to the extent stock options are not vested and exercisable, a participant's stock options shall be forfeited upon his Termination of Service.

**Stock Appreciation Rights.** The Administrator may, from time to time, grant to eligible individuals Awards of stock appreciation rights. A stock appreciation right entitles the participant to receive, subject to the provisions of the 2018 Plan and the applicable award agreement, a payment having an aggregate value equal to the product of (a) the excess of (i) the fair market value on the exercise date of one share over (ii) the base price per share specified in the award agreement, and (b) the number of shares of common stock specified by the stock appreciation right, or portion thereof, which is exercised. The base price per share specified in the applicable award agreement shall not be less than the lower of the fair market value on the date of grant or the exercise price of any tandem stock option to which the stock appreciation right is related, or with respect to stock appreciation rights that are granted in substitution of similar types of awards of a company acquired by our company or with which our company combines (whether in connection with a corporate transaction, such as a merger, combination, consolidation or acquisition of property or stock, or otherwise) such base price as is necessary to preserve the intrinsic value of such awards.

Stock appreciation rights shall be exercisable at such time or times and subject to such terms and conditions as shall be determined by the Administrator; provided, however, that stock appreciation rights granted under the 2018 Plan may not have a term in excess of ten years unless otherwise required by applicable law.

Except as provided in the applicable award agreement or otherwise determined by the Administrator, to the extent stock appreciation rights are not vested and exercisable, a participant's stock appreciation rights shall be forfeited upon his Termination of Service.

**Stock Awards.** The Administrator may, from time to time, grant to eligible individuals Awards of unrestricted stock or restricted stock, collectively, Stock Awards. For the purposes of the 2018 Plan, "Restricted Stock" means an Award of shares of common stock that may be subject to certain transferability

and other restrictions and to a risk of forfeiture, including by reason of not satisfying certain performance goals.

Restricted Stock shall be subject to such vesting, restrictions on transferability and other restrictions, if any, and risk of forfeiture as the Administrator may impose at the date of grant or thereafter. The period during which such vesting or transferability and other restrictions and/or risk of forfeiture applies, or the Restriction Period, may lapse under such circumstances, including without limitation upon the attainment of performance goals, in such instalments, or otherwise, as the Administrator may determine. Subject to the provisions of the 2018 Plan and the applicable award agreement, during the Restriction Period, the Participant shall not be permitted to sell, assign, transfer, pledge or otherwise encumber Restricted Stock.

Except to the extent restricted under the applicable award agreement, a participant granted Restricted Stock shall have all of the rights of a stockholder including, without limitation, the right to vote. Cash dividends declared payable on of common stock shall be paid, with respect to outstanding Restricted Stock, either as soon as practicable following the dividend payment date or deferred for payment to such later date as determined by the Administrator, and shall be paid in cash or as unrestricted shares of common stock having a fair market value equal to the amount of such dividends or may be reinvested in additional shares of Restricted Stock as determined by the Administrator; provided, however, that dividends declared payable on Restricted Stock granted as a Performance Award shall be held by our company and made subject to forfeiture at least until achievement of the applicable performance goal relating to such shares of Restricted Stock. Shares of common stock distributed in connection with a stock split or stock dividend, and other property distributed as a dividend, shall be subject to restrictions and a risk of forfeiture to the same extent as the Restricted Stock with respect to which such shares of common stock or other property have been distributed.

Except as provided in the applicable award agreement, upon termination of service during the applicable Restriction Period, Restricted Stock and any accrued but unpaid dividends that are at that time subject to restrictions shall be forfeited; provided that the Administrator may provide, by rule or regulation or in any Award Agreement, or may determine in any individual case, that restrictions or forfeiture conditions relating to Restricted Stock will be waived in whole or in part in the event of terminations resulting from specified causes, and the Administrator may in other cases waive in whole or in part the forfeiture of Restricted Stock.

**Stock Units.** The Administrator may, from time to time, grant to eligible individuals Awards of unrestricted stock units or Restricted Stock Units. For the purposes of the 2018 Plan, "Restricted Stock Unit" means a right granted to a participant to receive shares of common stock or cash at the end of a specified deferral period, which right may be conditioned on the satisfaction of certain requirements, including the satisfaction of certain performance goals.

Restricted Stock Units shall be subject to such vesting, risk of forfeiture and/or payment provisions as the Administrator may impose at the date of grant. The Restriction Period to which such vesting and/or risk of forfeiture applies may lapse under such circumstances, including without limitation upon the attainment of performance goals, in such instalments, or otherwise, as the Administrator may determine.

Until shares of common stock are issued to the participant in settlement of stock units, the participant shall not have any rights of a stockholder with respect to the stock units or the shares of common stock issuable thereunder. The Administrator may grant the participant the right to dividend equivalents on stock units, on a current, reinvested and/or restricted basis, subject to such terms as the Administrator may determine; provided, however, that dividend equivalents declared payable on stock units granted as a Performance Award shall rather than be paid on a current basis, be accrued and made subject to forfeiture at least until achievement of the applicable performance goal relating to such stock units.

**Other Stock-Based Awards.** The Administrator may, from time to time, grant to eligible individuals Awards in the form of Other Stock-Based Awards. For the purposes of the 2018 Plan, "Other Stock-Based Award" means an Award of shares of common stock or any other Award that is valued in whole or in part by reference to, or that is otherwise based upon, shares of common stock, including without limitation dividend equivalents and convertible debentures.

#### *Adjustment Events*

In the event of a merger, consolidation, rights offering, statutory share exchange or similar event affecting our company, each, a Corporate Event, or a stock dividend, stock split, reverse stock split, separation, spinoff, reorganization, extraordinary dividend of cash or other property, share combination or subdivision or recapitalization or similar event affecting the capital structure of our company, each, a Share Change, that occurs at any time after the Effective Date (including any such Corporate Event or Share Change that occurs after such adoption and coincident with or prior to the Effective Date), the Administrator shall make equitable and appropriate substitutions or proportionate adjustments to (a) the aggregate number and kind of shares of common stock or other securities on which Awards under the 2018 Plan may be granted to eligible individuals, (b) the maximum number of shares of common stock or other securities with respect to which Awards may be granted during any one calendar year to any individual, (c) the maximum number of shares of common stock or other securities that may be issued with respect to ISOs granted under the 2018 Plan, (d) the number of shares of common stock or other securities covered by each outstanding Award and the exercise price, base price or other price per share, if any, and other relevant terms of each outstanding Award and (e) all other numerical limitations relating to Awards, whether contained in the 2018 Plan or in award agreements; provided, however, that any fractional shares resulting from any such adjustment shall be eliminated and that no such adjustment shall be made if as a result, the participant receives a benefit that a stockholder does not receive and any adjustment (except in relation to a capitalization issue) must be confirmed in writing by the auditors of our company (acting as experts and not as arbitrators) to be, in their opinion, fair and reasonable.

In the case of Corporate Events, the Administrator may make such other adjustments to outstanding Awards as it determines to be appropriate and desirable, which adjustments may include, without limitation, (a) the cancellation of outstanding Awards in exchange for payments of cash, securities or other property or a combination thereof having an aggregate value equal to the value of such Awards, as determined by the Administrator in its sole discretion (it being understood that in the case of a Corporate Event with respect to which stockholders receive consideration other than publicly traded equity securities of the ultimate surviving entity, any such determination by the Administrator that the value of a stock option or stock appreciation right shall for this purpose be deemed to equal the excess, if any, of the value of the consideration being paid for each share of common stock pursuant to such Corporate Event over the exercise price or base price of such stock option or stock appreciation right shall conclusively be deemed valid and that any stock option or stock appreciation right may be cancelled for no consideration upon a Corporate Event if its exercise price or base price equals or exceeds the value of the consideration being paid for each share of common stock pursuant to such Corporate Event), (b) the substitution of securities or other property (including, without limitation, cash or other securities of our company and securities of entities other than our company) for the shares of common stock subject to outstanding Awards and (c) the substitution of equivalent awards, as determined in the sole discretion of the Administrator, of the surviving or successor entity or a parent thereof; provided, however, that no such adjustment shall be made if as a result, the participant receives a benefit that a stockholder does not receive and any adjustment (except in relation to a capitalization issue) must be confirmed in writing by the auditors of our company (acting as experts and not as arbitrators) to be, in their opinion, fair and reasonable.

*Change in Control*

In the event of a change in control, as defined in the 2018 Plan, of our company, outstanding awards will terminate upon the effective time of the change in control unless provision is made for the continuation, assumption or substitution of awards by the surviving or successor entity or its parent. Unless an award agreement says otherwise, the following will occur with respect to awards that terminate in connection with a change in control of our company:

- § stock options and stock appreciation rights will become fully exercisable and holders of these awards will be permitted immediately before the change in control to exercise them;
- § restricted stock and stock units with time-based vesting (i.e., not subject to achievement of performance goals) will become fully vested immediately before the change in control, and stock units will be settled as promptly as is practicable in accordance with applicable law; and
- § performance shares and units that vest based on the achievement of performance goals will vest as if the performance goal for the unexpired performance period had been achieved at the target level; and the performance units will be settled as promptly as is practicable in accordance with applicable law.

*2018 Plan Amendments*

Our Board or our Compensation Committee may amend, alter or discontinue the 2018 Plan, but no amendment, alteration or discontinuation shall be made which would materially impair the rights of a participant with respect to a previously granted Award without such participant's consent, except such an amendment made to comply with applicable law or rule of any securities exchange or market on which our shares of common stock are listed or admitted for trading or to prevent adverse tax or accounting consequences to our company or the participant.

Our Board or our Compensation Committee may, at any time, modify and/or alter any or all of the provisions of the 2018 Plan, except that no modification or alternation of any provision shall be made to the advantage of participants except with the prior approval of stockholders a stockholders' meeting to the extent such amendment requires stockholders' approval under the applicable provisions of the applicable listing exchange rule, including but not limited to (a) expanding the eligibility for participation in the 2018 Plan, (b) increasing the number of shares of common stock which may be issued under the 2018 Plan or to a participant, (c) eliminating or modifying the prohibition set forth in Section 7(f) of the 2018 Plan on repricing of stock options and stock appreciation rights, (d) lengthening the maximum term or lowering the minimum exercise price or base price permitted for stock options and stock appreciation rights, (e) modifying the prohibition on the issuance of reload or replenishment options or (f) materially increasing the benefits accruing to participants under the 2018 Plan.

*Amendment of Awards*

The Administrator may unilaterally amend the terms of any Award theretofore granted, but no such amendment shall materially impair the rights of any participant with respect to an Award without the participant's consent, except such an amendment made to cause the 2018 Plan or Awards thereunder to comply with applicable law, applicable rule of any securities exchange on which our shares of common stock are listed or admitted for trading, or to prevent adverse tax or accounting consequences for the participant or our company or any of our affiliates. For purposes of the foregoing sentence, an amendment to an Award that results in a change in the tax consequences of the Award to the participant shall not be considered to be a material impairment of the rights of the participant and shall not require the participant's consent.

As of December 31, 2018, options to purchase 348,479 shares of common stock and 58,192 restricted stock units were outstanding under the 2018 Plan.

**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

The following is a description of transactions since January 1, 2016, to which we have been a party, in which the amount involved exceeds or will exceed \$120,000 and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

**Series D Preferred Stock Financing**

On February 2, 2018, pursuant to a Series D Preferred Stock Purchase Agreement, we issued and sold, at a price per share equal to \$0.59808, shares of our Series D preferred stock to Canaan VIII L.P., or Canaan, Morningside Venture Investments Limited, or Morningside, New Enterprise Associates, or NEA, Xeraya LT Ltd, or Xeraya, and Robert Lippe, our Chief Operations Officer. The following table sets forth the aggregate number of shares of Series D preferred stock issued to our related parties in this offering:

Participants	Shares of Series D Preferred Stock <sup>(5)</sup>	Aggregate Purchase Price	
		Cash (\$)	Conversion of Promissory Note (\$)
Canaan <sup>(1)</sup>	15,887,155	7,500,000	2,001,790
Morningside <sup>(2)</sup>	1,849,490	—	1,106,143
NEA <sup>(3)</sup>	16,502,833	7,500,000	2,370,015
Xeraya <sup>(4)</sup>	17,445,780	—	10,433,973
Robert Lippe	91,814	—	54,912

<sup>(1)</sup> Dr. Bloch, a member of our Board, is a General Partner at Canaan, which is a beneficial holder of more than 5% of our capital stock.

<sup>(2)</sup> Dr. Cheng, a member of our Board from January 2010 to July 2018, is an Investment Partner at Morningside Technology Advisory, LLC, an affiliate of Morningside, which was a beneficial holder of more than 5% of our capital stock at the time of the Series D financing.

<sup>(3)</sup> Mr. Mathers, a member of our Board, is a partner at New Enterprise Associates, Inc., an affiliate of NEA, which is a beneficial holder of more than 5% of our capital stock.

<sup>(4)</sup> Mr. Rushton, a member of our Board from July 2017 to July 2018, is a partner at Xeraya Capital Labuan Ltd., an affiliate of Xeraya, which is a beneficial holder of more than 5% of our capital stock.

<sup>(5)</sup> Following the reverse stock split and the filing of our amended and restated certificate of incorporation, each share of Series D preferred stock converted into approximately 0.06 shares of common stock.

**Issuance of Unsecured Subordinated Convertible Promissory Notes and Warrants**

On January 9, 2017, pursuant to a Note Purchase Agreement, as amended, we issued unsecured subordinated convertible promissory notes, or the Insider Notes, each accruing simple interest at a rate of 8% per year, to Canaan, Morningside, NEA and Robert Lippe in the principal amounts set forth in the following table:

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<b>Participants</b>	<b>Principal Amounts of Subordinated Convertible Promissory Notes (\$)</b>	<b>Warrants to Purchase Shares of Common Stock<sup>(1)</sup></b>
Canaan	1,845,271	34,378
Morningside	1,019,654	18,996
NEA	2,184,704	40,702
Robert Lippe	50,927	948

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<sup>(1)</sup> Represents the number of shares of common stock underlying warrants exercisable for common stock. The exercise price per share underlying the warrants is \$0.0168.

On July 17, 2017, pursuant to an additional Note Purchase Agreement, or the Xeraya NPA, we issued an unsecured subordinated convertible promissory note to Xeraya in the principal amount of \$10 million, or the Xeraya Note, accruing simple interest at a rate of 8% per year. In connection with such agreement, we appointed Jason Rushton, a partner at Xeraya Capital Labuan Ltd, an affiliate of Xeraya, to our Board, effective July 17, 2017.

On February 2, 2018, each of the Insider Notes and the Xeraya Note converted into shares of our Series D preferred stock pursuant to the Series D Preferred Stock Purchase Agreement at the rate of one share for each \$0.59808 in principal and accrued interest outstanding under the notes.

**Certain Transactions Involving Envisia Therapeutics Inc.**

In 2013, we formed Envisia and granted it an exclusive, worldwide, fully paid license to develop therapies using our PRINT technology in specified fields, including ophthalmology, dermatology, articular and otic, or the Envisia License, in exchange for an aggregate of 1,000,000 shares of Envisia common stock. Certain of our significant stockholders purchased shares of Envisia Series A-1 preferred stock in 2013 in a transaction contingent upon the execution of the Envisia License. Each share of preferred stock was initially convertible into one share of common stock. The following table summarizes the ownership of Envisia common and

preferred stock following this transaction, including the relative percentage ownership of the stock on an as-converted basis:

Name	Shares of Common Stock	Shares of Series A Preferred Stock	Aggregate Purchase Price (\$)	Ownership Percentage (%)
Liquidia	1,000,000	—	— <sup>(1)</sup>	11.6
Canaan	—	2,360,739	9,584,600	27.4
Morningside	—	450,936	1,830,800	5.2
NEA	—	2,360,739	9,584,600	27.4
Other stockholders <sup>(2)</sup>	—	983,484	3,992,968	28.4

<sup>(1)</sup> We received an aggregate of 1,000,000 shares of Envisia common stock as consideration for the Envisia License.

<sup>(2)</sup> Consists of Envisia stockholders who were not our related parties.

We understand that Canaan, Morningside and NEA participated in subsequent equity financings with Envisia.

In May 2015, we repurchased the Envisia License with respect to the dermatology and articular fields in exchange for 50,000 shares of the Envisia common stock we held. In March 2017, we repurchased the Envisia License with respect to the otic field, along with other intellectual property rights, in exchange for 75,000 shares of the Envisia common stock we held.

From November 2013 to June 2016, we funded expenses of Envisia related to its facilities, intellectual property and manufacturing under a shared services agreement, totaling \$873,474, \$614,893 and \$105,623 for the years ended December 31, 2015, 2016 and 2017, respectively. We also provided management services worth \$1.5 million to Envisia during the year ended December 31, 2015. In May 2016, we converted Envisia's unpaid expenses under the shared services agreement into a promissory note in the principal amount of \$985,594, which carried interest at an annual rate of 5.0% and had a stated maturity date of December 31, 2016. Envisia repaid the promissory note in full in August 2016. In October 2017, we entered into a mutual release agreement with Envisia related to intellectual property services under our shared services agreement, pursuant to which we waived \$121,473 in fees owed by Envisia.

In October 2017, Aerie purchased substantially all of the assets of Envisia for \$24.8 million, comprised of \$10.5 million in cash and 263,146 shares of Aerie common stock valued at \$14.3 million. In addition, Aerie agreed to make potential milestone payments to Envisia of up to an aggregate of \$45.0 million, contingent upon achievement of certain product regulatory approvals. To the extent funds are to be distributed by Envisia, such distributions will be first allocated to the Envisia preferred stockholders in light of their liquidation preferences. After such liquidation preferences are satisfied, we do not currently expect that we will receive any portion of the proceeds of this transaction as a holder of Envisia common stock. We are not aware of any plans for distributions to Envisia's stockholders.

#### Investors' Rights Agreement

We have entered into the Seventh Amended and Restated Investors' Rights Agreement, or the IRA, dated as of February 2, 2018. The IRA contains information rights and registration rights, among other things, for certain holders of our capital stock. Pursuant to the terms of the agreement, each of these rights terminated upon the closing of our initial public offering, except for the registration rights as more fully described below in "Description of Capital Stock — Registration Rights."

**Indemnification Agreements and Directors' and Officers' Liability Insurance**

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, penalties fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

**Participation in our Initial Public Offering**

Certain of our existing stockholders, including certain affiliates of our directors, purchased an aggregate of \$20.0 million of our common stock in our initial public offering at the public offering price, as shown in the following table:

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<b>Participants</b>	<b>Shares of Common Stock</b>	<b>Aggregate Purchase Price (\$)</b>
Canaan	727,273	8,000,003
NEA	545,455	6,000,005
Xeraya	363,636	3,999,996
Morningside	181,818	1,999,998

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The underwriters received the same underwriting discount on these shares as they did on the other shares sold to the public in the initial public offering.

**Policies and Procedures for Related Party Transactions**

Our Board has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee, but only those independent directors who are disinterested, will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction. All of the transactions described in this section, with the exception of the related party participation in our initial public offering, occurred prior to the adoption of this policy.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 1, 2019, and as adjusted to reflect the sale of our common stock offered by us in this offering, for:

- § each of our named executive officers;
- § each of our directors;
- § all of our current directors and executive officers as a group; and
- § each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock.

We have determined beneficial ownership in accordance with the rules of the SEC, which generally means that a person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security, including options or warrants that are currently exercisable or exercisable within 60 days of March 1, 2019. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, convertible securities or other rights, held by such person that are currently exercisable or will become exercisable within 60 days of March 1, 2019, are considered outstanding. We did not, however, deem such shares outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, to our knowledge, the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to community property laws where applicable. The information in the table below does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Act.

We have based our calculation of the percentage of beneficial ownership prior to this offering on 15,566,692 shares of common stock outstanding as of March 1, 2019.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Liquidia Technologies, Inc., 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering <sup>(1)</sup>
<b>5% Stockholders:</b>			
Canaan VIII L.P. <sup>(2)</sup>	2,597,681	16.7%	14.0%
New Enterprise Associates 12, Limited Partnership <sup>(3)</sup>	2,526,764	16.2%	13.6%
Xeraya LT Ltd <sup>(4)</sup>	1,400,388	9.0%	7.5%
Bill & Melinda Gates Foundation <sup>(5)</sup>	797,073	5.1%	4.3%
<b>Named Executive Officers and Directors:</b>			
Neal Fowler <sup>(6)</sup>	268,254	1.7%	1.4%
Kevin Gordon <sup>(7)</sup>	62,153	*	*
Robert Lippe <sup>(8)</sup>	60,016	*	*
Stephen Bloch <sup>(9)</sup>	6,747	*	*
Seth Rudnick <sup>(10)</sup>	70,688	*	*
Edward Mathers <sup>(11)</sup>	6,747	*	*
Ralph Snyderman <sup>(12)</sup>	40,227	*	*
Arthur Kirsch <sup>(13)</sup>	12,610	*	*
Raman Singh <sup>(14)</sup>	8,628	*	*
<b>All executive officers and directors as a group (13 persons)<sup>(15)</sup></b>	<b>686,281</b>	<b>4.3%</b>	<b>3.7%</b>

\* Represents ownership of less than 1.0%.

- (1) Assumes no exercise of the underwriters' option to purchase additional shares of common stock.
- (2) Consists of (i) 2,563,303 shares of common stock and (ii) 34,378 shares of common stock issuable upon the conversion of an outstanding warrant held by Canaan VIII L.P. Canaan Partners VIII LLC is the general partner of Canaan VIII L.P. and may be deemed to have sole investment, dispositive and voting power over the shares held by Canaan VIII L.P. Brenton K. Ahrens, John V. Balen, Stephen M. Bloch, Wendie S. Hutton, Mahta S. Ibrahim, Deepak Kamra, Guy M. Russo and Eric A. Young are the managing members of Canaan Partners VIII LLC. Investment and voting decisions with respect to the shares held by Canaan VIII L.P. are made by the managers of Canaan Partners VIII LLC, collectively. Dr. Bloch, a member of our Board, is a managing member of Canaan Partners VIII LLC. No manager or member of Canaan Partners VIII LLC has beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of any shares held by Canaan VIII L.P. The address of Canaan VIII L.P. is 285 Riverside Avenue, Suite 250, Westport, CT 06880.
- (3) Consists of (i) 2,486,062 shares of common stock held by NEA and NEA Ventures 2006 Limited Partnership, or NEA 2006, an affiliate of NEA, and (ii) 40,702 shares of common stock issuable upon the conversion of an outstanding warrant. The securities held by NEA are indirectly held by (x) NEA Partners 12, Limited Partnership, or NEA Partners 12, the sole general partner of NEA, (y) NEA 12 GP, LLC, or NEA 12 LLC, the sole general partners of NEA Partners 12, and each of the individual managers of NEA 12 LLC. The individual managers of NEA 12 LLC, or the NEA 12 Managers, are Peter J. Barris, Forest Baskett, Patrick J. Kerins and Scott D. Sandell. The shares directly held by NEA 2006 are indirectly held by Karen P. Welsh, the general partner of NEA 2006. NEA, NEA Partners 12, NEA 12 LLC and the NEA 12 Managers share voting and dispositive power with regard to our securities directly held by NEA. Karen P. Welsh, the general partner of NEA 2006, has voting and dispositive power with regard to our securities directly held by NEA 2006. All indirect holders of the above referenced securities disclaim beneficial ownership of all applicable securities, except to the extent of their actual pecuniary interest therein. The address of NEA is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093.
- (4) Consists of 1,400,388 shares of common stock held by Xeraya. Pulau Manukan Ventures Labuan Ltd. is the holding company of Xeraya and may therefore be deemed to share beneficial ownership of the shares held by Xeraya. Fares Zahir, a director of Xeraya, has sole voting and dispositive power with respect to the shares held by Xeraya. Mr. Zahir disclaims beneficial ownership of the shares held by Xeraya. The principal address of Xeraya is Lot 26.03-26.08, Level 26, G Tower, No. 199, Jalan Tun Razak, 50400, Kuala Lumpur, Malaysia.
- (5) Consists of 797,073 shares of common stock. For purposes of Rule 13d-3 under the Exchange Act, all shares beneficially owned by the Bill & Melinda Gates Foundation may be deemed to be beneficially owned by William H. Gates III and Melinda French Gates as Co-Trustees of the Bill & Melinda Gates Foundation. The principal address of the Bill & Melinda Gates Foundation is 1432 Elliot Avenue West, Seattle, WA 98119.
- (6) Consists of (i) 44,989 shares of common stock and (ii) 223,265 shares of common stock underlying outstanding options which will have vested within 60 days of March 1, 2019.
- (7) Consists of (i) 22,286 former restricted stock units which settled in common stock through March 1, 2019, the date Mr. Gordon resigned as our President and Chief Financial Officer, on a net basis following the sales of an aggregate of 12,265 shares of common stock to cover estimated taxes, transaction costs and fees associated with the vesting events, (ii) 2,658 restricted stock units which will have vested through March 31, 2019, the date Mr. Gordon's consulting period with the Company expires, and (iii) 37,209 shares of common stock underlying an outstanding option which will have vested through March 31, 2019.
- (8) Consists of (i) 17,527 shares of common stock, (ii) 41,541 shares of common stock underlying an outstanding option which will have vested within 60 days of March 1, 2019 and (iii) 948 shares of common stock issuable upon the conversion of an outstanding warrant.
- (9) Consists of 6,747 shares of common stock underlying an outstanding option which will have vested within 60 days of March 1, 2019.
- (10) Consists of (i) an aggregate of 24,142 shares of common stock held by Dr. Rudnick and the Carolyn F. Rudnick, and successors, Trustee Seth A. Rudnick Irrevocable GST Trust u/a 3/1/2014 which is managed by Dr. Rudnick's wife for the benefit of his wife and children, and (ii) 46,546 shares of common stock underlying outstanding options which will have vested within 60 days of March 1, 2019.
- (11) Consists of 6,747 shares of common stock underlying an outstanding option which will have vested within 60 days of March 1, 2019.
- (12) Consists of (i) 24,862 shares of common stock and (ii) 15,365 shares of common stock underlying outstanding options which will have vested within 60 days of March 1, 2019.

<sup>(13)</sup> Consists of (i) 2,000 shares of common stock and (ii) 10,610 shares of common stock underlying outstanding options which will have vested within 60 days of March 1, 2019.

<sup>(14)</sup> Consists of 8,628 shares of common stock underlying an outstanding option which will have vested within 60 days of December 31, 2018.

<sup>(15)</sup> Consists of an aggregate of (i) 154,599 shares of common stock, (ii) 22,286 former restricted stock units which settled in common stock through March 1, 2019, the date Mr. Gordon retired as our President and Chief Financial Officer, on a net basis following the sales of an aggregate of 12,265 shares of common stock to cover estimated taxes, transaction costs and fees associated with the vesting events, (iii) 2,658 restricted stock units which will have vested through March 31, 2019, the date Mr. Gordon's consulting period with the Company expires, (iv) 505,790 shares of common stock underlying outstanding options which will have vested within 60 days of March 1, 2019, and (v) 948 shares of common stock issuable upon the conversion of an outstanding warrant, held by 13 executive officers and directors.

## DESCRIPTION OF CAPITAL STOCK

*The following description summarizes important terms of our capital stock. For a complete description, you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant portions of the Delaware General Corporation Law, or the DGCL.*

### General

The following is a summary of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus forms a part.

Our authorized capital stock consists of 40,000,000 shares of common stock and 10,000,000 shares of preferred stock.

### Common Stock

As of December 31, 2018, there were 15,519,469 shares of common stock outstanding held of record by 133 stockholders. There will be 18,519,469 shares of common stock outstanding following the closing of this offering, assuming no exercise of the underwriters' option to purchase additional shares and assuming no exercise of outstanding options and warrants and no delivery of any shares of common stock underlying outstanding restricted stock units.

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

As of December 31, 2018, there are no outstanding shares of 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 December 31, 2018, we had outstanding warrants to purchase an aggregate of 170,925 shares of our common stock at an exercise price of \$0.0168 per share. These warrants expire on December 31, 2026.

## Registration Rights

We entered into a Seventh Amended and Restated Investors' Rights Agreement, or IRA, on February 2, 2018 with our 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.

**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 amended and restated certificate of incorporation and amended and restated bylaws could make the following transactions more difficult:

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

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

#### **Election and Removal of Directors**

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that establish specific procedures for appointing and removing members of our Board. Under our amended and restated certificate of incorporation and amended and restated 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 amended and restated certificate of incorporation and amended and restated 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 amended and restated 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 amended and restated certificate of incorporation and amended and restated 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 amended and restated 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 amended and restated certificate of incorporation and amended and restated 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 amended and restated 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 amended and restated certificate of incorporation and our amended and restated 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 amended and restated 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 amended and restated certificate of incorporation will not adversely affect any right or protection of a director existing at the time of such modification or repeal.

Our amended and restated 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 amended and restated 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 amended and restated certificate of incorporation or our amended and restated bylaws or (4) action asserting a claim against our company governed by the internal affairs doctrine. 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 amended and restated 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 and Registrar**

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.

### **Listing**

Our common stock is listed on the Nasdaq Capital Market under the symbol "LQDA".

## SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of shares of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital through sales of equity securities. Although our common stock is listed on the Nasdaq Capital Market, we cannot assure you that there will be an active public market for shares of our common stock.

Based upon the number of shares of our common stock outstanding as of December 31, 2018, we will have 18,519,469 shares of common stock outstanding upon the closing of this offering. All of such outstanding shares, including the shares sold in this offering, will be freely tradable without restriction under the Securities Act, except for any shares held by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Approximately 5.2 million shares will be subject to the 90-day lock-up period under the lock-up agreements entered into in connection with this offering, as described below. Upon expiration of the lock-up period, these restricted securities will be eligible for public sale only if they are registered under the Securities Act, or if they qualify for an exemption from registration, for example, under Rule 144 or Rule 701, which are summarized below.

### Rule 144

In general, under Rule 144 as in effect on the date of this prospectus, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months, would be entitled to sell an unlimited number of shares of our common stock provided current public information about us is available and, after owning such shares for at least one year, would be entitled to sell an unlimited number of shares of our common stock without restriction. Our affiliates who have beneficially owned restricted securities within the meaning of Rule 144 for at least six months would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- § 1.0% of the number of shares of our common stock then outstanding, which will be equal to approximately 185,000 shares immediately after this offering; and
- § the average weekly trading volume of our common stock on the during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Resales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price of \$50,000, the seller must file a notice on Form 144 with the SEC and the Nasdaq Capital Market concurrently with either the placing of a sale with the broker or the execution directly with a market maker.

### Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144.

The SEC has indicated that Rule 701 will apply to stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of

such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act

#### Form S-8 Registration Statement

On July 26, 2018, we filed a registration statement on Form S-8 under the Securities Act to register the issuance of up to 3,097,230 shares of common stock under our equity incentive plans. This registration statement became effective upon filing. On March 5, 2019, we filed a registration statement on Form S-8 under the Securities Act to register the issuance of up to 620,778 shares of common stock under the 2018 Plan which were automatically added to the 2018 Plan share reserve on January 1, 2019 pursuant to the evergreen provision contained therein. All of the shares issued or to be issued upon the exercise of stock options or settlement of other awards under our stock plans are or will be eligible for resale in the public market without restrictions, subject to Rule 144 limitations applicable to affiliates and the lock-up agreements described below.

#### Lock-up Agreements

In connection with this offering, we and each of our executive officers, directors and certain stockholders have agreed that, without the prior written consent of Jefferies LLC and Cowen and Company, LLC on behalf of the underwriters, we and they will not, subject to limited exceptions, offer, sell, contract to sell, pledge, or otherwise dispose of, or to enter into any hedging or swap transaction with respect to, any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock for a period ending 90 days after the date of this prospectus.

The foregoing does not prohibit the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act during the period, or sales made thereunder for trading plans in existence on the date hereof, or transfers or dispositions by our directors, executive officers and certain stockholders:

- § with the prior written consent of Jefferies LLC and Cowen and Company, LLC;
- § of shares of common stock or other securities acquired in this offering or in open market transactions after the completion of this offering;
- § as a transfer pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction involving a change of control of our company;
- § as a distribution to limited partners, members or stockholders of a holder of our common stock;
- § as a transfer by a business entity to another business entity so long as the transferee controls or is under common control with the holder;
- § as a transfer to a legal representative, heir, beneficiary or a member of the holder's immediate family;
- § as a transfer to any trust for the direct or indirect benefit the holder or the immediate family of the holder and/or charitable organizations;
- § as a bona fide gift, including pursuant to a domestic order or a negotiated divorce settlement, or estate or intestate succession;
- § to cover the payment of taxes due upon or consideration required in connection with the vesting, conversion or exercise of securities issued under an equity incentive plan or stock purchase plan, including the withholding of shares by, or surrender of shares to, us or pursuant to a "net" or "cashless" exercise or settlement feature, provided that if the undersigned is required to make a filing under the Exchange Act, such filing shall include a footnote describing the purpose of the transaction;
- § as a transfer by operation of law, including pursuant to a court or regulatory agency order, a qualified domestic relations order or in connection with a divorce settlement.

Unless a transfer or disposition is made with the written consent of Jefferies LLC and Cowen and Company, LLC, the permitted transfers and dispositions described above may not be made (i) by any of our directors, executive

officers and other holders unless the transfer or disposition does not result in any public disclosure or filing under the Exchange Act reporting a reduction in beneficial ownership of shares of common stock being required or voluntarily made during the lock-up period and (ii) by any of our directors, executive officers and other holders unless the transferee of each such shares agrees to be bound by the lock-up agreement.

For more information regarding the lock-up agreements, see "Underwriters."

**Rule 10b5-1 Sales Plans**

Our directors and officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy.

As of December 31, 2018, four of our officers, including Kevin Gordon, our former President and Chief Financial Officer, have entered into Rule 10b5-1 plans, in which they have contracted with a broker to exercise stock options and/or sell up to an aggregate of 88,114 shares of our common stock on a periodic basis pursuant to the terms of their individual Rule 10b5-1 plans. As of March 1, 2019, an aggregate of 14,452 of the 88,114 shares underlying individual Rule 10b5-1 plans have been sold. On April 1, 2019, following the expiration of Mr. Gordon's consulting term, Mr. Gordon's Rule 10b5-1 plan, comprising 22,394 of the 88,114 shares underlying individual Rule 10b5-1 plans, is expected to terminate. The first possible trade date of such Rule 10b5-1 plans ranges from January 22, 2019 to April 1, 2019 and the continuing Rule 10b5-1 plans have an automatic termination date ranging from November 29, 2019 to December 31, 2019.

**MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS  
TO NON-U.S. HOLDERS**

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders, as defined below, of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- § U.S. expatriates and former citizens or long-term residents of the United States;
- § persons subject to the alternative minimum tax;
- § persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- § banks, insurance companies and other financial institutions;
- § brokers, dealers or traders in securities;
- § "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- § partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- § tax-exempt organizations or governmental organizations;
- § persons deemed to sell our common stock under the constructive sale provisions of the Code;
- § persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- § tax-qualified retirement plans; and
- § "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, entities and arrangements treated as partnerships for U.S. federal income tax purposes holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

**THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S.**

**FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

**Definition of a Non-U.S. Holder**

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- § an individual who is a citizen or resident of the United States;
- § a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- § an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- § a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

**Distributions**

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "— Sale or Other Taxable Disposition."

Dividends paid to a Non-U.S. Holder on our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) to us and/or any applicable paying agent certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a Non-U.S. Holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the Non-U.S. Holder within the United States, are generally exempt from the 30% withholding tax if the Non-U.S. Holder satisfies applicable certification and disclosure requirements (generally including provision of a valid IRS Form W-8ECI (or applicable successor form) certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States). However, such U.S. effectively connected income, net of specified deductions and credits, is taxed in the hands of the Non-U.S. Holder at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by Non-U.S. Holder that is classified as a corporation for U.S. federal income tax purposes may also be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such Non-U.S. Holder's country of residence.

## Sale or Other Taxable Disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- § the gain is effectively connected with the Non-U.S. Holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States, in which case the Non-U.S. Holder generally will be taxed on a net income basis at the U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the Non-U.S. Holder is a foreign corporation, the branch profits tax described above in "Distributions" also may apply;
- § the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- § our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

However, no assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. If we are a USRPHC and either our common stock is not regularly traded on an established securities market or a Non-U.S. Holder holds, or is treated as holding, more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, any gain recognized by such Non-U.S. Holder will generally be subject to U.S. federal income tax rates in the same manner as if the Non-U.S. Holder were a resident of the United States. If we are a USRPHC and our common stock is not regularly traded on an established securities market, such Non-U.S. Holder's proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

## Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN or W-8BEN-E, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the

Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

#### **Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners", as defined in the Code, or furnishes identifying information regarding each substantial United States owner or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock.

FATCA withholding on the gross proceeds payable upon the sale, exchange, or disposition of property that can produce United States-source interest or dividends, such as our common stock, had been scheduled to go into effect on and after January 1, 2019. However, the U.S. Treasury issued proposed regulations on December 13, 2018 eliminating the requirement to withhold under FATCA on gross proceeds. Taxpayers may rely on the proposed regulations until final regulations are issued. Prospective investors should consult their tax advisors regarding withholding under FATCA.

**UNDERWRITING**

Subject to the terms and conditions set forth in the underwriting agreement, dated \_\_\_\_\_, 2019, among us, Jefferies LLC and Cowen and Company, LLC, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

<u>UNDERWRITER</u>	<u>NUMBER OF SHARES</u>
Jefferies LLC	
Cowen and Company, LLC	
Needham & Company, LLC	
Wedbush Securities Inc.	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the pricing of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Commission and Expenses**

The underwriters have advised us that they propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ \_\_\_\_\_ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of \$ \_\_\_\_\_ per share of common stock to certain brokers and dealers. After the offering, the public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions paid by us	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$0.7 million. We have also agreed to reimburse the underwriters for certain expenses, including an amount not to exceed \$25,000 in connection with the clearance of this offering with the Financial Industry Regulatory Authority, Inc., as set forth in the underwriting agreement.

#### Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol "LQDA".

#### Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 450,000 shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

#### No Sales of Similar Securities

We, our officers, directors and holders of all of our outstanding capital stock have agreed, subject to specified exceptions, not to directly or indirectly:

- § sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-(h) under the Exchange Act;
- § otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially; or
- § publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus without the prior written consent of Jefferies LLC and Cowen and Company, LLC.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Jefferies LLC and Cowen and Company, LLC may, in their discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up

agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

#### **Stabilization**

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, and certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

#### **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by any of the underwriters is not

part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

#### **Other Activities and Relationships**

The underwriter and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

#### **Selling Restrictions**

##### ***Australia***

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- § a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- § a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- § a person associated with our company under Section 708(12) of the Corporations Act; or
- § a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

## Canada

### Resale Restrictions

The distribution of our common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of our common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

### Representations of Canadian Purchasers

By purchasing our common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- § the purchaser is entitled under applicable provincial securities laws to purchase the common stock without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106 — Prospectus Exemptions;
- § the purchaser is a "permitted client" as defined in National Instrument 31-103 — Registration Requirements, Exemptions and Ongoing Registrant Obligations;
- § where required by law, the purchaser is purchasing as principal and not as agent; and
- § the purchaser has reviewed the text above under "— Resale Restrictions."

### Conflicts of Interest

Canadian purchasers are hereby notified that the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 — *Underwriting Conflicts* from having to provide certain conflict of interest disclosure in this document.

### Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of our common stock in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

### Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

### Taxation and Eligibility for Investment

Canadian purchasers of our common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in our common stock in their particular circumstances and about the eligibility of our common stock for investment by the purchaser under relevant Canadian legislation.

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément*

*exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

#### **European Economic Area**

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each, a Relevant Member State, an offer to the public of any shares of common stock which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any shares of common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- § to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- § to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- § in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common stock shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression "offer shares of common stock to the public" in relation to the shares of common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common stock to be offered so as to enable an investor to decide to purchase or subscribe to the common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

#### **Hong Kong**

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or SFO, and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or CO, or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is

not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

#### Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

#### Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the common stock is subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- § a corporation (which is not an accredited investor, as defined in Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- § a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities, as defined in Section 239(1) of the SFA, of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common stock pursuant to an offer made under Section 275 of the SFA except:

- § to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- § where no consideration is or will be given for the transfer;
- § where the transfer is by operation of law;
- § as specified in Section 276(7) of the SFA; or
- § as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

#### Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, our company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

#### **United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated, each such person being referred to as a "relevant person".

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

#### **LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by DLA Piper LLP (US), Short Hills, New Jersey. Cooley LLP is serving as counsel for the underwriters.

#### **EXPERTS**

The financial statements as of December 31, 2017 and 2018 and for each of the two years in the period ended December 31, 2018 included in this prospectus have been so included 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.

#### **WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, 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 common stock 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](http://www.sec.gov). We also maintain a website at [www.liquidia.com](http://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.

LIQUIDIA TECHNOLOGIES, INC.  
FINANCIAL STATEMENTS  
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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
Liquidia Technologies, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Liquidia Technologies, Inc. (the "Company") as of December 31, 2018 and 2017, and the related statements of operations and comprehensive loss, of stockholders' equity (deficit), and of cash flows for the years then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

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

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses and cash outflows from operations, has an accumulated deficit and has debt maturing within twelve months that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Change in Accounting Principle**

As discussed in Note 2 to the financial statements, the Company changed the manner in which it accounts for revenue from contracts with customers in 2018.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
Raleigh, North Carolina

February 26, 2019

We have served as the Company's auditor since 2014.

**Liquidia Technologies, Inc.**  
**Balance Sheets**

	December 31, 2017	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash	\$ 3,418,979	\$ 39,534,985
Accounts receivable, less allowance of \$48,108 and \$0, respectively	1,622,179	272,557
Prepaid expenses and other current assets	443,460	219,057
Total current assets	5,484,618	40,026,599
Property, plant and equipment, net	8,243,012	8,130,708
Prepaid expenses and other assets	1,115,972	1,260,951
Total assets	<u>\$ 14,843,602</u>	<u>\$ 49,418,258</u>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 4,424,948	\$ 3,235,949
Accrued expenses	2,785,618	1,459,182
Accrued compensation	1,952,505	2,515,519
Accrued interest	1,408,869	—
Deferred rent	268,628	268,599
Current portion of capital lease obligations	469,798	452,703
Current portion of deferred revenue	3,605,199	—
Current portion of long-term debt	15,608,349	316,906
Total current liabilities	30,523,914	8,248,858
Long-term capital lease obligations	510,625	376,082
Long-term deferred rent	2,612,552	2,406,084
Long-term deferred revenue	5,527,296	8,071,920
Long-term debt	5,556,782	11,627,643
Deferred financing obligation	1,341,810	—
Warrant liabilities	2,462,859	—
Total liabilities	48,535,838	30,730,587
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock — Series A, \$0.001 par value, 1,974,430 and 0 shares authorized, issued and outstanding as of December 31, 2017 and December 31, 2018, respectively	1,974	—
Preferred stock — Series A-1, \$0.001 par value, 1,834,862 and 0 shares authorized, issued and outstanding as of December 31, 2017 and December 31, 2018, respectively	1,835	—
Preferred stock — Series B, \$0.001 par value, 4,620,123 and 0 shares authorized as of December 31, 2017 and December 31, 2018, respectively, 4,496,908 and 0 shares issued and outstanding as of December 31, 2017 and December 31, 2018, respectively	4,497	—
Preferred stock — Series C, \$0.001 par value, 17,102,578 and 0 shares authorized, issued and outstanding as of December 31, 2017 and December 31, 2018, respectively	17,103	—
Preferred stock — Series C-1, \$0.001 par value, 91,000,000 and 0 shares authorized as of December 31, 2017 and December 31, 2018, respectively, 17,556,178 and 0 shares issued and outstanding as of December 31, 2017 and December 31, 2018, respectively	17,556	—
Preferred stock — Series D, \$0.001 par value, 0 shares authorized, issued and outstanding as of December 31, 2017 and December 31, 2018, respectively	—	—
Common stock — Class B (non-voting), \$0.001 par value, 330,664 and 0 shares authorized as of December 31, 2017 and December 31, 2018, respectively, 19,645 and 0 shares issued and outstanding as of December 31, 2017 and December 31, 2018, respectively	20	—
Common stock — \$0.001 par value, 175,000,000 and 40,000,000 shares authorized as of December 31, 2017 and December 31, 2018, respectively, 549,952 and 15,519,469 issued and outstanding as of December 31, 2017 and December 31, 2018, respectively	550	15,520
Additional paid-in capital	79,677,540	185,726,048
Accumulated deficit	(113,413,311)	(167,053,897)
Total stockholders' equity (deficit)	(33,692,236)	18,687,671
Total liabilities and stockholders' equity (deficit)	<u>\$ 14,843,602</u>	<u>\$ 49,418,258</u>

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

**Liquidia Technologies, Inc.**  
**Statements of Operations and Comprehensive Loss**

	For the Year ended December 31,	
	2017	2018
Revenues	\$ 7,258,123	\$ 2,706,981
Costs and expenses:		
Cost of sales	319,759	121,391
Research and development	24,753,876	28,699,576
General and administrative	10,212,774	8,754,088
Total costs and expenses	35,286,409	37,575,055
Loss from operations	(28,028,286)	(34,868,074)
Other income (expense):		
Interest income	268	304,981
Interest expense	(13,010,475)	(18,988,176)
Gain on early extinguishment of long-term debt	—	137,695
Derivative and warrant fair value adjustments	11,884,253	277,715
Total other income (expense), net	(1,125,954)	(18,267,785)
Net loss	(29,154,240)	(53,135,859)
Other comprehensive loss	—	—
Comprehensive loss	\$ (29,154,240)	\$ (53,135,859)
Net loss per common share:		
Basic	\$ (51.78)	\$ (7.42)
Diluted	(51.78)	(7.51)
Weighted average common shares outstanding:		
Basic	563,076	7,163,304
Diluted	563,076	7,078,757

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

**Liquidia Technologies, Inc.**  
**Statement of Stockholders' Equity (Deficit)**  
**For the Years Ended December 31, 2017 and 2018**

	Preferred Stock												Common Stock				Additional Paid-In Capital	Related Party Note Receivable	Accumulated Deficit	Stockholders' Equity (Deficit)
	Series A		Series A-1		Series B		Series C		Series C-1		Series D		Voting		Class B Nonvoting					
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance as of December 31, 2016</b>	<b>1,974,430</b>	<b>\$ 1,974</b>	<b>1,834,862</b>	<b>\$ 1,835</b>	<b>4,496,908</b>	<b>\$ 4,497</b>	<b>17,102,578</b>	<b>\$ 17,103</b>	<b>17,556,178</b>	<b>\$ 17,556</b>	<b>—</b>	<b>\$ —</b>	<b>533,593</b>	<b>\$ 534</b>	<b>19,645</b>	<b>\$ 20</b>	<b>\$ 66,025,349</b>	<b>\$ (55,000)</b>	<b>\$ (84,259,071)</b>	<b>\$ (18,245,203)</b>
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	15,170	15	—	—	86,688	—	—	86,703
Exercise of warrants	—	—	—	—	—	—	—	—	—	—	—	—	1,189	1	—	—	9,999	—	—	10,000
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	514,092	—	—	514,092
Repayment of note to related party shareholder	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	55,000	—	55,000
Beneficial conversion feature on Convertible Notes	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	13,041,412	—	—	13,041,412
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(29,154,240)	(29,154,240)
<b>Balance as of December 31, 2017</b>	<b>1,974,430</b>	<b>1,974</b>	<b>1,834,862</b>	<b>1,835</b>	<b>4,496,908</b>	<b>4,497</b>	<b>17,102,578</b>	<b>17,103</b>	<b>17,556,178</b>	<b>17,556</b>	<b>—</b>	<b>—</b>	<b>549,952</b>	<b>550</b>	<b>19,645</b>	<b>20</b>	<b>79,677,540</b>	<b>—</b>	<b>(113,413,311)</b>	<b>(33,692,236)</b>
Adjustment to remove partial shares resulting from reverse split	—	—	—	—	—	—	—	—	—	—	—	—	(63)	—	—	—	—	—	—	—
Cumulative adjustment — adoption of ASC 506	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(504,727)	(504,727)
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	—	—	119,793	120	—	—	334,591	—	—	334,711
Exercise of common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	48,836	49	—	—	773	—	—	822
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2,195,075	—	—	2,195,075
Issuance of Series D preferred stock, net	—	—	—	—	—	—	—	—	—	—	91,147,482	91,147	—	—	—	—	53,893,361	—	—	53,893,361
Initial public offering	—	—	—	—	—	—	—	—	—	—	—	—	4,833,099	4,833	—	—	53,159,256	—	—	53,164,089
Automatic conversion preferred stock and Class B common stock	(1,974,430)	(1,974)	(1,834,862)	(1,835)	(4,496,908)	(4,497)	(17,102,578)	(17,103)	(17,556,178)	(17,556)	(91,147,482)	(91,147)	9,967,852	9,968	(19,645)	(20)	124,164	—	—	91,147
Reclassification of warrant liabilities	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2,185,144	—	—	2,185,144
IPO financing costs	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(5,843,856)	—	—	(5,843,856)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(53,135,859)	(53,135,859)
<b>Balance as of December 31, 2018</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>—</b>	<b>\$ —</b>	<b>15,519,469</b>	<b>\$ 15,520</b>	<b>—</b>	<b>\$ —</b>	<b>\$ 185,726,048</b>	<b>\$ —</b>	<b>\$ (167,053,897)</b>	<b>\$ 18,687,671</b>

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

Liquidia Technologies, Inc.  
Statements of Cash Flows

	For the Year ended December 31,	
	2017	2018
<b>Operating activities</b>		
Net loss	\$ (29,154,240)	\$ (53,135,859)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	514,092	2,195,075
Depreciation	931,931	1,543,667
Amortization of discount on long-term debt and convertible notes	9,837,985	17,550,541
Non-cash interest expense	2,859,102	343,103
Non-cash gain on early extinguishment of long-term debt	—	(137,695)
Derivative fair value adjustment	(9,872,990)	—
Warrant fair value adjustment	(2,011,263)	(277,715)
Non-cash rent (income) expense	233,449	(206,498)
Lease incentive	1,981,915	—
Changes in operating assets and liabilities:		
Accounts receivable	(328,458)	1,349,622
Prepaid expenses and other current assets	25,206	(67,154)
Other non-current assets	(123,249)	2,408,097
Accounts payable	1,872,852	(1,281,784)
Accrued expenses	1,985,263	(1,055,564)
Accrued compensation	(1,310)	563,013
Accrued interest	(105,036)	—
Deferred revenue	(2,935,603)	(1,621,384)
Net cash used in operating activities	<u>(24,290,354)</u>	<u>(31,830,535)</u>
<b>Investing activities</b>		
Purchases of property, plant and equipment	(2,544,064)	(870,943)
Net cash used in investing activities	<u>(2,544,064)</u>	<u>(870,943)</u>
<b>Financing activities</b>		
Principal payments on capital lease obligations	(384,024)	(608,154)
Proceeds from issuance of convertible notes	27,388,524	—
Proceeds from issuance of long-term debt	4,000,000	11,000,000
Refund of principal payments on long-term debt	—	588,889
Principal payments on long-term debt	(888,890)	(12,406,010)
Payments for debt issuance costs	(1,397,628)	(397,000)
Proceeds from issuance of Series D preferred stock, net of issuance costs	—	25,106,896
Proceeds from initial public offering, net of underwriting fees and commissions	—	47,320,233
Payments for deferred offering costs	—	(2,122,903)
Proceeds from exercise of stock options and warrants	96,703	335,533
Net cash provided by financing activities	<u>28,814,685</u>	<u>68,817,484</u>
Net increase in cash	1,980,267	36,116,006
Cash, beginning of period	1,438,712	3,418,979
Cash, end of period	<u>\$ 3,418,979</u>	<u>\$ 39,534,985</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 313,390	\$ 1,094,532
Purchase of equipment with capital leases	\$ 796,508	\$ 456,517
Changes in purchases of equipment in accounts payable	\$ 144,852	\$ 25,934
Purchase of build-to-suit asset with deferred financing obligation	\$ 1,341,810	\$ 272,656
Reclassification of deferred financing obligation to long-term debt	\$ —	\$ 277,009
Reclassification of financing costs on deferred financing obligation to discount on long-term debt	\$ —	\$ 1,614,466
Recording of discount on long-term debt	\$ —	\$ 168,174
Conversion of accrued interest to long-term debt	\$ 41,271	\$ 144,993
Recording of warrant liabilities with corresponding discount on convertible notes	\$ 4,474,122	\$ —
Recording of derivative liabilities with corresponding discount on convertible notes	\$ 9,872,990	\$ —
Conversion of convertible notes and accrued interest into Series D preferred stock	\$ —	\$ 28,877,498
Recording of discount on convertible notes as paid-in capital for beneficial conversion feature	\$ 12,119,584	\$ —
Debt issuance costs incurred but not paid	\$ 75,000	\$ —
Deferred offering costs incurred but not paid	\$ —	\$ 108,694
Exercise of stock options through exchange of vested stock options	\$ —	\$ 162,156
Issuance of convertible note for debt issuance costs	\$ 442,356	\$ —

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

**Liquidia Technologies, Inc.**

**Notes to Financial Statements**

**1. Organization and Description of the Business**

Liquidia Technologies, Inc. ("Liquidia" or the "Company"), is a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using the Company's 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. The Company is currently focused on the development of two product candidates for which it holds worldwide commercial rights: LIQ861 for the treatment of pulmonary arterial hypertension and LIQ865 for the treatment of local post-operative pain.

The development and commercialization activities are conducted at the Company's headquarters located in Morrisville, North Carolina. The Company was incorporated under the laws of the state of Delaware in 2004.

**2. Significant Accounting Policies**

**Basis of Presentation**

The Company has prepared the accompanying financial statements in conformity with generally accepted accounting principles in the United States of America ("GAAP"). Such financial statements reflect all adjustments that are, in management's opinion, necessary to present fairly, in all material respects, the Company's financial position, results of operations and cash flows and are presented in U.S. Dollars. Certain prior period amounts have been reclassified to conform to the current period presentation.

**Reverse Stock Split**

On July 12, 2018 and July 19, 2018, the Company's Board of Directors and stockholders, respectively, approved an amendment to the Company's amended and restated certificate of incorporation effecting a 1-for-16.8273325471348 reverse stock split of the Company's issued and outstanding shares of common stock and convertible preferred stock. The reverse stock split was effective on July 19, 2018. The par value of the common and redeemable convertible preferred stock was not adjusted as a result of the reverse stock split. All issued and outstanding share and per share amounts included in the accompanying financial statements have been adjusted to reflect this reverse stock split for all periods presented.

**Variable Interest Entities**

The Company identifies entities (i) that do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (ii) in which the equity investors lack an essential characteristic of a controlling financial interest as variable interest entities ("VIE" or "VIEs"). The Company performs an initial and ongoing evaluation of the entities with which the Company has variable interests to determine if any of these entities are VIEs. If an entity is identified as a VIE, the Company performs an assessment to determine whether the Company has both (i) the power to direct activities that most significantly impact the VIE's economic performance and (ii) the obligation to absorb losses from or the right to receive benefits of the VIE that could potentially be significant to the VIE. If both of these criteria are satisfied, the Company is identified as the primary beneficiary of the VIE and the entity must be consolidated. As of December 31, 2018, the Company determined that Envisia Therapeutics Inc. ("Envisia") was a variable interest entity ("VIE"), although the Company does not consolidate it as the Company is not the primary beneficiary for Envisia. Envisia is accounted for under the equity method.

Envisia has operated at a net loss since inception in 2013 and therefore full impairment in the basis of the equity investment was recorded in 2013, the year of initial recognition of the investment. As such, the aggregate investment balance of this VIE as of December 31, 2017 and 2018, was \$0. The initial

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**2. Significant Accounting Policies (Continued)**

investment amount recorded represents the Company's maximum risk of loss related to the identified VIE. As of December 31, 2017 and 2018, Liquidia's common equity ownership percentage in Envisia was approximately 75%, and its ownership percentage of voting shares was 4.4%. Although Liquidia's common equity ownership in Envisia was greater than 50%, control did not rest with the Company; however, the Company had the ability to exercise significant influence over operating and financial policies of Envisia and for a limited time had certain management personnel in common with Envisia. The Company does not have the power to direct activities of Envisia that most significantly impact Envisia's economic performance. Envisia has a board that is independent from Liquidia which approves all activities that affect Envisia's performance, such as selling and purchasing of goods or services; selecting, acquiring or disposing of assets; and researching and developing new products or processes. Additionally, the license rights given to Envisia are irrevocable. Accordingly, the Company accounts for Envisia using the equity method.

In March 2017, the license related to the Otic field, along with other intellectual property rights, as defined, was purchased back by the Company from Envisia in exchange for 75,000 shares of its Envisia common stock. The purchase prices were not material. In October 2017, Envisia sold its license to the PRINT technology to Aerie Pharmaceuticals, Inc. ("Aerie") for initial consideration of \$25 million in the form of a combination of cash and Aerie common stock, with the potential to earn additional payments subject to achievement of certain product approval milestones. The Company did not receive any proceeds from this transaction at closing. There have been no activities between Envisia and the Company in 2018.

**Going Concern**

The Company's financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company closed its initial public offering ("IPO") in July and August 2018 resulting in total net proceeds of \$49.4 million, after underwriting discounts but prior to payment of other offering expenses.

The Company's operations have consisted primarily of developing its technology, developing products, prosecuting its intellectual property and securing financing. The Company has incurred recurring losses and cash outflows from operations, has an accumulated deficit, and has debt maturing within twelve months. The Company expects to continue to incur losses in the foreseeable future and will require additional financial resources to continue to advance its products and intellectual property, in addition to repaying its maturing debt and other obligations.

These circumstances raise substantial doubt about the Company's ability to continue as a going concern. Management's plans with regard to this matter include continuing attempts to obtain additional financing to sustain its operations. However, there is no assurance that the Company will be successful in obtaining sufficient financing on terms acceptable to the Company, and the failure of the Company to obtain sufficient funds on acceptable terms, when needed, could have a material adverse effect on the Company's business, results of operations and financial condition. If sufficient financings are not obtained, this may necessitate other actions by the Company. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**2. Significant Accounting Policies (Continued)**

assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual amounts could differ from those estimates.

**Equity Method Investments**

The Company holds investments in equity method investees. Investments in equity method investees are those for which the Company has the ability to exercise significant influence but does not control and is not the primary beneficiary. Significant influence typically exists if the Company has a 20% or more voting interest in the venture, unless predominant evidence to the contrary exists. Under this method of accounting, the Company records its proportionate share of the net earnings or losses of equity method investees and a corresponding increase or decrease to the investment balances. Cash payments to equity method investees such as additional investments, loans and advances, as well as payments from equity method investees such as dividends, distributions and repayments of loans and advances, are recorded as adjustments to investment balances. The Company evaluates its equity method investments for impairment whenever events or changes in circumstances indicate that the carrying amounts of such investments may not be recoverable.

**Cash**

The Company considers all highly liquid investments with a maturity of three months or less, when purchased, to be cash equivalents. The Company had no cash equivalents as of December 31, 2017 and 2018.

**Accounts Receivable**

Accounts receivable are stated at historical cost less an allowance for doubtful accounts as of each Balance Sheet date. The Company does not accrue interest on trade receivables. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write offs and the current status of all receivables. The Company writes off customer receivables when it becomes apparent, based upon customer facts and circumstances, that such amounts will not be collected.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and accounts receivable. The Company is exposed to credit risk, subject to federal deposit insurance, in the event of default by the financial institutions holding its cash to the extent of amounts recorded on the Balance Sheet. With regards to cash, 100% of the Company's cash is held on deposit with Pacific Western Bank. With regards to revenues and accounts receivable, GlaxoSmithKline plc ("GSK" and "GSK Inhaled") accounted for 84% and 16% of the Company's revenues for the years ended December 31, 2017 and 2018, respectively, and \$1.1 million or 69% and \$0 or 0% of the Company's accounts receivable as of December 31, 2017 and 2018, respectively.

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****2. Significant Accounting Policies (Continued)****Property, Plant and Equipment**

Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment is computed using the straight-line method over the estimated useful lives of the assets beginning when the assets are placed in service. Estimated useful lives for the major asset categories are:

Lab and build-to-suit equipment	5 - 7years
Office equipment	5 years
Furniture and fixtures	10 years
Computer equipment	3 years
Leasehold improvements	Lesser of life of the asset or remaining lease term

The Company has entered into grant agreements with governmental agencies to perform defined research activities. Under those grants, the Company purchases lab equipment required to perform the necessary research. Those specific assets are depreciated over the lesser of the useful life of the assets or the effective duration of the grant.

Major renewals and improvements are capitalized to the extent that they increase the useful economic life or increase the expected economic benefit of the underlying asset. Maintenance and repairs are charged to operations as incurred. When items of property, plant and equipment are sold or retired, the related cost and accumulated depreciation or amortization is removed from the accounts, and any gain or loss is included in operating expenses in the accompanying Statements of Operations and Comprehensive Loss.

**Impairment of Long-Lived Assets**

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If the estimated future cash flows (undiscounted and without interest charges) from the use of an asset are less than the carrying value, a write-down is recorded to reduce the related asset to its estimated fair value. To date, no such write-downs have occurred.

**Deferred Rent**

Rent expense is recognized on a straight-line basis over the life of the lease. The difference between rent expense recognized and rental payments, as stipulated in the lease, is reflected as deferred rent in the accompanying Balance Sheets and amortized over the life of the lease. In addition, deferred rent also includes landlord incentives on a portion of the leasehold improvement cost, which is amortized over the life of the lease.

**Revenue Recognition**

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("Topic 606"). The FASB issued Topic 606 to clarify the principles for recognizing revenue and to develop a common revenue standard for U.S. GAAP. The standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. Topic 606 also includes Subtopic 340-40, *Other Assets and Deferred Costs — Contracts with Customers*, which requires the deferral of incremental costs of obtaining a contract with a customer and certain contract fulfillment costs. The Company adopted this standard and all the related amendments ("new revenue standard") on January 1, 2018, applying the modified retrospective

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****2. Significant Accounting Policies (Continued)**

method. The modified retrospective transition method is applied on a prospective basis from the adoption date and does not recast historical financial statement periods. Any contracts with customers that were not complete as of the adoption date are reviewed and the Company recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of accumulated deficit as of January 1, 2018. Financial information in comparative periods have not been restated and continue to be reported under the accounting methods in effect for that period.

This adoption primarily affected the recognition of non-refundable up-front fees and milestone payments. The Company previously recognized non-refundable up-front fees as deferred revenue which was recognized into revenue on a straight-line basis over the estimated period of the Company's substantive performance obligations, as a component of a multiple element arrangement. Milestone payments were previously accounted for under Accounting Standards Codification ("ASC") 605-28-50-2(e), which had required recognition of a milestone payment when the applicable event was considered to be both substantive and achieved. The adoption of the new revenue standard generally requires licenses that are not considered distinct performance obligations from other goods or services within a contract to be bundled with those goods or services as a combined performance obligation. Revenue associated with the combined performance obligation is recognized over time as those goods or services are delivered.

The adoption of the new revenue standard also impacted the deferral of sublicense payments related to the milestone payments, which were previously expensed when the milestone payments were recognized, and the timing of recognition of deferred sublicense payments related to up-front license payments. Under the new revenue standard, the incremental sublicense payments related to milestone payments will be deferred as contract fulfillment costs and amortized over time, consistent with the method of recognition for the related revenues.

The cumulative effect of the changes made to the January 1, 2018 balance of accumulated deficit on the Balance Sheet for the adoption of Topic 606 was \$0.5 million as follows:

<b>Balance Sheet:</b>	<b>Balance at December 31, 2017</b>	<b>Adjustments Due to Topic 606</b>	<b>Balance at January 1, 2018</b>
<b>Assets</b>			
Prepaid expenses and other current assets	\$ 443,460	\$ 10,550	\$ 454,010
Prepaid expenses and other assets	1,115,972	45,529	1,161,501
<b>Liabilities</b>			
Current portion of deferred revenue	3,605,199	105,511	3,710,710
Long-term deferred revenue	5,527,296	455,295	5,982,591
<b>Stockholders' equity (deficit)</b>			
Accumulated deficit	(113,413,311)	(504,727)	(113,918,038)

## Liquidia Technologies, Inc.

## Notes to Financial Statements (Continued)

## 2. Significant Accounting Policies (Continued)

In accordance with the new revenue standard requirements, the impact of adoption on the Statement of Operations and Comprehensive Loss and Balance Sheet was as follows:

	For the Year ended December 31, 2018		
	As Reported	Balances Without Adoption of Topic 606	Effect of Change Higher/(Lower)
<b>Statement of Operations and Comprehensive Loss:</b>			
Revenues	\$ 2,706,981	\$ 5,436,630	\$ (2,729,649)
<b>Costs and expenses</b>			
Cost of sales	121,391	394,356	(272,965)
Net loss	(53,135,859)	(50,679,175)	2,456,684

	December 31, 2018		
	As Reported	Balances Without Adoption of Topic 606	Effect of Change Higher/(Lower)
<b>Balance Sheet:</b>			
<b>Assets</b>			
Prepaid expenses and other current assets	\$ 219,057	\$ 519,057	\$ (300,000)
Prepaid expenses and other assets	1,260,951	657,092	603,859
<b>Liabilities</b>			
Current portion of deferred revenue	—	3,000,000	(3,000,000)
Long-term deferred revenue	8,071,920	2,033,333	6,038,587
<b>Stockholders' equity (deficit)</b>			
Accumulated deficit	(167,053,897)	(164,319,169)	2,734,728

## Segment Data

Up until the fourth quarter of 2018, the Company managed, reported and evaluated its business in the following two segments: Pharmaceutical Products and Partnering and Licensing. These reportable operating segments were determined in accordance with the Company's internal management structure, which was organized based on operating activities, the manner in which the Company organized segments for making operating decisions and assessing performance and the availability of separate financial results.

In the fourth quarter of 2018, due to significantly diminished activities pursuant to collaborations, the Company changed the way it manages and operates the reporting entity and modified the Company's information system to produce financial information for the CODM to support the new structure. The changes required the Company to revise its segment reporting. Management reorganized its operations and reporting structure and began to manage its operations under its new segment structure, resulting in a

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**2. Significant Accounting Policies (Continued)**

single reportable segment. The financial statements were adjusted to reflect this change in segment reporting for all periods presented.

All long-lived assets are domiciled within the United States and all revenues were earned within the United States.

**Research and Development Expense**

Research and development costs are expensed as incurred and include direct costs incurred to third parties related to the salaries of, and stock-based compensation for, personnel involved in research and development activities, contractor fees, grant expenses, administrative expenses and allocations of research-related overhead costs. Administrative expenses and research-related overhead costs included in research and development expense consist of allocations of facility and equipment lease charges, depreciation and amortization of assets and insurance directly related to research and development activities.

**Patent Maintenance**

Liquidia is responsible for all patent costs, past and future, associated with the preparation, filing, prosecution, issuance, maintenance, enforcement and defense of United States patent applications. Such costs are recorded as general and administrative expenses as incurred. To the extent that the Company's licensees share these costs, such benefit is recorded as a reduction of the related expenses.

**Stock-Based Compensation**

The Company accounts for stock-based compensation under the provisions of ASC 718, *Compensation — Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including employee stock options, based on estimated fair values. ASC 718 requires companies to estimate the fair value of share-based awards on the grant date using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recorded as expense over the requisite service periods in the Company's Statements of Operations and Comprehensive Loss.

The Company accounts for equity instruments issued to nonemployees in accordance with the provisions of ASC 505 50, *Equity-Based Payments to Non-Employees*, under which the stock-based compensation expense is recognized in the financial statements based on their grant date fair values. The Company values equity instruments, stock options and warrants for common stock granted to lenders and consultants using the Black-Scholes option-pricing model. The measurement of non-employee stock-based compensation is recognized as an expense over the term of the related financing or the period over which services are received.

**Defined Contribution Retirement Plan**

The Company maintains a defined contribution 401(k) retirement plan for its employees, pursuant to which employees who have completed sixty days of service may elect to contribute a portion of their compensation on a tax-deferred basis up to the maximum amount permitted by the Internal Revenue Code, as amended. The Company provides a 4% matching contribution to eligible employee contributions. Matching contributions are made subsequent to the year to which they relate. The Company's matching contributions due were \$377,623 and \$365,988 and were included in Accrued Expenses in the accompanying Balance Sheets as of December 31, 2017 and 2018, respectively.

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****2. Significant Accounting Policies (Continued)****Net Loss Per Share**

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period.

Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares adjusted for the dilutive effect of common equivalent shares outstanding during the period. Common stock equivalents consist of preferred stock, stock options and stock warrants. Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's convertible preferred stock contains participating rights in any dividend paid by the Company and are deemed to be participating securities. Net loss attributable to common stockholders and participating preferred shares are allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in the losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss. Common equivalent shares are excluded from the computation in periods in which they have an anti-dilutive effect on net loss per share.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Diluted net loss per share is equivalent to basic net loss per share for all years presented herein because common stock equivalent shares from unexercised stock options, outstanding warrants, preferred stock and common shares expected to be issued under the Company's employee stock purchase plan were anti-dilutive. Due to their dilutive effect, the calculation of diluted net loss per share for the years ended December 31, 2017 and 2018 does not include the following common stock equivalent shares:

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	<u>2017</u>	<u>2018</u>
Preferred Stock	4,542,665	—
Stock Options	497,329	1,658,112
Warrants	279,281	170,925
Total	<u>5,319,275</u>	<u>1,829,037</u>

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For the year ended December 31, 2017, there were no reconciling items between basic and diluted net loss per share. For the year ended December 31, 2018 the only reconciling item between basic and diluted net loss per share is the impact of the common stock warrants that are included in the calculation of basic net loss per share since their exercise price is de minimis, but excluded from the calculation of diluted net loss per share since the impact of such warrants is antidilutive.

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****2. Significant Accounting Policies (Continued)****Fair Value of Financial Instruments**

The carrying values of cash, accounts receivable, and accounts payable at December 31, 2017 and 2018 approximated fair value due to the short maturity of these instruments.

The Company's valuation of financial instruments is based on a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities;

Level 2 — Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly; and

Level 3 — Unobservable inputs for the asset and liability used to measure fair value, to the extent that observable inputs are not available.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following tables present the placement in the fair value hierarchy of financial liabilities measured at fair value as of December 31, 2017 and 2018:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
<b>December 31, 2017</b>				
Pacific Western Bank Tranche I note — LSA	\$ —	\$ 2,512,301	\$ —	\$ 2,488,572
Pacific Western Bank Tranche II note — LSA	—	2,845,194	—	2,820,382
Pacific Western Bank Tranche III note — LSA	—	3,793,644	—	3,760,509
UNC Promissory Note	—	2,257,684	—	2,257,684
Convertible notes	—	—	28,702,268	9,837,984
Warrant liabilities	—	—	2,462,859	2,462,859
<b>Total</b>	<b>\$ —</b>	<b>\$ 11,408,823</b>	<b>\$ 31,165,127</b>	<b>\$ 23,627,990</b>

Liquidia Technologies, Inc.

Notes to Financial Statements (Continued)

2. Significant Accounting Policies (Continued)

December 31, 2018	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
Pacific Western Bank note — A&R LSA	\$ —	\$ 10,412,650	\$ —	\$ 10,802,355
CSC build-to-suit equipment financing	—	1,311,135	—	1,142,194
Total	<u>\$ —</u>	<u>\$ 11,723,785</u>	<u>\$ —</u>	<u>\$ 11,944,549</u>

The fair value of debt was measured as the present value of the respective future cash outflows discounted at a current interest rate as of the year-end date, taking into account the remaining term of liabilities.

**Convertible Instruments**

The Company has utilized various types of financing to fund its business needs, including convertible debt and convertible preferred stock, in some cases with corresponding warrants. The Company considered guidance within FASB ASC 470-20, *Debt with Conversion and Other Options*, ("ASC 470-20"), ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"), when accounting for the issuance of convertible securities. Additionally, the Company reviews the instruments to determine whether they are freestanding or contain an embedded derivative and, if so, whether they should be classified in permanent equity, mezzanine equity or as a liability at each reporting period until the amount is settled and reclassified into equity.

When multiple instruments are issued in a single transaction, the Company allocates total proceeds from the transaction among the individual freestanding instruments identified. The allocation is made after identifying all the freestanding instruments and the subsequent measurement basis for those instruments. The subsequent measurement basis determines how the proceeds are allocated. Generally, proceeds are allocated based on one of the following methods:

- § Fair value method — The instrument being analyzed is allocated a portion of the proceeds equal to its fair value, with the remaining proceeds allocated to the other instruments as appropriate.
- § Relative fair value method — The instrument being analyzed is allocated a portion of the proceeds based on the proportion of its fair value to the sum of the fair values of all the instruments covered in the allocation.
- § Residual value method — The instrument being analyzed is allocated the remaining proceeds after an allocation is made to all other instruments covered in the allocation.

Generally, when there are multiple instruments issued in a single transaction that have different subsequent measurement bases, the proceeds from the transaction are first allocated to the instrument that is subsequently measured at fair value (i.e., instruments accounted for as derivative liabilities) at its issuance date fair value, with the residual proceeds allocated to the instrument not subsequently measured at fair value. In the event both instruments in the transaction are not subsequently measured at fair value (i.e., equity-classified instruments), the proceeds from the transaction are allocated to the freestanding instruments based on their respective fair values, using the relative fair value method.

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**2. Significant Accounting Policies (Continued)**

After the proceeds are allocated to the freestanding instruments, resulting in an initial discount on the host contract, those instruments are further evaluated for embedded features (i.e., conversion options) that require bifurcation and separate accounting as a derivative financial instrument pursuant to ASC 815. Embedded derivatives are initially and subsequently measured at fair value. Under ASC 815, a portion of the proceeds received upon the issuance of the hybrid contract is allocated to the fair value of the derivative.

The Company accounts for convertible instruments in which it is determined that the embedded conversion options should not be bifurcated from their host instruments in accordance with ASC 470-20. Under ASC 470-20, the Company records, when necessary, discounts to convertible notes or convertible preferred stock for the intrinsic value of conversion options embedded in the convertible instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the transaction and the effective conversion price embedded in the convertible instrument, unless limited by the proceeds allocated to such instrument.

**Warrant Liabilities**

The Company has classified warrants to purchase shares of preferred stock as liabilities on its Balance Sheets as these warrants were freestanding financial instruments that will require the Company to issue convertible securities upon exercise. The warrants were initially recorded at fair value on date of grant, and were subsequently remeasured to fair value at each reporting period. Changes in fair value of the warrants are recognized as a component of other income (expense) in the Statements of Operations and Comprehensive Loss. In conjunction with the Company's IPO, the warrants were converted to warrants for common stock. Following that conversion, these warrants no longer meet the criteria to be presented as a liability and have been reclassified to additional paid-in capital. The Company will no longer include the warrants as liabilities or recognize changes in their fair value on the Statements of Operations and Comprehensive Loss.

The Company used the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the preferred stock warrants. The Company assessed these assumptions and estimates on a quarterly basis as additional information impacting the assumptions was obtained. Estimates and assumptions impacting the fair value measurement included the fair value per share of the underlying preferred stock, the remaining contractual term of the warrant, the risk-free interest rate, the expected dividend yield and the expected volatility of the price of the underlying preferred stock. The Company determined the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of its convertible preferred stock, results obtained from third-party valuations and additional factors that were deemed relevant. The Company estimated its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. Expected dividend yield was based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**2. Significant Accounting Policies (Continued)**

**Embedded Derivatives**

Embedded derivatives that are required to be bifurcated from the underlying instrument are accounted for and valued as a separate financial instrument. In conjunction with the Company's convertible notes (see Note 11), embedded derivatives exist associated with the future consummation of a qualified financing event, as defined in the notes, and a subsequent discounted conversion of the instrument to capital stock. The embedded derivatives were bifurcated and classified as derivative liabilities on the Balance Sheets and separately adjusted to their fair values at the end of each reporting period. Changes in fair values of the derivative liabilities are recognized as a component of other income (expense) in the Statements of Operations and Comprehensive Loss. These embedded derivatives were eliminated upon conversion of the underlying convertible notes into Series D preferred stock, \$0.001 par value per share ("Series D") (see Note 3).

**Issuance Costs Related to Equity and Debt**

The Company allocates issuance costs between the individual freestanding instruments identified on the same basis as proceeds were allocated. Issuance costs associated with the issuance of stock or equity contracts (i.e., equity-classified warrants and convertible preferred stock) are recorded as a charge against the gross proceeds of the offering. Any issuance costs associated with the issuance of liability-classified warrants are expensed as incurred. Issuance costs associated with the issuance of debt (i.e., convertible debt) is recorded as a direct reduction of the carrying amount of the debt liability, but limited to the notional value of the debt. The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount to interest expense using the straight-line method over the expected term of the notes pursuant to ASC 835, *Interest* ("ASC 835"). To the extent that the reduction from issuance costs of the carrying amount of the debt liability would reduce the carrying amount below zero, such excess is recorded as interest expense.

**Deferred Offering Costs**

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such equity financings are consummated. After consummation of the equity financing, these costs were recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. As of December 31, 2017 and 2018 the Company recorded deferred offering costs relating to its financing activities of \$125,000 and \$110,365, respectively, which is included in Prepaid Expenses and Other Assets in the accompanying Balance Sheets.

**Income Taxes**

The asset and liability method is used in the Company's accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company records a valuation allowance against deferred tax assets when realization of the tax benefit is uncertain.

A valuation allowance is recorded, if necessary, to reduce net deferred taxes to their realizable values if management does not believe it is more likely than not that the net deferred tax assets will be realized.

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**2. Significant Accounting Policies (Continued)**

The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was enacted into law. This new law 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 revenues 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. The Company calculated its best estimate of the impact of the TCJA in its income tax provision for the year ended December 31, 2017 in accordance with its 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. Using the guidance issued by the SEC staff in Staff Accounting Bulletin No. 118, the Company completed its accounting for the TCJA during the fourth quarter of 2018. No changes to the provisional amounts as of December 31, 2017 were recorded.

**Recent Accounting Pronouncements**

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10) — Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). The provisions of ASU 2016-01 make targeted improvements to enhance the reporting model for financial instruments to provide users of financial statements with more useful information, including certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The guidance was effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2017, and will be effective for the Company for the year ending December 31, 2018. The Company adopted this standard effective January 1, 2018 and the adoption of this standard did not have a material impact on the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). The provisions of ASU 2016-02 set out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for in a similar manner as under existing guidance for operating leases. ASU 2016-02 supersedes the previous lease standard, Topic 840, *Leases*. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2018, and will be effective for the Company for the year ending December 31, 2019. The Company's implementation efforts are ongoing, including the installation of an enhanced technology solution, which will aid in determining the magnitude of the increases in assets and liabilities and their impact on the financial statements. The Company expects

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**2. Significant Accounting Policies (Continued)**

to recognize lease liabilities and corresponding right-of-use assets related to predominantly all of the future minimum lease payments required under all leases as disclosed in Note 10 in addition to the CSC build-to-suite equipment financing disclosed in Note 11. Upon implementation, the balance sheet effects of the new lease accounting standard will also impact other measures which are dependent upon asset or liability balances. The Company expects the impact of this implementation to be material to the financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) — Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). The provisions of ASU 2016-15 address eight specific cash flow issues and how those certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, *Statement of Cash Flows*, and other Topics. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018 and the adoption of this standard did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018 and the adoption of this standard did not have a material impact on the Company's financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this update addresses the complexity of accounting for certain financial instruments with "down round" features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, *Distinguishing Liabilities from Equity*, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is evaluating the effect that ASU 2017-11 will have on its financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)* ("ASU 2018-13"). The provisions of ASU 2018-13 set out modifications to the disclosure requirements regarding fair value measurements. The modifications removed certain disclosure requirements regarding transfers between levels of the fair value hierarchy and valuation processes for Level 3 fair value measurements. In addition,

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**2. Significant Accounting Policies (Continued)**

the modifications added requirements to disclose changes in unrealized gains and losses for recurring Level 3 fair value measurements and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2019, and will be effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's financial statements.

In October 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements* (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 ("ASU 2018-17"). The provisions of ASU 2018-18 clarify when certain transactions between collaborative arrangement participants should be accounted for under ASC 606 and incorporates unit-of-account guidance consistent with ASC 606 to aid in this determination. The guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2019, with early adoption permitted, and is effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's financial statements.

**3. Common and Preferred Stock**

**Authorized Capital**

As of December 31, 2018, in conjunction with the IPO and the reverse stock split, the authorized capital of the Company was decreased to consist of 50,000,000 shares of capital stock, \$0.001 par value per share, of which 40,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock.

As of December 31, 2018 the Company had reserved a total of 422,640 shares of common stock for issuance under the Liquidia Technologies, Inc. Stock Option Plan, as amended (the "2004 Plan"), 1,011,138 shares of common stock for issuance under the Liquidia Technologies, Inc. 2016 Equity Incentive Plan, as amended (the "2016 Plan"), and 1,600,000 shares of common stock for issuance under the Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan (the "2018 Plan").

During 2017, the Company issued an aggregate of \$27.4 million in principal of convertible promissory notes (see Note 11). The convertible notes had an original maturity date of December 31, 2018, as amended, and bore interest at eight percent (8%) per annum. Interest was earned daily and computed on the actual number of days elapsed until all the amounts under the notes have been paid in full. The convertible notes carried multiple conversion scenarios into equity with various discounts.

In February 2018, the Company received proceeds of \$25.6 million in exchange for the corresponding sale of Series D and related rights offering to new and existing investors. The applicable issue price per share for the Series D was \$0.59808, subject to adjustment as provided in the certificate of incorporation. In addition, all outstanding convertible notes, plus accrued interest, totaling \$28.9 million were converted into Series D at the same price per share without a discount. Outstanding warrants to purchase shares of Series C-1 preferred stock, \$0.001 par value per share ("Series C-1"), were converted to warrants to purchase the equivalent number of shares of Series D. All references herein to these warrants refer to them as warrants to purchase Series D. In total, 91,147,482 shares of Series D were issued. Each share of Series D was voting and was convertible at any time into a share of common stock with such conversion ratio subject to future adjustment. Conversion was automatic upon a qualified financing, as defined in the

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**3. Common and Preferred Stock (Continued)**

certificate of incorporation. Each series of preferred stock had anti-dilution protection in the event of a dilutive issuance, as defined in the certificate of incorporation. The Series D bore an 8% per annum noncumulative dividend (\$0.0478 per share of Series D) when and if declared. The Series D had a liquidation preference equal to the aggregate of the proceeds and the note conversions, or \$54.5 million plus accrued but unpaid dividends, after which holders of Series D participate with all other stockholders in the remainder of liquidation proceeds on an as converted basis. The Series D was senior to all other series of preferred stock.

In the third quarter of 2018, the Company closed the initial public offering of 4,833,099 shares of common stock, including the underwriters' partial exercise of their over-allotment option in connection therewith, which resulted in aggregate net proceeds of \$47.3 million, after underwriting discounts and the payment of other offering expenses.

In conjunction with the Company's IPO, all outstanding shares of convertible preferred stock were converted into an aggregate of 9,948,207 shares of common stock.

**Common Stock**

Upon any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company, the holders of the common stock shall be entitled to receive that portion of the remaining funds to be distributed to the stockholders, subject to the liquidation preferences of any outstanding preferred stock, if any. Such funds shall be paid to the holders of common stock on the basis of the number of shares so held by each of them.

The Class B non-voting common stock, \$0.001 par value per share, was converted into shares of voting common stock in conjunction with the Company's IPO.

**Warrants**

In connection with historical private placement offerings, the Company issued warrants to purchase its preferred stock with an exercise term of ten years from the date of issuance. Pursuant to the terms of the warrants, upon the conversion of the preferred stock underlying the warrant into common stock, the warrants automatically become exercisable for common stock-based upon the conversion ratio of the underlying preferred stock.

As of December 31, 2017, there were outstanding warrants for 123,215 shares of Series B that were convertible into warrants for 14,663 shares of common stock at the same time as all outstanding shares of Series B were converted to common stock. These Series B warrants had an exercise price of \$3.56 per share and expired on March 28, 2018.

Upon closing of the Series D financing, the Company had warrants outstanding to purchase 3,698,128 shares of Series D. In conjunction with the IPO, these warrants were automatically converted into warrants to purchase 219,761 shares of common stock. During the year ended December 31, 2018, 48,836 warrants were exercised resulting in 170,925 warrants outstanding as of December 31, 2018. The exercise price of these warrants is \$0.0168 per share.

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****4. Stock Options**

In November 2004, the Board of Directors adopted, and the stockholders approved, the 2004 Plan to create an additional incentive for employees, directors, consultants and advisors. The 2004 Plan authorized the issuance of stock options to be granted as incentive stock options along with nonqualified stock options, restricted stock and other stock-based awards. The Board of Directors determines the exercise price of all options granted. The options vest based on terms provided for in the individual stock option agreements issued pursuant to the 2004 Plan. Options generally vest on a monthly basis over a period of up to 4 years and have a contractual life of ten years. The 2016 Plan is the successor to the 2004 Plan. The terms of the 2016 Plan are similar to the 2004 Plan. The 2016 Plan provides for accelerated vesting under certain change of control transactions.

On July 19, 2018, in conjunction with the Company's IPO, the stockholders approved the 2018 Plan. A total of 1,600,000 shares of the Company's common stock was initially authorized and reserved for issuance under the 2018 Plan. This reserve will automatically increase on January 1, 2019 and each subsequent anniversary through 2028, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the Board of Directors. In addition to stock options, the 2018 Plan provides for the granting of stock appreciation rights, stock awards, stock units, and other stock-based awards. The 2018 Plan provides for accelerated vesting under certain change of control transactions.

Determining the appropriate fair value model and the related assumptions requires judgment. The fair value of each option grant is estimated using a Black-Scholes option-pricing model. The following table summarizes the assumptions used for estimating the fair value of stock options granted during:

	Year ended December 31,	
	2017	2018
Expected dividend yield	—%	—%
Risk-free interest rate	1.34% - 1.99%	2.67% - 3.01%
Volatility	69% - 100%	78% - 99%
Expected life	6.25 years	6.25 years
Weighted-average fair value per share	\$13.97	\$7.25

The Company considers many factors when estimating expected forfeitures, including the employee or consultant class and historical experience. The Company estimates volatility based upon the identification of similar public entities for which option price information is available to consider the historical, expected or implied volatility of those entities' share prices in estimating the Company's expected volatility. The expected term of options and warrants granted represents the period that options and warrants granted are expected to be outstanding. The risk-free interest rate for periods within the contractual life of the option and warrant is based on the yield of the U.S. Treasury securities at the time of grant. The Company amortizes the fair value, net of estimated forfeitures, over the remaining vesting term on a straight-line basis.

Liquidia Technologies, Inc.

Notes to Financial Statements (Continued)

4. Stock Options (Continued)

The following table summarizes stock option activity under the 2004 Plan, the 2016 Plan, and the 2018 Plan:

	Shares Available for Issuance	Options Outstanding	Weighted Average Exercise Price
<b>Outstanding at December 31, 2016</b>	45,275	728,344	\$ 4.38
Shares reserved for future issuance	—	—	\$ —
Granted	(14,083)	14,083	\$ 20.36
Exercised	—	(15,169)	\$ 5.72
Cancelled/expired	—	(58,942)	\$ 2.19
<b>Outstanding at December 31, 2017</b>	31,192	668,316	\$ 4.54
Removal of partial options resulting from reverse split	—	(323)	—
Shares reserved for future issuance for 2016 Plan	979,446	—	—
Shares reserved for future issuance for 2018 Plan	1,600,000	—	—
Options granted	(1,231,541)	1,231,541	\$ 10.22
RSU's granted	(185,768)	—	\$ 11.04
Exercised	—	(119,793)	\$ 4.15
Cancelled/expired from 2004 Plan	—	(70,298)	\$ 7.39
Cancelled/expired from 2016 Plan	—	(51,331)	\$ 8.68
<b>Outstanding at December 31, 2018</b>	<u>1,193,329</u>	<u>1,658,112</u>	\$ 8.76

The following summarizes certain information about stock options vested and expected to vest as of December 31, 2018:

	Number of Options	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price
Outstanding and expected to vest	1,442,803	8.09	\$ 8.49
Vested and exercisable	408,693	5.36	\$ 4.62

The weighted-average grant date price per share was \$20.36 and \$10.22 and per share for the shares issued during the years ended December 31, 2017 and 2018, respectively.

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**4. Stock Options (Continued)**

During the year ended December 31, 2018, 119,793 stock options were exercised for the purchase of common stock for total cash proceeds of \$334,711. The intrinsic value for the options exercised was \$2,097,888.

As of December 31, 2018, the intrinsic value of options outstanding and exercisable was \$21,397,470. The weighted average remaining contractual term of options outstanding and exercisable is 8.25 years as of December 31, 2018.

During the years ended December 31, 2017 and 2018, stock-based compensation expense for employee stock option awards totaled \$514,092 and \$2,195,075, respectively. As of December 31, 2018, there was \$7,547,104 of total unrecognized compensation cost related to non-vested stock option grants, which is expected to be recognized over a weighted average period of 2.99 years.

During 2018, the Board of Directors approved grants of 185,768 non-performance based restricted stock units ("RSUs"). The weighted average fair value of such RSUs was \$11.04 per share for the year ended December 31, 2018. RSUs represent the right to receive shares of common stock of the Company at the end of a specified time period. The RSUs vest over a four-year period similar to stock options. RSUs can only be settled in shares of the Company's common stock. The Company also estimates forfeitures on RSUs and considers many factors when doing so, including the employee or consultant class and historical experience. RSUs are valued at the date of grant and recognized in compensation expense, net of estimated forfeitures, over the vesting period.

On February 6, 2019, the Board of Directors approved stock option grants to various employees in the aggregate amount of 395,408 shares of common stock underlying such grants, with an exercise price of \$14.20 per share. In addition, on January 1, 2019, the number of shares of common stock available for issuance under the 2018 Plan automatically increased from 1,600,000 to 2,220,778 pursuant to the evergreen provision contained in the 2018 Plan.

**Stock Option Modification**

During the year ended December 31, 2018, certain stock options were modified pursuant to a separation agreement with one of the Company's former Senior Vice Presidents. A total of 20,383 options had their term extended to include the term of the post separation consulting agreement of up to two months, resulting in additional stock option expense of \$17,497 for the year ended December 31, 2018.

**5. License Agreements**

Liquidia performs research under a license agreement with The University of North Carolina at Chapel Hill ("UNC") as amended to date (the "UNC Letter Agreement"). As part of the UNC Letter Agreement, Liquidia holds an exclusive license to certain research and development technologies and processes in various stages of patent pursuit, for use in its research and development and commercial activities, with a term until the expiration date of the last to expire patent subject to the UNC Letter Agreement, subject to industry standard diligence compliance. Under the UNC Letter Agreement, Liquidia is obligated to pay UNC royalties equal to a low single-digit percentage of all net sales of Liquidia drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC Letter Agreement. Liquidia may grant sublicenses of UNC licensed intellectual property in return for specified payments based on a percentage of any fee, royalty or other consideration received.

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**5. License Agreements (Continued)**

In connection with the development and collaboration agreements (see Note 6) entered into with GSK in June 2012, Liquidia paid sublicense fees to UNC and amortized each into research and development expense over the period of specific performance with GSK. Also, in connection with that sublicense fee, Liquidia agreed to issue \$1.2 million of Series C-1 preferred shares to UNC under the same terms provided to other Series C-1 holders and an unsecured promissory note for \$0.6 million. Refer to Note 11 for additional details on the unsecured promissory note.

In 2012 and 2015, GSK Vaccines and GSK Inhaled made up-front payments to the Company of \$14.0 million and \$20.0 million combined, respectively. On such payments, the Company incurred sublicense fees to UNC of \$2.8 million and \$2.5 million, respectively, which were amortized into Cost of Sales in the accompanying Statements of Operations and Comprehensive Loss on a straight-line basis over the corresponding periods of revenue recognition of the related payments.

In June 2016, Liquidia entered into an amendment to the UNC Letter Agreement, whereby the date for completion of a milestone requiring launch of a commercial product was extended from January 1, 2018 to December 31, 2020. In addition, a 2016 letter agreement was accepted by UNC that detailed Liquidia's efforts in satisfying the obligations of two milestones related to developing and commercializing the licensed technology under the UNC Letter Agreement as of December 31, 2015, and accepted such efforts as satisfying the two milestones dated January 1, 2016. The 2016 letter agreement also included extending the maturity date of the promissory note (see Note 11) to December 31, 2017 and payment of an additional \$1.5 million fee in exchange for modifying these progress milestones required under the UNC Letter Agreement. In December 2017, the Company executed an amendment to the UNC Letter Agreement that extended the maturity date of the promissory note from December 31, 2017 to June 30, 2018. In June 2018, the Company executed an amendment to the UNC Promissory Note that extended the maturity date of the promissory note from June 30, 2018 to December 31, 2018 with the potential for acceleration depending on the proceeds of the IPO. The UNC Letter Agreement was repaid in full and extinguished in 2018 (see Note 11).

**6. Revenue From Contracts With Customers**

The Company derives revenues primarily from licensing its proprietary PRINT technology and from performing research and development services. Revenues are recognized as services are performed in an amount that reflects the consideration we expect to be entitled to in exchange for those services and technology.

In September 2015, GSK Inhaled exercised the option to permanently license the technology for a non-refundable payment to the Company of \$15.0 million. Pursuant to the license provisions of the collaboration agreement, GSK Inhaled is potentially required to pay Liquidia for certain milestones reached in addition to tiered royalties on the worldwide sales of the licensed products at percentages ranging from the mid-single digits to low-single digits depending on the total number of products developed and other royalty step-down events with a fixed low-single digit royalty floor. On July 20, 2018, GSK notified the Company of its plans to discontinue development of the inhaled antiviral for viral exacerbations in chronic obstructive pulmonary disease under the GSK Inhaled collaboration agreement after completion of the related Phase 1 clinical trial. The result of this change will likely be a delay in resumption of research services from when previously estimated but no change in estimate with regard to estimated progress under the collaboration. Therefore, there was no impact on the financial statements for the year ended December 31, 2018.

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**6. Revenue From Contracts With Customers (Continued)**

In June 2016, the Company entered into a development and license agreement with G&W Laboratories ("G&W") to develop multiple products for topical delivery in dermatology using the Company's PRINT technology (the "G&W Agreement"). The first non-refundable up-front fee of \$1.0 million was received in June 2016. Research and development services commenced in July 2016 on the first program pursuant to this agreement. In April 2018, the Company and G&W mutually agreed to terminate the G&W Agreement. As a result, during the second quarter of 2018, the remaining unamortized balances in the related deferred revenue and deferred sublicense payments of \$0.9 million and \$0.1 million, respectively, were fully recorded as Revenues and Cost of Sales, respectively, in the accompanying Statement of Operations and Comprehensive Loss for the year ended December 31, 2018.

The Company's research, development and licensing agreements provide for multiple promised goods and services to be satisfied by the Company and include a license to the Company's technology in a particular field of study, participation in collaboration committees, performance of certain research and development services and obligations for certain manufacturing services. The transaction price for these contracts includes non-refundable fees and fees for research and development services. Non-refundable up-front fees which may include, for example, an initial payment upon effectiveness of the contractual relationship or payment to secure a right for a future license, are recorded as deferred revenue and recognized into revenue over time as the Company provides the research services under the contract required to advance the products to the point where the Company is able to transfer control of the licensed technology to the customer ("Technology Transfer"). The contract consideration may also include additional non-refundable payments due to the Company based on the achievement of research, development, regulatory or commercialization milestone events. In agreements involving multiple goods or services promised to be transferred to customers, the Company must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation. As these goods and services are considered to be highly interrelated, they were considered to represent a single, combined performance obligation. The Company includes an estimate of the probable amount of milestone payments to which it will be entitled in the transaction price. The estimate requires evaluation of factors which are outside of the Company's control and significantly limit the Company's ability to achieve the remaining milestone payments. Therefore, the Company has not included any future milestone payments in the transaction price allocated to research, development and licensing agreements as of December 31, 2018. The Company revises the transaction price to include milestone payments once the specific milestone achievement is not considered to be subject to a significant reversal of revenue. At that time, the estimated transaction price is adjusted and a cumulative catch-up adjustment is recorded to adjust the amount of revenue to be recognized from the license inception to the date the milestone was deemed probable of achievement. The milestone is included with other non-refundable up-front fees and recognized into revenue over time as the Company continues to provide services under the contract prior to the Company's Technology Transfer. The amount of revenue recognized is based on the proportion of total research services performed to date to the expected services to be provided until Technology Transfer is expected to occur.

The estimate of the research services to be provided prior to the Technology Transfer requires significant judgment to evaluate assumptions regarding the level of effort required for the Company to have performed sufficient obligations for the customer to be able to utilize the licensed technology without requiring further services from the Company. If the estimated level of effort changes, the remaining deferred revenue is recognized over the revised period in which the expected research services required to achieve Technology Transfer. Changes in estimates occur for a variety of reasons, including but not limited to (i) research and

## Liquidia Technologies, Inc.

## Notes to Financial Statements (Continued)

## 6. Revenue From Contracts With Customers (Continued)

development acceleration or delays, (ii) customer prioritization of research projects, or (iii) results of research and development activities. The Company recognizes the consideration expected to be received for research and development services, which are primarily billed quarterly in arrears on a time and materials basis, as the services are performed and collection is reasonably assured.

Royalties related to product sales will be recognized as revenue when the sale occurs since payments relate directly to products that will have been fully developed and for which the Company will have satisfied all of its performance obligations.

The following tables represent a disaggregation of revenue by each significant research, development and licensing agreement and payment type for the years ended December 31, 2017 and 2018:

	2017 Revenue Recognized From			
	Non-Refundable Payments			
	Milestones	Up-front Payments	Research and Development Services	Total
<b>Under Topic 605</b>				
GSK Inhaled	\$ —	\$ 3,000,000	\$ 3,114,311	\$ 6,114,311
Other	—	343,216	800,596	1,143,812
<b>Total</b>	<b>\$ —</b>	<b>\$ 3,343,216</b>	<b>\$ 3,914,907</b>	<b>\$ 7,258,123</b>

	2018 Revenue Recognized From			
	Non-Refundable Payments			
	Milestones	Up-front Payments	Research and Development Services	Total
<b>Under Topic 606</b>				
GSK Inhaled	\$ 45,058	\$ 225,293	\$ 168,000	\$ 438,351
Other	—	943,419	1,325,211	2,268,630
<b>Total</b>	<b>\$ 45,058</b>	<b>\$ 1,168,712</b>	<b>\$ 1,493,211</b>	<b>\$ 2,706,981</b>

## Deferred Revenue

The Company recognized \$3.3 million of revenue during the year ended December 31, 2017 under ASC 605, and \$1.2 million of revenue from non-refundable payments under Topic 606 during the year ended December 31, 2018, which was included in deferred revenue balances at the beginning of these respective periods.

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****6. Revenue From Contracts With Customers (Continued)****Transaction Price Allocated to the Remaining Performance Obligations**

In December 2017, the Company was made aware of delays and reduced requirements and budget for support for its GSK and G&W Laboratories collaborators and revised its estimate of the remaining estimated period of the performance obligations. As a result, approximately \$3.0 million of deferred revenue previously considered current was reclassified to long-term deferred revenue as it was not expected to be recognized within 12 months. As of December 31, 2018, approximately \$8.0 million of revenue is expected to be recognized from remaining performance obligations for non-refundable payments. The Company expects to recognize revenue on approximately 0%, 3% and 11% of these remaining performance obligations in 2019, 2020 and 2021 respectively, with the balance recognized thereafter. Revenue from remaining performance obligations for research and development services as of December 31, 2018 was not material.

**Deferred Sublicense Payments**

Sublicense payments to UNC are considered direct and incremental fulfillment costs of the Company's research, development and licensing agreements as the PRINT technology resources used by the Company are continually researched by UNC. These costs are deferred and then amortized into Cost of Sales over the same estimated period of benefit as the period of the underlying revenue recognition. As of December 31, 2017, the balances of these unamortized payments under ASC 605 included in current and long-term prepaid expenses and other assets was \$319,758 and \$552,730, respectively. As of December 31, 2018, the balances of these unamortized payments included in current and long-term prepaid expenses and other assets was \$0 and \$807,192, respectively.

**7. Property, Plant and Equipment**

Property, plant and equipment consisted of the following:

	2017	2018
Lab and build-to-suit equipment	\$ 3,847,546	\$ 6,123,194
Grant equipment	1,143,701	1,143,701
Office equipment	123,655	130,460
Furniture and fixtures	205,051	205,051
Computer equipment	677,569	799,515
Leasehold improvements	7,218,687	8,878,361
Construction-in-progress	2,830,407	155,148
Total property, plant and equipment	16,046,616	17,435,430
Accumulated depreciation	(7,803,604)	(9,304,722)
Property, plant and equipment, net	<u>\$ 8,243,012</u>	<u>\$ 8,130,708</u>

The Company recorded depreciation expense of \$931,931 and \$1,543,667 for the years ended December 31, 2017 and 2018, respectively. Maintenance and repairs are expensed as incurred and were \$244,885 and \$153,278, respectively, for the years ended December 31, 2017 and 2018.

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**7. Property, Plant and Equipment (Continued)**

In December 2016, the Company executed an agreement with a commercial manufacturer to build a PRINT particle fabrication line for the production in support of its products. The ultimate cost was approximately \$1.6 million. The Company financed this transaction with a third-party vendor, CSC Leasing Company ("CSC"). CSC made payments to the manufacturer per the payment schedule in the agreement as the asset was fabricated. CSC charged the Company a monthly lease rate on the scheduled payments made to the manufacturer as interim financing costs until the asset was completed and placed in service. Upon completion of fabrication, the lease commenced on March 1, 2018.

In accordance with ASC 840, *Leases*, for build-to-suit arrangements where the Company is involved in the fabrication of an asset prior to the commencement of the ultimate financing or takes some level of construction risk, the Company is considered the accounting owner of the assets during the fabrication period. Accordingly, during the fabrication phase, the Company recorded a construction-in-progress asset within Property, Plant and Equipment and a corresponding deferred financing obligation liability for contributions by CSC toward fabrication. Upon completion of the fabrication in March 2018, since the Company maintained substantially all of the risk and rewards of ownership of the asset, the Company recorded the transaction as a financing, continuing to record the asset and reclassifying the deferred financing obligation to debt. As of December 31, 2017, \$1,341,810 was recorded in construction-in-progress with an equal deferred financing obligation. As of December 31, 2018, the net book value of the build-to-suit asset was \$1,422,268 and \$1,142,194 was also recorded as long-term debt (see Note 11).

The following table details the activity of Construction in Progress ("CIP") in 2017 and 2018 and and the associated transfer to Leasehold Improvements and Lab Equipment when the assets were placed in service:

	Leasehold Improvements	Build-to-suit Equipment	Lab Equipment	Total
<b>Balance as of December 31, 2016</b>	\$ 337,255	\$ —	\$ —	\$ 337,255
Add: Purchases related to CIP	2,298,714	1,583,054	39,246	3,921,014
Less: Transfer due to placed in service	(1,427,862)	—	—	(1,427,862)
<b>Balance as of December 31, 2017</b>	1,208,107	1,583,054	39,246	2,830,407
Add: Purchases related to CIP	425,438	82,687	114,102	622,227
Less: Transfer due to placed in service	(1,570,194)	(1,665,741)	(61,551)	(3,297,486)
<b>Balance as of December 31, 2018</b>	\$ 63,351	\$ —	\$ 91,797	\$ 155,148

The Construction in Progress balance includes \$57,625 and \$3,925 of capitalized interest costs for the years ended December 31, 2017 and 2018, respectively.

**8. Income Taxes**

No provision for federal and state income tax expense has been recorded for the years ended December 31, 2017 and 2018 due to the valuation allowance recorded against the net deferred tax asset and recurring losses.

## Liquidia Technologies, Inc.

## Notes to Financial Statements (Continued)

## 8. Income Taxes (Continued)

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows at December 31, 2017 and 2018:

	2017	2018
Non-current deferred income tax assets:		
Tax loss carryforwards	\$ 22,274,378	\$ 30,239,898
Deferred revenue	2,098,191	1,856,507
Research and development credits	2,382,047	2,382,047
Stock-based compensation	277,948	489,694
Bad debt	11,053	—
Compensation	9,766	431,649
Fixed assets	63,570	160,784
Patent amortization	106,622	97,942
Other	768,936	669,151
Valuation allowance	(27,992,511)	(36,327,672)
Total non-current deferred income tax assets	\$ —	\$ —

At December 31, 2017 and 2018, the Company established a full valuation allowance against its net deferred tax assets since, at the time, the Company could not assert that it was more likely than not that its deferred tax assets would be realized. As a result, there was an increase in the valuation allowance in 2018 of \$8,335,161.

At December 31, 2018, the Company had federal and state income tax loss carryforwards of \$97,268,927 and \$132,387,480, respectively, which begin to expire in 2024 for federal purposes and in 2019 for state purposes. At December 31, 2018, the Company had federal and state income tax loss carryforwards of \$34,183,499 and \$293,910, respectively, which carryforward indefinitely. In addition, the Company has tax credit carryforwards for federal tax purposes of \$2,382,047 as of December 31, 2018, which begin to expire in 2026. The utilization of the net operating loss and tax credit carryforwards to reduce future income taxes will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the loss and credit carryforwards.

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was enacted into law. This new law 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 revenues 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. The Company calculated its best estimate of the impact of the TCJA in its income tax provision for the year ended December 31, 2017 in accordance with its understanding of the

Liquidia Technologies, Inc.

Notes to Financial Statements (Continued)

8. Income Taxes (Continued)

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. The Company completed its accounting for the TCJA during the fourth quarter of 2018. No changes to the provisional amounts as of December 31, 2017 were recorded.

The Internal Revenue Code of 1986, as amended, contains provisions which limit the ability to utilize the net operating loss and tax credit carryforwards in the case of certain events, including significant changes in ownership interests. If the Company's net operating loss and tax credit carryforwards are limited, and the Company has taxable income which exceeds the permissible yearly net operating loss and tax credit carryforwards, the Company would incur a federal income tax liability even though net operating loss and tax credit carryforwards would be available in future years.

The reasons for the difference between actual income tax expense for the years ended December 31, 2017 and 2018 and the amount computed by applying the statutory federal income tax rate to income before income tax are as follows:

	2017		2018	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate	\$ (9,912,442)	34.0%	\$ (11,158,530)	21.0%
State income taxes, net of federal tax benefit	(581,901)	2.0%	(1,062,492)	2.0
Non-deductible expenses	12,757	(0.1)%	6,810	—
Stock-based compensation	153,033	(0.5)%	10,925	—
Non-deductible interest expense	3,795,060	(13.0)%	4,074,501	(7.7)
Derivative and warrant fair value adjustments	(4,040,646)	13.9%	(63,873)	0.1
Change in federal rate	14,113,550	(48.4)%	—	—
Change in state rate	371,138	(1.3)%	(2,842)	—
Other	24,235	(0.1)%	(139,660)	0.3
Change in valuation allowance	(3,934,784)	13.5%	8,335,161	(15.7)
Provision for income taxes	\$ —	0.0%	\$ —	0.0%

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. As of December 31, 2018, the Company had no unrecognized tax benefits. The Company's policy for recording interest and penalties related to uncertain tax provisions is to record them as a component of the provision for income taxes. The Company did not have any accrued interest or penalties associated with any unrecognized tax positions as of December 31, 2017 and 2018, and there were no such interest or penalties recognized during the years ended December 31, 2017 and 2018.

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

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**9. Related-Party Transactions**

In 2016 the Company's Chief Executive Officer entered into a loan agreement with the Company to finance the exercise of stock options to purchase 29,713 shares of common stock for \$94,271, which loan bore interest at 1.00% per annum. The balance of the note receivable at the beginning of 2017 was \$55,000, which was repaid in full in 2017.

For shared services provided by Liquidia to Envisia, Liquidia recorded \$105,623 and \$0, respectively, for sharing of patent costs as a reduction of Research and Development Expenses in the accompanying Statements of Operations and Comprehensive Loss for the years ended December 31, 2017 and 2018, respectively. In March 2017, the license related to the Otic field, along with other intellectual property rights, as defined, was purchased back by the Company from Envisia in exchange for 75,000 shares of its Envisia common stock.

**10. Commitments and Contingencies**

**Operating Leases**

The Company conducts its operations from leased facilities in Morrisville, North Carolina, the leases for which expire in 2026. The leases are for general office, laboratory, research and development and light manufacturing space. The lease agreements require the Company to pay property taxes, insurance, common area expenses and maintenance costs.

In November 2014 and November 2015, the Company executed the first and second extension period clauses, respectively, resulting in additional months to the lease for the related premises extending until October 2022. As part of these extensions, the Company received tenant allowances of \$228,973 and \$392,020, respectively, for expansion of laboratory and office space.

In January 2017, the Company signed a second extension to the lease of its primary building for an additional 48 months expiring October 31, 2026. A tenant allowance of approximately \$2,000,000 was also made available for use to partially fund the expansion and build out of the primary building. This allowance was fully utilized as of December 31, 2018.

These allowance amounts were recorded as a long-term deferred rent liability and amortized as a reduction in rent expense over the remaining term of the lease. The balance of all unamortized deferred rent and allowances totaled \$2,881,180 and \$2,674,683 as of December 31, 2017 and 2018, respectively.

In November 2018, the Company amended the lease of its primary building to expand by 8,264 additional square footage expiring October 31, 2026 in exchange for terminating the Company's other lease with the same landlord for 4,400 noncontiguous square feet. A tenant allowance of approximately \$1.0 million was also made available for use to help fund the build out related to the expansion of the primary building lease. The incremental rent over the terminated lease for the first 12 months of this lease expansion amounts to \$0.1 million, subject to lease escalation in subsequent periods.

The Company also leases copier equipment under an operating lease, which expires in 2019.

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****10. Commitments and Contingencies (Continued)**

As of December 31, 2018, future minimum lease payments under operating leases having initial or remaining non-cancelable lease terms in excess of one year were as follows:

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2019	\$	1,077,532
2020		1,168,710
2021		1,203,658
2022		1,239,885
2023		1,276,356
Thereafter		3,818,795
Total	\$	<u>9,784,936</u>

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Rent expense, including other facility expenses, for the years ended December 31, 2017 and 2018 was \$1,046,721 and \$953,733, respectively.

**Capital Leases**

The Company leases specialized lab equipment under leases classified as capital leases. The related capitalized assets are amortized on a straight-line basis over the estimated useful life of the asset. The interest rates related to these lease obligations range from 0.2% to 12.2%.

The following table shows the future minimum lease payments under the capital leases by year and the present value of the minimum lease payments:

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Year ending December 31:		
2019	\$	464,797
2020		354,739
2021		33,774
Thereafter		—
Total minimum lease payments		853,310
Less: Amount representing interest		<u>(24,525)</u>
Present value of minimum lease payments	\$	<u>828,785</u>

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The net book value of assets under capital leases was \$2,399,634 as of December 31, 2018. At December 31, 2018, the present value of minimum lease payments due within one year was \$452,703.

**Other**

In March 2012, the Company entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to the Company's manufacturing capabilities during the term of the agreement. As future contingent consideration under the agreement, the Company agreed to pay

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****10. Commitments and Contingencies (Continued)**

\$400,000 related to the timing of the Company's first Phase 3 clinical trial which commenced site initiation in December 2017. The consideration of \$400,000 is comprised of initial consideration of \$20,000 paid in 2017, \$80,000 to be paid upon first dosing of the first patient in the Phase 3 clinical trial, and \$300,000 due no later than December 31, 2018. In addition, the Company also agreed to pay future contingent royalties on net sales totaling no more than \$1,500,000. As of December 31, 2017 and 2018, \$380,000 and \$0, respectively, was recorded as Current Liabilities in the accompanying Balance Sheets.

In December 2017, GSK Inhaled made the Company aware of its modified plans under the GSK Inhaled Collaboration and Option Agreement, and the reduced requirement and budget for Liquidia support, commensurate with its research and development plans related to PRINT effective March 31, 2018. As a result, in December 2017, the Company committed to a plan to reduce its workforce which was communicated to the workforce and completed the plan in January 2018. The total employee severance expense paid for the plan was \$404,407, which was recorded in Research and Development Expense in the accompanying Statements of Operations and Comprehensive Loss for the year ended December 31, 2018.

In June 2017, the Company was served with a lawsuit filed by Allergan, Inc., in the United States District Court for the Central District of California, naming Liquidia and Envisia as defendants. The lawsuit alleged that Envisia's development efforts of one of its product candidates misused Allergan confidential information. The Company's involvement results from its possibly related activities that occurred prior to November 8, 2013, the date of formation of Envisia. In October 2017, the Company settled the litigation with Allergan, Inc., with no financial payments due from the Company or other consideration that materially affects the operation of the Company. There was no accrual for this in the Balance Sheets as of December 31, 2017 and 2018.

**11. Long-Term Debt**

Long-term debt consisted of the following as of:

	Maturity Date	December 31,	
		2017	2018
Pacific Western Bank notes — LSA		\$ 9,069,463	\$ —
Pacific Western Bank note — A&R LSA	October 25, 2022	—	10,802,355
UNC Promissory Note	December 31, 2018	2,257,684	—
Convertible notes, net of discounts	December 31, 2018	9,837,984	—
CSC build-to-suit equipment financing, net of discount	February 28, 2021	—	1,142,194
Less current portion		(15,608,349)	(316,906)
Long-term debt, less current portion		\$ 5,556,782	\$ 11,627,643

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**11. Long-Term Debt (Continued)**

**Pacific Western Bank**

In January 2016 and October 2016, the Company entered into a Loan and Security Agreement ("LSA") and an amendment, respectively, with Pacific Western Bank ("Pacific Western"). The LSA provided that the Company may borrow up to \$10.0 million three tranches of a term loan ("Term Loan") to supplement working capital and finance facility expansion and capital equipment purchases. The Term Loan was collateralized by a lien on all assets of the Company that are not otherwise encumbered, including a negative pledge on intellectual property prohibiting its sale without Pacific Western's consent. Amounts borrowed under the Term Loan could be repaid at any time without penalty or premium. The Term Loan was interest-only through July 6, 2017, followed by an amortization period of 30 months of equal monthly payments of principal plus interest, beginning on August 6, 2017 and continuing on the same day of each month thereafter until paid in full. Any amounts borrowed under the Term Loan bore interest at 3.75% during the initial 18-month interest-only period. Following the interest-only period, the interest rate increased to 5.00%, which was to be fixed for the duration of the Term Loan. Subsequent to the Company closing its IPO, on August 6, 2018 the Company paid Pacific Western a liquidity event success fee of \$400,000, which was recorded as Interest Expense in the accompanying Statement of Operations and Comprehensive Loss.

In early 2017, the Company breached a covenant in the LSA with Pacific Western Bank by failing to set mutually agreeable financial or milestone covenants on or before January 30, 2017. On March 30, 2017, pursuant to a Fourth Amendment to the LSA entered into between the Company and Pacific Western, Pacific Western waived the breach of this covenant and the covenant remains in effect.

In October 2017, the Company breached a covenant in its LSA with Pacific Western by failing to maintain minimum levels of cash. On November 30, 2017, pursuant to the Eighth Amendment to the LSA, Pacific Western waived the breach of this covenant and amended the LSA to require the Company to maintain a cash balance of at least \$2.5 million monitored daily, from November 30, 2017 until the Company receives at least \$12.0 million from the issuance of equity instruments by December 31, 2017. The Company was in breach of this covenant as of December 31, 2017. In February 2018, Pacific Western waived the breach of this covenant as a result of the Company receiving equity financing in excess of the requirement.

On March 29, 2018, the Company and Pacific Western executed the Ninth Amendment to the LSA (the "Ninth Amendment"). With the Ninth Amendment, new covenants were enacted requiring the Company to (1) at all times maintain a balance of cash at Pacific Western of at least \$8.0 million, an increase of \$5.5 million from its prior cash balance covenant, and (2) not observe any materially adverse data from its LIQ861 Phase 3 study on or before December 31, 2018. Pursuant to this Ninth Amendment, the interest-only period for the Tranche I loan was amended to include the period from January 7, 2018 to July 6, 2018, and the interest-only period for the Tranche II and Tranche III loans was amended to include the period from January 13, 2018 to July 12, 2018. Prior to executing the amendment, the Company had made principal payments of \$0.6 million inside of the defined interest-only period, which were subsequently refunded on the same day. All amendments to the Pacific Western LSA were accounted for as a modification.

On October 26, 2018, the Company and Pacific Western entered into an Amended and Restated Loan and Security Agreement (the "A&R LSA") in which the Company received an initial tranche of \$11.0 million to extinguish its existing debt of \$8.0 million under the LSA, repay in full the \$1.8 million in outstanding indebtedness under the UNC Promissory Note (as described below) and for general corporate purposes. The

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**11. Long-Term Debt (Continued)**

indebtedness under the A&R LSA bears interest at the greater of the Prime rate or 5% and has a four-year term and maturity. The A&R LSA provides for access to a second tranche of up to \$5.0 million available to be drawn at our option through June 30, 2019 upon the full enrollment of the LIQ861 Phase 3 clinical trial, provided that we have not observed any materially adverse data through the two-week endpoint. Both tranches require payments of interest-only through December 31, 2019, which interest-only period can be extended by six months if the Company closes on at least \$40.0 million in new financing from either equity sales or licensing activities by October 31, 2019 (the "Financing Condition"). As a result of this refinancing, the Company recorded a gain of \$0.1 million in accordance with ASC 470-50, *Debt — Modifications and Extinguishments*.

The A&R LSA carries a one-time success fee tiered by tranche totaling between \$187,000 and \$375,000 depending upon whether the Financing Condition is met, and a prepayment penalty of 1% to 2% for the first 24 months of the drawn tranche. The minimum cash covenant is \$8.5 million, which can be reduced to \$6 million in the event the Financing Condition is met and the Company has publicly disclosed its safety data analysis for LIQ861 with no materially adverse data observed. Pacific Western maintains a blanket lien on all assets excluding intellectual property, for which it has been provided a negative pledge. Pursuant to the A&R LSA, the Company is also obligated to comply with various other customary covenants, including, among other things, restrictions on its ability to dispose of assets, replace or suffer the departure of the CEO or CFO without delivering ten days' prior written notification to Pacific Western, suffer a change on the Board of Directors which would result in the failure of at least one partner of either New Enterprise Associates or Canaan Partners or their respective affiliates to serve as a voting member in each case without having used best efforts to deliver at least 15 days' prior written notification to Pacific Western, make acquisitions, be acquired, incur indebtedness, grant liens, make distributions to its stockholders, make investments, enter into certain transactions with affiliates or pay down subordinated debt, subject to specified exceptions.

**CSC Build-To-Suit Equipment Financing**

See Note 7 for further discussion of the background of the equipment financing ("CSC Financing"). The CSC Financing has a term of three years with equal monthly payments that by themselves imply an interest rate equal to approximately 5.4% per annum. The effective interest rate is 14.9%. The CSC Financing is collateralized by a lien on the related build-to-suit equipment and includes an option to purchase the build-to-suit equipment at maturity at an amount equal to the lesser of fair market value or 23% of the initial financed amount.

**UNC Promissory Note**

In September 2012, the Company issued an unsecured promissory note with principal amount of \$0.6 million as a sublicense fee to UNC, with principal and interest due in full on September 1, 2016, bearing an interest rate equal to the one-year LIBOR plus 2%, compounding annually or the UNC Promissory Note. In June 2016, the Company (as licensee) negotiated modifications to its license agreement with UNC in exchange for an increase of \$1.5 million to the note payable and extension of the maturity to December 31, 2017. As the Company had previously recorded a contingent liability of \$1.5 million related to this license, the increase to the note payable was recorded as a reduction to the accrued expense balance at this time. In addition, the initial note of \$0.6 million plus accrued interest were extended under the same terms. The combined note payable interest rate was increased by 1%. In December 2017, the Company executed an amendment to the UNC Promissory Note that extended the

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**11. Long-Term Debt (Continued)**

maturity date of the promissory note from December 31, 2017 to June 30, 2018. All other terms and conditions of the Letter Agreement continue in force through the new maturity date. In June 2018, the Company executed an amendment to the UNC Promissory Note that extended the maturity date of the promissory note from June 30, 2018 to December 31, 2018 with the potential for acceleration depending on the proceeds of the IPO. All other terms and conditions of the Letter Agreement were to continue in force through the new maturity date. All such amendments to the UNC Promissory Note were accounted for as a modification. On August 2, 2018, the Company made a payment of \$600,000 to UNC. The Company repaid the entire balance outstanding plus accrued interest pursuant to the closing of the A&R LSA with Pacific Western in October 2018. The balance of the promissory note at December 31, 2017 and 2018 was \$2,257,684 and \$0, respectively.

**Convertible Notes**

In January and February 2017, the Company issued an aggregate of \$11.8 million in principal of convertible promissory notes (the "January and February Notes"). The January and February Notes were accompanied by warrants to purchase of up to 25% of the aggregate principal amounts of the notes, equal to 3,698,128 shares of Series D. The January and February Notes were scheduled to mature on December 31, 2018, as amended, and bore interest at eight percent (8%) per annum. Interest was earned daily and computed on the actual number of days elapsed until all the amounts under the notes had been paid in full. All unpaid principal and all accrued, but unpaid interest of each investor's note was due and payable on demand at the request of the investor at any time after December 31, 2018. In addition, upon the consummation of an asset sale, acquisition, or IPO, as defined, the investors may have elected to accelerate the repayment of the note or convert into common stock or Series C-1 based on various scenarios.

*Singapore IPO*

Upon the consummation of an IPO of the Company's capital stock registered on the Singapore Exchange Securities Trading Limited (a "Singapore IPO") after August 1, 2017, the holders had the right to elect to (i) receive payment from the Company equal to the outstanding principal plus all accrued but unpaid interest or (ii) convert the outstanding principal and accrued but unpaid interest into such shares of the Company's capital stock at a price per share that was equal to 70% of the price per share paid by the purchasers of such shares in such IPO.

*Domestic IPO*

Upon the consummation of an IPO of the Company's Common Stock registered under the Securities Act of 1933, after which such Common Stock is listed for trading on a United States national securities exchange (a "Domestic IPO"), the holders had the right to elect to (i) receive payment from the Company equal to the outstanding principal plus accrued but unpaid interest or (ii) convert all outstanding principal and accrued but unpaid interest into shares of the Company's Common Stock at a price per share that was equal to 75% of the price per share paid by the purchasers of the shares in such IPO.

*Automatic Conversion upon Qualified Financing*

The principal and accrued but unpaid interest would have automatically converted into shares of Preferred Stock issued in a Qualified Financing, as defined. The number of shares of Preferred Stock issued would have been equal to the quotient of (i) the principal amount plus accrued but unpaid interest and (ii) 75% of the lowest price per share paid by investors participating in the Qualified Financing. If a Qualified Financing had not occurred prior to December 31, 2017, the holders of the notes had the right to elect to

**Liquidia Technologies, Inc.**

**Notes to Financial Statements (Continued)**

**11. Long-Term Debt (Continued)**

convert the outstanding principal plus accrued but unpaid interest into shares of the Company's Series C-1 at \$0.59808 per share. The holders did not exercise this right.

*Conversion upon Non-qualified Financing*

The holders may elect to convert the outstanding principal and accrued but unpaid interest on the notes into any shares of the Company's capital stock that are issued in any financing transaction other than a Qualified Financing, a Domestic IPO or a Singapore IPO (a "Non-qualified Financing"). The number of shares issued would have been equal to the quotient of (i) the sum of the principal amount plus accrued but unpaid interest and (ii) 75% of the lowest price per share paid by investors participating in the Non-qualified Financing.

*Strategic Transaction*

Upon the consummation of an asset sale of all or substantially all of the Company's assets or an acquisition, merger or change in control (a "Strategic Transaction"), the holders of the notes had the right to elect to (i) receive a payment from the Company equal to the sum of (1) 200% of the then outstanding principal and (2) accrued but unpaid interest or (ii) convert the outstanding principal and accrued but unpaid interest into shares of the Company's Series C-1 at \$0.59808 per share.

Additionally, upon the occurrence of certain Events of Default, as defined in the notes, each investor may have elected to accelerate the repayment of all unpaid principal and accrued interest under each note and the notes provide for automatic redemption upon the occurrence of certain bankruptcy related Events of Default, as defined in the notes.

In July 2017, the Company entered into a series of unsecured convertible note agreements of \$10.4 million in the aggregate (the "July Notes"). The July Notes bore interest at a rate of 8% per annum with a scheduled maturity date of December 31, 2018. In conjunction with this financing, the Company also entered into a commitment with an advisor in the form of a convertible note amounting to \$0.4 million with terms similar to the related transaction. The July Notes were not accompanied by warrants. Principal plus accrued interest were convertible into either preferred or common stock at the time of a qualified financing, as defined in the July Notes, at a discount to the share price, depending on the type of financing similar to the January and February Notes. Conversion discounts on these convertible notes were largely similar to the January and February Notes except that the discount for a Singapore and Domestic IPO were both 50%.

In November 2017, the Company issued a series of unsecured subordinated convertible notes with an aggregate principal amount of \$5.2 million to new and existing investors (the "November Notes"). The November Notes bore interest at a rate of 8% per annum with a scheduled maturity date of December 31, 2018. Principal plus accrued interest were convertible into either preferred or common stock at the time of a qualified financing, as defined in the November Notes, at a discount to the share price, depending on the type of financing. In conjunction with this financing, the Company also incurred fees of \$0.4 million. The November Notes were not accompanied by warrants. Conversion discounts on these convertible notes were largely similar to the July Notes except that there was no discount upon mandatory conversion into a private financing round. In addition, at maturity, the November Notes (principal plus accrued but unpaid interest) would have converted into shares of the Company's Series C-1 at \$0.72877 per share.

*Accounting for Convertible Notes*

The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from allocation of proceeds to interest expense using the straight-line method over the expected term of the notes pursuant to ASC 835, *Interest* (ASC 835).

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****11. Long-Term Debt (Continued)**

In connection with the issuance of the convertible notes and warrants, the Company recorded discounts equal to the full amount of each series of notes based on an allocation of proceeds to the warrants, an allocation to bifurcated derivatives which consist of a contingent put option upon a change of control or acceleration upon event of default and a contingent call option upon a change of control included in the notes, and a beneficial conversion feature, before issuance costs, based on the difference between the fair value of the underlying common stock at the commitment date of each note transaction and the effective conversion price of the notes, as limited by the proceeds allocated to the notes. Since the initial carrying value of all three series of convertible notes was \$0, the combined debt issuance costs of \$1,397,624 were charged to Interest Expense. See Note 2 for discussion of the Company's policies for accounting for convertible instruments with detachable liability-classified warrants.

The following is a summary of the liability component of Convertible Notes as of December 31, 2017:

	February Notes	July Notes	November Notes	Total
Principal amount of Convertible Notes	\$ 11,796,168	\$ 10,442,356	\$ 5,150,000	\$ 27,388,524
Unamortized discount on the notes	(5,504,878)	(7,291,816)	(4,753,846)	(17,550,540)
	<u>\$ 6,291,290</u>	<u>\$ 3,150,540</u>	<u>\$ 396,154</u>	<u>\$ 9,837,984</u>

In February 2018, the Company received proceeds of \$25.6 million in exchange for the corresponding sale of shares of Series D at a price per share of \$0.59808. In addition, all outstanding convertible notes, plus accrued interest, totaling \$28.9 million, were converted into Series D at the same price per share. The unamortized balances of the discounts on convertible notes of \$17.6 million were then amortized to interest expense. Therefore, the balances of these notes at December 31, 2018 was \$0. No gain or loss was recorded upon the conversion of the convertible notes.

*Accounting for the Warrant Liabilities*

The Company's liability-classified warrants were recorded as liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in derivative and warrant fair value adjustments in the Company's Statements of Operations and Comprehensive Loss. The warrants, with a fair value of \$4,474,122 at inception, were initially recorded as warrant liabilities on the Balance Sheets with a corresponding discount to the notes. The change in the estimated fair value of the warrant liabilities resulted in a fair value adjustment and is included in derivative and warrant fair value adjustments in the Statements of Operations and Comprehensive Loss. In conjunction with the IPO, the warrants automatically converted to warrants to purchase common stock. Therefore, upon IPO, the warrant

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****11. Long-Term Debt (Continued)**

liabilities were marked to fair market value and transferred to additional paid-in capital. Changes in the values of the warrant liabilities for the years ended December 31, 2017 and 2018 are summarized below:

	For the Year ended December 31,	
	2017	2018
Fair value, beginning of period	\$ —	\$ 2,462,859
Issuance of warrants	4,474,122	—
Change in fair value	(2,011,263)	(277,715)
Transfer to additional paid-in capital	—	(2,185,144)
Fair value, end of period	\$ 2,462,859	\$ —

*Assumptions Used in Determining Fair Value of Liability-classified Warrants*

To estimate the fair value of the warrants, the Company used a combination of the Current Value Method, Option Pricing Method ("OPM") and Black-Scholes Option Pricing Model, in a Probability-Weighted Expected Return Method ("PWERM") context, or the Hybrid Method ("Hybrid Method"). The Company estimated the fair value of the most senior series of preferred stock and estimated the fair value of common stock in the various conversion scenarios. The Company used a Black-Scholes option-pricing model to estimate the fair value of the warrants using the life of the warrants, assuming a sale of the Company does not occur, and the fair value of underlying equity values from the first step. The Company probability-weighted each scenario to arrive at an estimated fair value of the warrants.

Depending upon the scenario, warrants could be exercised to purchase either common stock or the most senior series of preferred stock. To value the warrants in each scenario, the Company used either an OPM or the Black-Scholes option-pricing model. The hybrid method is a useful alternative to explicitly modeling all PWERM scenarios in situations when the Company has transparency into one or more near-term exits but is unsure about what will occur if the current plans fall through.

Key assumptions in the hybrid method include:

- § OPM-various conversion scenarios
- § Probability
- § Timing (Each financing scenario)
- § Enterprise value
- § Type of Security
- § Estimated security value
- § Methodology of valuing warrant OPM

*Accounting for the Derivative Liabilities*

Management determined that the various conversion features discussed above represent, in substance, a put option (redemption feature) designed to provide the investor with a fixed monetary amount, settled in shares. Management determined that this put option and the contingent interest should be separated from

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****11. Long-Term Debt (Continued)**

the notes and accounted for as a compound derivative liability primarily because the notes were issued at a substantial discount because the warrants, put option, and the contingent interest meet the net settlement criterion. The compound derivative liabilities were initially recorded as derivative liabilities on the Balance Sheets and a corresponding discount to the notes. The change in the estimated fair value of the derivative liabilities for the year ended December 31, 2017 resulted in a fair value adjustment and is included in Derivative and Warrant Fair Value Adjustments in the Statements of Operations and Comprehensive Loss. As the estimated fair value of the derivative liabilities was \$0 at December 31, 2017 and such derivatives did not exist as of December 31, 2018, no fair value adjustment was recorded for the year ended December 31, 2018.

Changes in the values of the derivative liabilities for the years ended December 31, 2017 and 2018 are summarized below:

	For the Year ended December 31,	
	2017	2018
Fair value, beginning of period	\$ —	\$ —
Issuance of derivatives	9,872,990	—
Change in fair value	(9,872,990)	—
Fair value, end of period	\$ —	\$ —

**Assumptions Used in Determining Fair Value of Compound Bifurcated Derivative**

The Company assessed the accounting for the convertible notes and determined that there were several embedded derivatives that required bifurcation from the host debt instrument at fair value in accordance with ASC 815, *Derivatives and Hedging*. These embedded derivatives are more like equity instruments, and thus not "clearly and closely related" to the economic characteristics of the convertible notes. Further, they were determined not to meet the definition of being indexed to the Company's own stock due to the variable number of shares to be converted under different scenarios. When a host instrument has multiple embedded derivative features that require bifurcation, ASC 815 requires that they be bundled as one and accounted for separately from the convertible notes at fair value.

To determine the fair value of such derivatives, the Company compared (1) the expected payout from the different conversion scenarios upon their expected date of occurrence, discounted to present value at a risk-free rate, to (2) the fair value of the convertible notes if it were paid in cash or converted into Series C-1 on December 31, 2017. The difference between these two results represents the fair value of the bundled derivative.

First, the Company estimated the expected payout under the various conversion scenarios. The principal and accrued interest on the convertible notes were calculated through the expected payout date, and divided by the stated conversion price discount to determine the amount that would be paid upon occurrence of the event. The payoff from each scenario was then discounted to present value at the risk-free rate and the Company probability-weighted each scenario to arrive at the expected payout value for purposes of the

**Liquidia Technologies, Inc.****Notes to Financial Statements (Continued)****11. Long-Term Debt (Continued)**

valuation. Next, it was assumed that if conversion under the certain financing scenarios did not occur by December 31, 2017, it would be most advantageous for the investors to convert the convertible notes into Series C-1 or request payment of principal and interest in cash. The value of the convertible notes under these scenarios was modeled using the OPM. The difference between the payout value under the various conversion scenarios and the value of the convertible notes under the OPM, assuming the convertible notes are not converted or paid until December 31, 2017, results in the fair value of the bundled derivative.

*Accounting for the Beneficial Conversion Feature*

The Company did not separate from the notes the conversion feature in which the holders may convert the principal and interest on the notes into shares of the Company's Series C-1 at \$0.59808 per share if a qualified financing, as defined in the notes, had not occurred prior to December 31, 2017. The Company concluded that this conversion feature is a beneficial conversion feature that should be recognized separately and measured initially at its intrinsic value. Since the intrinsic value of this beneficial conversion feature is greater than the proceeds allocated to the notes, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the proceeds allocated to the notes. The Company recorded the beneficial conversion feature of \$2,956,166, \$4,935,246, and \$5,150,000 as additional paid-in capital upon issuance of the respective convertible notes and a corresponding discount to the notes on the Balance Sheet for the January and February Notes, July Notes and November Notes, respectively.

Scheduled annual maturities of long-term debt as of December 31, 2018 are as follows:

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<b>Year ending December 31:</b>	
2019	\$ 416,989
2020	4,483,486
2021	4,410,660
Thereafter	3,000,000
Total	<u>12,311,135</u>
Less: Unamortized discount	(326,246)
Less: Unamortized debt issuance costs	(40,340)
Less: Current portion of long-term debt	(316,906)
	<u>\$ 11,627,643</u>

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**12. Subsequent Events**

On February 6, 2019, the Board of Directors approved stock option grants to various employees in the aggregate amount of 395,408 shares of common stock underlying such grants, with an exercise price of \$14.20 per share. In addition, on January 1, 2019, the number of shares of common stock available for issuance under the 2018 Plan automatically increased from 1,600,000 to 2,220,778 pursuant to the evergreen provision contained in the 2018 Plan (see Note 4).

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3,000,000 Shares



**Liquidia Technologies, Inc.**

**Common Stock**

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**PRELIMINARY PROSPECTUS**

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*Joint Book-Running Managers*

**Jefferies  
Cowen**

*Co-Managers*

**Needham & Company  
Wedbush PacGrow**

, 2019

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## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

**Item 13. Other Expenses of Issuance and Distribution**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the U.S. Securities and Exchange Commission, or the SEC, registration fee, the FINRA filing fee and Nasdaq listing fee.

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	<u>Amount</u>
SEC registration fee	\$ 7,121
FINRA filing fee	9,313
Accountants' fees and expenses	110,000
Legal fees and expenses	375,000
Transfer agent's fees and expenses	5,000
Printing and engraving expenses	130,000
Miscellaneous	63,566
Total expenses	<u>\$ 700,000</u>

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**Item 14. 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 amended and restated certificate of incorporation and amended and restated 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 amended and restated certificate of incorporation and amended and restated 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 15. *Recent Sales of Unregistered Securities.***

The following sets forth information as to all securities we have sold since January 1, 2016, which were not registered under the Securities Act.

#### **Series D Preferred Stock**

On February 2, 2018, we issued and sold an aggregate of 82,560,006 shares of Series D preferred stock at a price per share equal to \$0.59808. Of the 27 investors which participated in the initial closing of this offering, six investors purchased an aggregate of 34,276,349 shares of Series D preferred stock for an aggregate of \$20.5 million and 26 holders of outstanding convertible notes in the aggregate amount of \$28.9 million converted into an aggregate of 48,283,657 shares of Series D preferred stock.

Pursuant to the terms of the Series D Preferred Stock Purchase Agreement, on February 15, 2018 we sold 8,360,085 shares of Series D preferred stock to an accredited investor for a total purchase price of \$5.0 million.

Additionally, pursuant to the terms of the Series D Preferred Stock Purchase Agreement, we offered our existing stockholders who are accredited investors the opportunity to purchase their pro rata portion of the Series D preferred stock in a rights offering. On February 28, 2018, we sold an aggregate of 227,391 shares of Series D preferred stock for an aggregate purchase price of \$135,998.

We claimed an exemption from registration under the Securities Act for the issuance and sale of the Series D preferred stock under Section 4(a)(2) of the Securities Act in that such sales and issuances do not involve a public offering.

#### **Unsecured Subordinated Convertible Promissory Notes**

In a series of closings from January 9, 2017 to November 29, 2017, we issued and sold an aggregate of approximately \$27.4 million underlying a total of 27 unsecured subordinated convertible promissory notes, each accruing simple interest at a rate of 8% per annum, or the Notes.

We claimed an exemption from registration under the Securities Act for the issuance and sale of the Notes under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering.

#### **Warrants**

On July 6, 2017, a warrant holder exercised a warrant to purchase shares of our common stock, issued on July 10, 2007, for 1,188 shares of our common stock.

In connection with the closings of the Notes from January 9, 2017 to February 17, 2017, we issued and sold 17 warrants to purchase an aggregate of 3,698,128 shares of preferred stock at an exercise price of \$0.0168 per share which were convertible into an aggregate of 219,761 shares of common stock. See "Description of Capital Stock — Warrants" for more information.

On August 14, 2018, a warrant holder exercised a warrant to purchase shares of our common stock, issued on February 8, 2017, for 2,261 shares of our common stock.

On September 5, 2018, a warrant holder exercised a warrant to purchase shares of our common stock, issued on January 9, 2017, for 18,630 shares of our common stock.

On December 6, 2018, a warrant holder exercised a warrant to purchase shares of our common stock, issued on January 12, 2017, for 27,945 shares of our common stock.

On January 11, 2019, a warrant holder exercised a warrant to purchase shares of our common stock, issued on February 16, 2017, for 9,315 shares of our common stock.

On March 4, 2019, Canaan VIII L.P. exercised a warrant to purchase shares of our common stock, issued on January 9, 2017, for 34,378 shares of our common stock.

On March 12, 2019, a warrant holder exercised a warrant to purchase shares of our common stock, issued on February 8, 2017, for 464 shares of our common stock on a net basis.

On March 13, 2019, a warrant holder exercised a warrant to purchase shares of our common stock, issued on January 9, 2017, for 20,472 shares of our common stock on a net basis.

We claimed an exemption from registration under the Securities Act for the issuance and sale of such warrants under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering.

## Options

On February 10, 2016, we granted incentive stock options to six employees to purchase an aggregate of 39,381 shares of common stock under our 2004 Plan, with an exercise price equal to \$5.89 per share. Options to purchase 169 shares have subsequently been exercised for common stock. Options to purchase 2,205 shares were terminated without being exercised.

On August 10, 2016, we granted incentive stock options to eight employees to purchase an aggregate of 27,665 shares of common stock under the Liquidia Technologies, Inc. 2016 Equity Incentive Plan, as amended, or the 2016 Plan, with an exercise price equal to \$5.89 per share. Options to purchase 11,749 shares have subsequently been exercised for common stock. Options to purchase 11,016 shares were terminated without being exercised.

On August 30, 2016, we granted incentive stock options to three employees to purchase an aggregate of 13,964 shares of common stock under the 2016 Plan, with an exercise price equal to \$5.89 per share. Options to purchase 5,682 shares have subsequently been exercised for common stock. Options to purchase 4,420 shares were terminated without being exercised.

On December 7, 2016, we granted a non-statutory stock option to Arthur Kirsch, a director, to purchase 8,914 shares of common stock under the 2016 Plan, with an exercise price equal to \$20.36 per share.

On March 15, 2017, we granted incentive stock options to seven employees to purchase an aggregate of 13,010 shares of common stock under the 2016 Plan, with an exercise price equal to \$20.36 per share. Options to purchase 1,722 shares were terminated without being exercised.

On May 31, 2017, we granted an incentive stock option to an employee to purchase 1,069 shares of common stock under the 2016 Plan, with an exercise price equal to \$20.36 per share.

On March 7, 2018, we granted incentive stock options to 64 employees to purchase an aggregate of 703,330 shares of common stock under the 2016 Plan, with an exercise price equal to \$9.31 per share. Included in these 64 grants were grants to: (i) Neal Fowler, our Chief Executive Officer, for 231,765 shares; (ii) Kevin Gordon, our former President and Chief Financial Officer, for 127,576 shares; (iii) Timothy Albury, our Interim Chief Financial Officer, for 30,545 shares; (iv) Robert Lippe, our Chief Operations Officer, for 43,678 shares; (v) Dr. Robert Roscigno, our Senior Vice President, Product Development, for 35,656 shares; and (vi) Dr. Benjamin Maynor, our Senior Vice President, Research and Development, for 41,598 shares. Options to purchase 36,096 shares were terminated without being exercised.

On March 7, 2018, we also granted non-statutory stock options to four directors to purchase an aggregate of 107,561 shares of common stock under the 2016 Plan, with an exercise price equal to \$9.31 per share. These four grants comprised grants to: (i) Arthur Kirsch, for 8,022 shares; (ii) Dr. Seth Rudnick, for 55,267 shares; (iii) Dr. Ralph Snyderman, for 27,336 shares; and (iv) Raman Singh, for 16,936 shares.

On March 7, 2018, in connection with his employment agreement, we granted Mr. Gordon 127,576 restricted stock units, equal to one percent of our issued and outstanding capital stock on a fully-diluted

basis on the date of grant. As of the date of this registration statement, 34,551 restricted stock units had settled in common stock.

On March 27, 2018, we granted incentive stock options to two employees to purchase an aggregate of 1,485 shares of common stock under our 2016 Plan, with an exercise price equal to 9.31 per share.

On May 10, 2018, on a net basis, Mr. Fowler exercised an option granted on May 12, 2008 under the 2004 Plan, resulting in 15,276 shares of our common stock being issued to Mr. Fowler.

On June 19, 2018, we granted incentive stock options to four employees to purchase an aggregate of 70,686 shares of common stock under our 2016 Plan, with an exercise price equal to \$11.32 per share.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, or Rule 701, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Since January 1, 2016, 317,138 shares of common stock have been issued upon the exercise of stock options pursuant to the 2004 Plan and 17,454 shares of common stock have been issued upon the exercise of stock options pursuant to the 2016 Plan.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued securities described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

The information presented in this Item 15 gives effect to a 1-for-16.8273325471348 reverse stock split, which became effective on July 19, 2018.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) The following exhibits are filed as part of this Registration Statement:

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<u>Exhibit Number</u>	<u>Description</u>
1.1	<a href="#">Form of Underwriting Agreement.</a>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Liquidia Technologies, Inc. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 30, 2018).</a>
3.2	<a href="#">Amended and Restated Bylaws of Liquidia Technologies, Inc. (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on July 30, 2018).</a>
4.1	<a href="#">Form of Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, filed with the SEC on July 13, 2018).</a>
4.2	<a href="#">Form of Warrant to Purchase Shares of Preferred Stock issued by the Company in January 2017 and February 2017 (incorporated herein by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>

<u>Exhibit Number</u>	<u>Description</u>
4.3	<a href="#">Seventh Amended and Restated Investors' Rights Agreement, dated as of February 2, 2018, by and among the Company, the Investors party thereto and the Common Holders party thereto (incorporated herein by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
5.1	<a href="#">Opinion of DLA Piper LLP (US).</a>
10.1#	<a href="#">Liquidia Technologies, Inc. Stock Option Plan (2004), as amended, and forms of award agreements thereunder (incorporated herein by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K, filed with the SEC on February 26, 2019).</a>
10.2#	<a href="#">Liquidia Technologies, Inc. 2016 Equity Incentive Plan, as amended, and forms of award agreements thereunder (incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.3#	<a href="#">Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan, and forms of award agreements thereunder (incorporated herein by reference to Exhibit 99.3 to the Company's Registration Statement on Form S-8, filed with the SEC on July 26, 2018).</a>
10.4	<a href="#">Form of Indemnification Agreement with the Company's executive officers and directors (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.5	<a href="#">Amended and Restated Loan and Security Agreement, dated as of October 26, 2018, by and between the Company and Pacific Western Bank (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on October 31, 2018).</a>
10.6+	<a href="#">Inhaled Collaboration and Option Agreement, dated as of June 15, 2012, by and between the Company and Glaxo Group Limited (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.7+	<a href="#">Amendment No. 1 to the Inhaled Collaboration and Option Agreement, dated as of May 13, 2015, by and between the Company and Glaxo Group Limited (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.8+	<a href="#">Second Amendment to the Inhaled Collaboration and Option Agreement, dated as of November 19, 2015, by and between the Company and Glaxo Group Limited (incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.9+	<a href="#">Amended and Restated License Agreement, dated as of December 15, 2008, by and between the Company and The University of North Carolina at Chapel Hill (incorporated herein by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.10+	<a href="#">First Amendment to Amended and Restated License Agreement, dated as of June 8, 2009, by and between the Company and The University of North Carolina at Chapel Hill (incorporated herein by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>

<u>Exhibit Number</u>	<u>Description</u>
10.11	<a href="#">Sixth Amendment to Amended and Restated License Agreement, dated as of June 10, 2016, by and between the Company and The University of North Carolina at Chapel Hill (incorporated herein by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.12 <sup>+</sup>	<a href="#">Manufacturing Development and Scale-up Agreement, dated as of March 19, 2012, by and between the Company and Chasm Technologies, Inc. (incorporated herein by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.13 <sup>+</sup>	<a href="#">1st Amendment to Manufacturing Development and Scale-up Agreement, dated as of May 25, 2017, by and between the Company and Chasm Technologies, Inc. (incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.14 <sup>#</sup>	<a href="#">Amended and Restated Executive Employment Agreement, dated as of January 31, 2018, by and between the Company and Neal Fowler (incorporated herein by reference to Exhibit 10.22 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).</a>
10.15 <sup>#</sup>	<a href="#">Amended and Restated Executive Employment Agreement, dated as of July 25, 2018, by and between the Company and Robert Lippe (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on July 30, 2018).</a>
10.16 <sup>#</sup>	<a href="#">Amended and Restated Executive Employment Agreement, dated as of July 25, 2018, by and between the Company and Timothy Albury (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 30, 2018).</a>
10.17 <sup>#</sup>	<a href="#">First Amendment to Amended and Restated Executive Employment Agreement, dated as of March 8, 2019, by and between the Company and Timothy Albury (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 11, 2019).</a>
10.18 <sup>#</sup>	<a href="#">Liquidia Technologies, Inc. Annual Cash Bonus Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the SEC on July 30, 2018).</a>
10.19 <sup>#</sup>	<a href="#">Executive Severance and Change in Control Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on July 30, 2018).</a>
10.20	<a href="#">Lease Agreement, dated as of June 29, 2007, by and between the Company and Durham KTP Tech 4, LLC, as amended (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K, filed with the SEC on February 26, 2019).</a>
23.1	<a href="#">Consent of PricewaterhouseCoopers LLP, independent Registered Public Accounting Firm.</a>
23.2	<a href="#">Consent of DLA Piper LLP (US) (included in Exhibit 5.1).</a>
23.3	<a href="#">Consent of Decision Resources Group.</a>
24.1	<a href="#">Power of Attorney (included on signature page).</a>
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.

<b>Exhibit Number</b>	<b>Description</b>
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

+ Confidential treatment has been granted with respect as to certain portions of this exhibit. Such portions have been redacted and submitted separately to the SEC.

# Indicates management contract or compensatory plan.

**Item 17. Undertakings.**

Insofar as indemnification for liabilities arising under the Securities Act, 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 Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a 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 this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, 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.

**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 the requirements for filing on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Town of Morrisville, State of North Carolina, on this 18<sup>th</sup> day of March, 2019.

**LIQUIDIA TECHNOLOGIES, INC.**

By:            /s/ NEAL FOWLER

Name: Neal Fowler  
Title: Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Neal Fowler and Timothy Albury 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 (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 of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Name</u>	<u>Position</u>	<u>Date</u>
<u>          </u> /s/ NEAL FOWLER Neal Fowler	Director and Chief Executive Officer (Principal Executive Officer)	March 18, 2019
<u>          </u> /s/ TIMOTHY ALBURY Timothy Albury	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 18, 2019
<u>          </u> /s/ DR. STEPHEN BLOCH Dr. Stephen Bloch	Chairman of the Board of Directors	March 18, 2019
<u>          </u> /s/ ARTHUR KIRSCH Arthur Kirsch	Director	March 18, 2019

<u>Name</u>	<u>Position</u>	<u>Date</u>
<u>/s/ EDWARD MATHERS</u> Edward Mathers	Director	March 18, 2019
<u>/s/ DR. SETH RUDNICK</u> Dr. Seth Rudnick	Director	March 18, 2019
<u>/s/ RAMAN SINGH</u> Raman Singh	Director	March 18, 2019
<u>/s/ DR. RALPH SNYDERMAN</u> Dr. Ralph Snyderman	Director	March 18, 2019



[-] Shares

Liquidia Technologies, Inc.

UNDERWRITING AGREEMENT

[-], 2019

JEFFERIES LLC  
COWEN AND COMPANY, LLC  
As Representatives of the several Underwriters

c/o JEFFERIES LLC  
520 Madison Avenue  
New York, New York 10022

c/o COWEN AND COMPANY, LLC  
599 Lexington Avenue  
New York, New York 10022

Ladies and Gentlemen:

**Introductory.** Liquidia Technologies, Inc., a Delaware corporation (the “**Company**”), proposes to issue and sell to the several underwriters named in Schedule A (the “**Underwriters**”) an aggregate of [-] shares of its common stock, par value \$0.001 per share (the “**Shares**”). The [-] Shares to be sold by the Company are called the “**Firm Shares**.” In addition, the Company has granted to the Underwriters an option to purchase up to an additional [-] Shares as provided in Section 2. The additional [-] Shares to be sold by the Company pursuant to such option are collectively called the “**Optional Shares**.” The Firm Shares and, if and to the extent such option is exercised, the Optional Shares are collectively called the “**Offered Shares**.” Jefferies LLC (“**Jefferies**”) and Cowen and Company, LLC (“**Cowen**”) have agreed to act as representatives of the several Underwriters (in such capacity, the “**Representatives**”) in connection with the offering and sale of the Offered Shares. To the extent there are no additional underwriters listed on Schedule A, the term “**Representatives**” as used herein shall mean you, as Underwriters, and the term “**Underwriters**” shall mean either the singular or the plural, as the context requires.

The Company has prepared and filed with the Securities and Exchange Commission (the “**Commission**”) a registration statement on Form S-1, File No. 333-[-] which contains a form of prospectus to be used in connection with the public offering and sale of the Offered Shares. Such registration statement, as amended, including the financial statements, exhibits and schedules thereto, in the form in which it became effective under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (collectively, the “**Securities Act**”), including any information deemed to be a part thereof at the time of effectiveness pursuant to Rule 430A under the Securities Act, is called the “**Registration Statement**.” Any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offer and sale of the Offered Shares is called the “**Rule 462(b) Registration Statement**,” and from and after the date and time of filing of any such Rule 462(b) Registration Statement the term “**Registration Statement**” shall include the Rule 462(b) Registration Statement. The prospectus, in the form first used by the Underwriters to confirm sales of the Offered Shares or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act, is called the “**Prospectus**.” The preliminary prospectus dated [-], 2019 describing the Offered Shares and the offering thereof is called the

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“**Preliminary Prospectus**,” and the Preliminary Prospectus and any other prospectus in preliminary form that describes the Offered Shares and the offering thereof and is used prior to the filing of the Prospectus is called a “**preliminary prospectus**.” As used herein, “**Applicable Time**” is [-] [a.m.][p.m.] (New York City time) on [·], 2019. As used herein, “**free writing prospectus**” has the meaning set forth in Rule 405 under the Securities Act, and “**Time of Sale Prospectus**” means the Preliminary Prospectus together with the free writing prospectuses, if any, identified in Schedule B hereto and the pricing information set forth on Schedule B hereto. As used herein, “**Road Show**” means a “road show” (as defined in Rule 433 under the Securities Act) relating to the offering of the Offered Shares contemplated hereby that is a “written communication” (as defined in Rule 405 under the Securities Act). As used herein, “**Section 5(d) Written Communication**” means each written communication (within the meaning of Rule 405 under the Securities Act) that is made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company to one or more potential investors that are qualified institutional buyers (“**QIBs**”) and/or institutions that are accredited investors (“**IAIs**”), as such terms are respectively defined in Rule 144A and Rule 501(a) under the Securities Act, to determine whether such investors might have an interest in the offering of the Offered Shares; “**Section 5(d) Oral Communication**” means each oral communication, if any, made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company made to one or more QIBs and/or one or more IAIs to determine whether such investors might have an interest in the offering of the Offered Shares; “**Marketing Materials**” means any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Offered Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically); and “**Permitted Section 5(d) Communication**” means the Section 5(d) Written Communication(s) and Marketing Materials listed on Schedule D attached hereto.

All references in this Agreement to the Registration Statement, any preliminary prospectus (including the Preliminary Prospectus), or the Prospectus, or any amendments or supplements to any of the foregoing, or any free writing prospectus, shall include any copy thereof filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System (“**EDGAR**”) and (ii) the Prospectus shall be deemed to include any “electronic Prospectus” provided for use in connection with the offering of the Offered Shares as contemplated by Section 3(o) of this Agreement.

The Company hereby confirms its agreements with the Underwriters as follows:

**Section 1. Representations and Warranties.**

The Company hereby represents, warrants and covenants to each Underwriter, as of the date of this Agreement, as of the First Closing Date (as hereinafter defined) and as of each Option Closing Date (as hereinafter defined), if any, as follows:

(a) **Compliance with Registration Requirements.** The Registration Statement has become effective under the Securities Act. The Company has complied, to the Commission’s satisfaction with all requests of the Commission for additional or supplemental information, if any. No stop order suspending the effectiveness of the Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission.

(b) **Disclosure.** Each preliminary prospectus and the Prospectus when filed complied in all material respects with the Securities Act and, if filed by electronic transmission pursuant to EDGAR, was identical (except as may be permitted by Regulation S-T under the Securities Act) to the copy thereof delivered to the Underwriters for use in connection with the offer and sale of the Offered Shares. Each of the Registration Statement and any post-effective amendment thereto, at the time it became or becomes

effective, complied and will comply in all material respects with the applicable requirements of the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Applicable Time, the Time of Sale Prospectus did not, and at the First Closing Date (as defined in Section 2) and at each applicable Option Closing Date (as defined in Section 2), will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as of its date, did not, and at the First Closing Date and at each applicable Option Closing Date, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement or any post-effective amendment thereto, or the Prospectus or the Time of Sale Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with written information relating to any Underwriter furnished to the Company in writing by the Representatives expressly for use therein, it being understood and agreed that the only such information consists of the information described in Section 9(b) below. There are no contracts or other documents required to be described in the Time of Sale Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which have not been described or filed as required.

(c) **Free Writing Prospectuses; Road Show.** As of the determination date referenced in Rule 164(h) under the Securities Act, the Company was not, is not or will not be (as applicable) an “ineligible issuer” in connection with the offering of the Offered Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Each free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act, including timely filing with the Commission or retention where required and legending, and each such free writing prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Offered Shares did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Prospectus or any preliminary prospectus and not superseded or modified. Except for the free writing prospectuses, if any, identified in Schedule B, and electronic road shows, if any, furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior written consent, prepare, use or refer to, any free writing prospectus. Each Road Show, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(d) **Distribution of Offering Material By the Company.** Prior to the later of (i) the expiration or termination of the option granted to the several Underwriters in Section 2, and (ii) the completion of the Underwriters’ distribution of the Offered Shares, the Company has not distributed and will not distribute any offering material in connection with the offering and sale of the Offered Shares other than the Registration Statement, the Time of Sale Prospectus, the Prospectus or any free writing prospectus reviewed and consented to by the Representatives, the free writing prospectuses, if any, identified on Schedule B hereto and any Permitted Section 5(d) Communications.

(e) **The Underwriting Agreement.** This Agreement has been duly authorized, executed and delivered by the Company.

(f) **Authorization of the Offered Shares.** The Offered Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Offered Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Offered Shares.

(g) **No Applicable Registration or Other Similar Rights.** There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(h) **No Material Adverse Change.** Except as otherwise disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement, the Time of Sale Prospectus and the Prospectus: (i) there has been no material adverse change, or any development that would be reasonably expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company (any such change being referred to herein as a “**Material Adverse Change**”); (ii) the Company has not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company, or has entered into any transactions not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company and there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of capital stock, or any repurchase or redemption by the Company of any class of capital stock.

(i) **Independent Accountants.** PricewaterhouseCoopers LLP, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus, is (i) an independent registered public accounting firm as required by the Securities Act and the rules of the Public Company Accounting Oversight Board (“**PCAOB**”), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(j) **Financial Statements.** The financial statements filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus present fairly in all material respects the consolidated financial position of the Company as of the dates indicated and the results of their operations, changes in stockholders’ equity and cash flows for the periods specified. Such financial statements have been prepared in conformity with generally accepted accounting principles as applied in the United States applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. No other financial statements or supporting schedules are required to be included in the Registration Statement, the Time of Sale Prospectus or the Prospectus. The financial data set forth in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus under the captions “Prospectus Summary—Summary Financial Data,” “Selected Financial Data” and “Capitalization” fairly present in all material respects the information set forth therein on a basis consistent with that of the audited financial statements contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus. To the Company’s knowledge, no person who has been suspended or

barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(k) **Company's Accounting System.** The Company makes and keeps accurate books and records and maintain a system of internal accounting controls sufficient to provide reasonable assurance that:

(i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles as applied in the United States and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(l) **Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting.** The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the "Exchange Act")), which (i) are designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter; and (iii) are effective in all material respects to perform the functions for which they were established. Since the end of the Company's most recent audited fiscal year, there have been no significant deficiencies or material weakness in the Company's internal control over financial reporting (whether or not remediated) and no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(m) **Incorporation and Good Standing of the Company.** The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the State of North Carolina and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so qualified or in good standing could not reasonably be expected individually or in the aggregate to have a material adverse effect on the condition (financial or other), earnings, business, properties, operations, assets, liabilities or prospects of the Company (a "Material Adverse Effect").

(n) **Subsidiaries.** The Company has no "subsidiaries" (for purposes of this Agreement, as defined in Rule 405 under the Securities Act) and the Company does not own or control, directly or indirectly, any corporation, association or other entity.

(o) **Capitalization and Other Capital Stock Matters.** The authorized, issued and outstanding capital stock of the Company is as set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Capitalization" (other than for subsequent issuances, if any, pursuant to employee benefit plans, or upon the exercise of outstanding options or warrants, in each case described in

the Registration Statement, the Time of Sale Prospectus and the Prospectus). The Shares (including the Offered Shares) conform in all material respects to the description thereof contained in the Time of Sale Prospectus. All of the issued and outstanding Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all federal and state securities laws. None of the outstanding Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company other than those described in the Registration Statement, the Time of Sale Prospectus and the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus accurately and fairly presents the information required to be shown with respect to such plans, arrangements, options and rights.

(p) **Stock Exchange Listing.** The Offered Shares have been approved for listing on The Nasdaq Global Market ("Nasdaq"), subject only to official notice of issuance.

(q) **Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required.** The Company is not in violation of its charter or by-laws, or similar organizational documents, and is not in default (or, with the giving of notice or lapse of time, would be in default) ("Default") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company is a party or by which it may be bound, or to which any of its properties or assets are subject (each, an "Existing Instrument"), except for such Defaults as would reasonably not be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company's execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus and the issuance and sale of the Offered Shares (including the use of proceeds from the sale of the Offered Shares as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Use of Proceeds") (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, or similar organizational documents, of the Company, (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, or require the consent of any other party to, any Existing Instrument, except as could reasonably not be expected, individually or in the aggregate, to have a Material Adverse Effect, and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or the Financial Industry Regulatory Authority, Inc. ("FINRA"). As used herein, a "Debt Repayment Triggering Event" means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company.

(r) **Compliance with Laws.** The Company has been and is in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance would reasonably not be expected, individually or in the aggregate, to have a Material Adverse Effect.

(s) **No Material Actions or Proceedings.** Except as disclosed in the Registration Statement, the Time of Sale Prospectus of the Prospectus, there is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company, which would be reasonably expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company is a party or of which its properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not reasonably be expected to have a Material Adverse Effect. No material labor dispute with the employees of the Company, or with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or, to the knowledge of the Company, is threatened or imminent.

(t) **Intellectual Property Rights.** The Company owns, or has obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as being owned or licensed by it or which are necessary for the conduct of its business as currently conducted or as currently proposed to be conducted, in each case as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus (collectively, "**Intellectual Property**"), except for such exceptions as could not be expected, individually or in the aggregate, to have a Material Adverse Effect. To the Company's knowledge: (i) there are no third parties who have rights to any Intellectual Property, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus as licensed to the Company; and (ii) there is no infringement by third parties of any Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company's rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the Time of Sale Prospectus or the Prospectus as under development, infringe or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. The Company has complied in all material respects with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company, and all such agreements are in full force and effect. The product candidates described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as under development by the Company fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company.

(u) **All Necessary Permits, etc.** The Company possesses such valid and current certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct its business as currently conducted and as described in the Registration Statement, the Time of Sale Prospectus or the Prospectus ("**Permits**"), except for such exceptions as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company is not in violation of, or in default under, any of the Permits and has not received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit, except

for such exceptions as would reasonably not be expected, individually or in the aggregate, to have a Material Adverse Effect. The representations and warranties contained in this Section 1(u) do not apply to any matter the subject matter of which is specifically covered by Section 1(o) below.

(v) **Title to Properties.** The Company owns no real property. The Company has good and marketable title to all of the personal property and other assets reflected as owned in the financial statements referred to in Section 1(j) above (or elsewhere in the Registration Statement, the Time of Sale Prospectus or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects. The real property, improvements, equipment and personal property held under lease by the Company are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company. The representations and warranties contained in this Section 1(v) do not apply to any matter the subject matter of which is specifically covered by Section 1(t) above.

(w) **Tax Law Compliance.** The Company has filed all necessary federal, state and foreign income and franchise tax returns or have properly requested extensions thereof and have paid all taxes required to be paid by it and, if due and payable, any related or similar assessment, fine or penalty levied against it except as may be being contested in good faith and by appropriate proceedings, except for such exceptions as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 1(j) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company has not been finally determined.

(x) **Insurance.** The Company is insured by recognized, financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are generally deemed adequate and customary, in the reasonable judgement of the Company's Board of Directors, for its business including, but not limited to, policies covering real and personal property owned or leased by the Company against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company for product liability claims and clinical trial liability claims. The Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Effect. The Company has not been denied any insurance coverage which it has sought or for which it has applied.

(y) **Compliance with Environmental Laws.** Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (i) the Company is not in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "**Hazardous Materials**") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "**Environmental Laws**"); (ii) the Company has all permits, authorizations and approvals required under any applicable Environmental Laws and is in compliance with their requirements; (iii) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company; and (iv) to the Company's knowledge, there are

no events or circumstances existing as of the date hereof that might reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company relating to Hazardous Materials or any Environmental Laws.

(z) **ERISA Compliance.** The Company and any “employee benefit plan” (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, “ERISA”)) established or maintained by the Company or its “ERISA Affiliates” (as defined below) are in compliance in all material respects with ERISA. “ERISA Affiliate” means, with respect to the Company, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the “Code”) of which the Company is a member. No “reportable event” (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any “employee benefit plan” established or maintained by the Company or any of its ERISA Affiliates. No “employee benefit plan” established or maintained by the Company or any of its ERISA Affiliates, if such “employee benefit plan” were terminated, would have any “amount of unfunded benefit liabilities” (as defined under ERISA). Neither the Company nor any of its ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any “employee benefit plan” or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each employee benefit plan established or maintained by the Company or any of its ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification.

(aa) **Company Not an “Investment Company.”** The Company is not, and will not be, either after receipt of payment for the Offered Shares or after the application of the proceeds therefrom as described under “Use of Proceeds” in the Registration Statement, the Time of Sale Prospectus or the Prospectus, required to register as an “investment company” under the Investment Company Act of 1940, as amended (the “Investment Company Act”).

(bb) **No Price Stabilization or Manipulation; Compliance with Regulation M.** The Company has not taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Shares or of any “reference security” (as defined in Rule 100 of Regulation M under the Exchange Act (“Regulation M”)) with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(cc) **Related-Party Transactions.** There are no business relationships or related-party transactions involving the Company or any other person required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus that have not been described as required.

(dd) **FINRA Matters.** All of the information provided to the Underwriters or to counsel for the Underwriters by the Company, its counsel, its officers and directors and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Offered Shares is true, complete, correct and compliant with FINRA’s rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct.

(ee) **Parties to Lock-Up Agreements.** The Company has furnished to the Underwriters a letter agreement substantially in the form attached hereto as Exhibit A (the “Lock-up Agreement”) from each of the persons listed on Exhibit B. Such Exhibit B lists under an appropriate caption the directors and officers of the Company. If any additional persons shall become directors or officers (as defined in Rule

16a-1(f) under the Exchange Act) of the Company prior to the end of the Company Lock-up Period (as defined below), the Company shall cause each such person, prior to or contemporaneously with their appointment or election as a director or officer of the Company, to execute and deliver to the Representatives a Lock-up Agreement.

(ff) **Statistical and Market-Related Data.** All statistical, demographic and market-related data included in the Registration Statement, the Time of Sale Prospectus or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate. To the extent required, the Company has obtained the written consent to the use of such data from such sources.

(gg) **No Unlawful Contributions or Other Payments.** Neither the Company nor, to the best of the Company's knowledge, any employee or agent of the Company, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law or of the character required to be disclosed in the Registration Statement, the Time of Sale Prospectus or the Prospectus.

(hh) **Foreign Corrupt Practices Act.** Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company has, in the course of its actions for, or on behalf of, the Company (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made any direct or indirect unlawful payment to any domestic government official, "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "FCPA") or employee from corporate funds; (iii) violated or is in violation of any provision of the FCPA or any applicable non-U.S. anti-bribery statute or regulation; or (iv) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any domestic government official, such foreign official or employee; and the Company and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(ii) **Money Laundering Laws.** The operations of the Company are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(jj) **OFAC.** Neither the Company nor, to the knowledge of the Company, after due inquiry, any director, officer, agent, employee, affiliate or person acting on behalf of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, or any joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person, or in any country or territory, that currently is the subject to any U.S. sanctions administered by OFAC or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of U.S. sanctions administered by OFAC.

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(kk) **Brokers.** Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(ll) **Forward-Looking Statements.** Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement, the Time of Sale Prospectus or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that it was false or misleading.

(mm) **Emerging Growth Company Status.** From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged in any Section 5(d) Written Communication or any Section 5(d) Oral Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company").

(nn) **Communications.** The Company (i) has not alone engaged in communications with potential investors in reliance on Section 5(d) of the Securities Act other than Permitted Section 5(d) Communications with the consent of the Representatives with entities that are QIBs or IAs and (ii) has not authorized anyone other than the Representatives to engage in such communications; the Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Marketing Materials, Section 5(d) Oral Communications and Section 5(d) Written Communications; as of the Applicable Time, each Permitted Section 5(d) Communication, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each Permitted Section 5(d) Communication, if any, does not, as of the date hereof, conflict with the information contained in the Registration Statement, the Preliminary Prospectus and the Prospectus; and the Company has filed publicly on EDGAR at least forty-eight hours prior to the Applicable Time, any confidentially submitted registration statement and registration statement amendments relating to the offer and sale of the Offered Shares.

(oo) **Clinical Data and Regulatory Compliance.** The preclinical tests and clinical trials, and other studies (collectively, "studies") that are described in, or the results of which are referred to in, the Registration Statement, the Time of Sale Prospectus or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company has no knowledge of any other studies the results of which are materially inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Time of Sale Prospectuses or the Prospectus; the Company has made all such filings and obtained all such approvals as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "Regulatory Agencies") based on the location and nature of the relevant study; the Company has not received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement, the Time of Sale Prospectus or the Prospectus; and the Company has

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operated and currently is in compliance in all material respects with all applicable rules, regulations and policies of the Regulatory Agencies.

**(pp) Compliance with Health Care Laws.** The Company is, and at all times has been, in material compliance with all applicable Health Care Laws. For purposes of this Agreement, "**Health Care Laws**" means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; (ii) all applicable federal, state, local and foreign health care laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil Monetary Penalties Law (42 U.S.C. Section 1320a-7a), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), all applicable federal, state, local and all foreign criminal laws relating to health care fraud and abuse, including but not limited to the U.S. False Statements Law (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. Section 1320a-7), the statutes, regulations and directives of applicable government funded or sponsored healthcare programs, and the regulations promulgated pursuant to such statutes; (iii) to the extent applicable, the Standards for Privacy of Individually Identifiable Health Information (the "**Privacy Rule**"), the Security Standards, and the Standards for Electronic Transactions and Code Sets promulgated under HIPAA, the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated thereunder and any state or non-U.S. counterpart thereof or other law or regulation the purpose of which is to protect the privacy of individuals or prescribers; (iv) the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, the regulations promulgated thereunder; (v) the U.S. Controlled Substances Act (21 U.S.C. Section 801 et seq.); (vi) licensure, quality, safety and accreditation requirements under applicable federal, state, local or foreign laws or regulatory bodies; and (vii) all other local, state, federal, national, supranational and foreign laws, relating to the regulation of the Company. The Company has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other material action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Health Care Laws nor is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened. The Company has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were in all material respects timely, complete, accurate and not misleading on the date filed (or were corrected or supplemented by a subsequent submission). The Company is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company nor any of its employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

**(qq) No Rights to Purchase Preferred Stock.** The issuance and sale of the Shares as contemplated hereby will not cause any holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company to have any right to acquire any shares of preferred stock of the Company.

**(rr) No Contract Terminations.** The Company has not sent or received any communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in any preliminary prospectus, the Prospectus or any free writing prospectus, or referred to or described in, or filed as an exhibit to, the Registration Statement, and no such termination or non-renewal has been

threatened by the Company or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

Any certificate signed by any officer of the Company and delivered to any Underwriter or to counsel for the Underwriters in connection with the offering, or the purchase and sale, of the Offered Shares shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

The Company has a reasonable basis for making each of the representations set forth in this Section 1. The Company acknowledges that the Underwriters and, for purposes of the opinions to be delivered pursuant to Section 6 hereof, counsel to the Company and counsel to the Underwriters, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

**Section 2. Purchase, Sale and Delivery of the Offered Shares.**

(a) **The Firm Shares.** Upon the terms herein set forth, the Company agrees to issue and sell to the several Underwriters an aggregate of [•] Firm Shares. On the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Underwriters agree, severally and not jointly, to purchase from the Company the respective number of Firm Shares set forth opposite their names on Schedule A. The purchase price per Firm Share to be paid by the several Underwriters to the Company shall be \$[•] per share.

(b) **The First Closing Date.** Delivery of the book-entry positions for the Firm Shares to be purchased by the Underwriters and payment therefor shall be made at the offices of Cooley LLP (or such other place as may be agreed to by the Company and the Representatives) at [9:00] a.m. New York City time, on [•], 2019, or such other time and date not later than 1:30 p.m. New York City time, on [the date that is 10 business days following the initial contemplated closing] as the Representatives shall designate by notice to the Company (the time and date of such closing are called the "**First Closing Date**"). The Company hereby acknowledges that circumstances under which the Representatives may provide notice to postpone the First Closing Date as originally scheduled include, but are not limited to, any determination by the Company or the Representatives to recirculate to the public copies of an amended or supplemented Prospectus or a delay as contemplated by the provisions of Section 11.

(c) **The Optional Shares; Option Closing Date.** In addition, on the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to an aggregate of [•] Optional Shares from the Company at the purchase price per share to be paid by the Underwriters for the Firm Shares, less an amount per share equal to any dividend or distribution declared by the Company and payable on the Firm Shares but not payable on the Optional Shares. The option granted hereunder may be exercised at any time and from time to time in whole or in part upon notice by the Representatives to the Company, which notice may be given at any time within 30 days from the date of this Agreement. Such notice shall set forth (i) the aggregate number of Optional Shares as to which the Underwriters are exercising the option and (ii) the time, date and place for the electronic settlement for the Optional Shares (which time and date may be simultaneous with, but not earlier than, the First Closing Date; and in the event that such time and date are simultaneous with the First Closing Date, the term "**First Closing Date**" shall refer to the time and date of delivery of the book-entry positions for the Firm Shares and such Optional Shares). Any such time and date of delivery, if subsequent to the First Closing Date, is called an "**Option Closing Date**," shall be determined by the Representatives and shall not be earlier than two or later than five full business days after delivery of such notice of exercise. If any Optional Shares are to be purchased, each Underwriter agrees, severally and not jointly, to purchase the number of Optional Shares (subject to such adjustments to eliminate fractional

shares as the Representatives may determine) that bears the same proportion to the total number of Optional Shares to be purchased as the number of Firm Shares set forth on Schedule A opposite the name of such Underwriter bears to the total number of Firm Shares. The Representatives may cancel the option at any time prior to its expiration by giving written notice of such cancellation to the Company.

(d) **Public Offering of the Offered Shares.** The Representatives hereby advise the Company that the Underwriters intend to offer for sale to the public, initially on the terms set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus, their respective portions of the Offered Shares as soon after this Agreement has been executed and the Registration Statement has been declared effective as the Representatives, in their sole judgment, have determined is advisable and practicable.

(e) **Payment for the Offered Shares.** Payment for the Offered Shares shall be made at the First Closing Date (and, if applicable, at each Option Closing Date) by wire transfer of immediately available funds to the order of the Company.

(i) It is understood that the Representatives have been authorized, for their own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Shares and any Optional Shares the Underwriters have agreed to purchase. Each of Jefferies and Cowen, individually and not as the Representatives of the Underwriters, may (but shall not be obligated to) make payment for any Offered Shares to be purchased by any Underwriter whose funds shall not have been received by the Representatives by the First Closing Date or the applicable Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

(f) **Delivery of the Offered Shares.** The Company shall deliver, or cause to be delivered to the Representatives for the accounts of the several Underwriters the book-entry positions for the Firm Shares at the First Closing Date, against release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The Company shall also deliver, or cause to be delivered to the Representatives for the accounts of the several Underwriters, the book-entry positions for the Optional Shares the Underwriters have agreed to purchase at the First Closing Date or the applicable Option Closing Date, as the case may be, against the release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The book-entry positions for the Offered Shares shall be registered in such names and denominations as the Representatives shall have requested at least two full business days prior to the First Closing Date (or the applicable Option Closing Date, as the case may be) and shall be made available for inspection on the business day preceding the First Closing Date (or the applicable Option Closing Date, as the case may be) at a location in New York City as the Representatives may designate. Time shall be of the essence, and delivery at the time and place specified in this Agreement is a further condition to the obligations of the Underwriters.

### **Section 3. Additional Covenants.**

(a) **Delivery of Registration Statement, Time of Sale Prospectus and Prospectus.** The Company shall furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the business day next succeeding the date of this Agreement and during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) **Representatives' Review of Proposed Amendments and Supplements.** During the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether

physically or through compliance with Rule 172 under the Securities Act or any similar rule), the Company (i) will furnish to the Representatives for review, a reasonable period of time prior to the proposed time of filing of any proposed amendment or supplement to the Registration Statement, a copy of each such amendment or supplement and (ii) will not amend or supplement the Registration Statement without the Representatives' prior written consent. Prior to amending or supplementing any preliminary prospectus, the Time of Sale Prospectus or the Prospectus, the Company shall furnish to the Representatives for review, a reasonable amount of time prior to the time of filing or use of the proposed amendment or supplement, a copy of each such proposed amendment or supplement. The Company shall not file or use any such proposed amendment or supplement without the Representatives' prior written consent. The Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) **Free Writing Prospectuses.** The Company shall furnish to the Representatives for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto prepared by or on behalf of, used by, or referred to by the Company, and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Representatives' prior written consent. The Company shall furnish to each Underwriter, without charge, as many copies of any free writing prospectus prepared by or on behalf of, used by or referred to by the Company as such Underwriter may reasonably request. If at any time when a prospectus is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares (but in any event if at any time through and including the First Closing Date) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, as the case may be; *provided, however*, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Representatives for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus, and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Representatives' prior written consent.

(d) **Filing of Underwriter Free Writing Prospectuses.** The Company shall not take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that such Underwriter otherwise would not have been required to file thereunder.

(e) **Amendments and Supplements to Time of Sale Prospectus.** If the Time of Sale Prospectus is being used to solicit offers to buy the Offered Shares at a time when the Prospectus is not yet available to prospective purchasers, and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus so that the Time of Sale Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with

applicable law, the Company shall (subject to Section 3(b) and Section 3(c) hereof) promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the information contained in the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

**(f) Certain Notifications and Required Actions.** After the date of this Agreement, the Company shall promptly advise the Representatives in writing of: (i) the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus; (iii) the time and date that any post-effective amendment to the Registration Statement becomes effective; and (iv) the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus or the Prospectus or of any order preventing or suspending the use of any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its reasonable efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with all applicable provisions of Rule 424(b), Rule 433 and Rule 430A under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

**(g) Amendments and Supplements to the Prospectus and Other Securities Act Matters.** If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading, or if in the opinion of the Representatives or counsel for the Underwriters it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, the Company agrees (subject to Section 3(b) and Section 3(c)) hereof to promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law. Neither the Representatives' consent to, nor delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 3(b) or Section 3(c).

**(h) Blue Sky Compliance.** The Company shall cooperate with the Representatives and counsel for the Underwriters to qualify or register the Offered Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Representatives, shall comply with such laws and shall continue such

qualifications, registrations and exemptions in effect so long as required for the distribution of the Offered Shares. Notwithstanding the foregoing, the Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified. The Company will advise the Representatives promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Offered Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its reasonable efforts to obtain the withdrawal thereof at the earliest possible moment.

(i) **Use of Proceeds.** The Company shall apply the net proceeds from the sale of the Offered Shares sold by it in the manner described under the caption "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(j) **Transfer Agent.** The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(k) **Earnings Statement.** The Company will make generally available to its security holders and to the Representatives as soon as practicable an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company commencing after the date of this Agreement that will satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(l) **Continued Compliance with Securities Laws.** The Company will comply with the Securities Act and the Exchange Act so as to permit the completion of the distribution of the Offered Shares as contemplated by this Agreement, the Registration Statement, the Time of Sale Prospectus and the Prospectus. Without limiting the generality of the foregoing, the Company will, during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), file on a timely basis with the Commission and Nasdaq all reports and documents required to be filed under the Exchange Act.

(m) **Listing.** The Company will use its best efforts to list, subject to notice of issuance, the Offered Shares on Nasdaq.

(n) **Company to Provide Copy of the Prospectus in Form That May be Downloaded from the Internet.** If requested by the Representatives, the Company shall cause to be prepared and delivered, at its expense, within one business day from the effective date of this Agreement, to the Representatives an "**electronic Prospectus**" to be used by the Underwriters in connection with the offering and sale of the Offered Shares. As used herein, the term "**electronic Prospectus**" means a form of Time of Sale Prospectus, and any amendment or supplement thereto, that meets each of the following conditions: (i) it shall be encoded in an electronic format, satisfactory to the Representatives, that may be transmitted electronically by the Representatives and the other Underwriters to offerees and purchasers of the Offered Shares; (ii) it shall disclose the same information as the paper Time of Sale Prospectus, except to the extent that graphic and image material cannot be disseminated electronically, in which case such graphic and image material shall be replaced in the electronic Prospectus with a fair and accurate narrative description or tabular representation of such material, as appropriate; and (iii) it shall be in or convertible into a paper format or an electronic format, satisfactory to the Representatives, that will allow investors to store and have continuously ready access to the Time of Sale Prospectus at any future time, without charge to investors (other than any fee charged for subscription to the Internet as a whole and for on-line time). The Company hereby confirms that it has included or will include in the Prospectus filed pursuant to EDGAR

or otherwise with the Commission and in the Registration Statement at the time it was declared effective an undertaking that, upon receipt of a request by an investor or his or her representative, the Company shall transmit or cause to be transmitted promptly, without charge, a paper copy of the Time of Sale Prospectus.

(o) **Agreement Not to Offer or Sell Additional Shares.** During the period commencing on and including the date hereof and continuing through and including the 90th day following the date of the Prospectus (such period, as extended as described below, being referred to herein as the “**Lock-up Period**”), the Company will not, without the prior written consent of the Representatives (which consent may be withheld in their sole discretion), directly or indirectly: (i) sell, offer to sell, contract to sell or lend any Shares or Related Securities (as defined below); (ii) effect any short sale, or establish or increase any “put equivalent position” (as defined in Rule 16a-1(h) under the Exchange Act) or liquidate or decrease any “call equivalent position” (as defined in Rule 16a-1(b) under the Exchange Act) of any Shares or Related Securities; (iii) pledge, hypothecate or grant any security interest in any Shares or Related Securities; (iv) in any other way transfer or dispose of any Shares or Related Securities; (v) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise; (vi) announce the offering of any Shares or Related Securities; (vii) file any registration statement under the Securities Act in respect of any Shares or Related Securities (other than as contemplated by this Agreement with respect to the Offered Shares); or (viii) publicly announce the intention to do any of the foregoing; *provided, however*, that the Company may (A) effect the transactions contemplated hereby, (B) issue Shares or options to purchase Shares, or issue Shares upon exercise of options, pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and (C) issue Shares upon the exercise of outstanding warrants described in the Registration Statement, the Time of Sale Prospectus and the Prospectus; *provided, however*, under clauses (B) and (C) above, only if the recipients of such equity awards or Shares agree in writing with the Underwriters not to sell, offer, dispose of or otherwise transfer any such Shares or options during such Lock-up Period without the prior written consent of the Representatives (which consent may be withheld in their sole discretion). For purposes of the foregoing, “**Related Securities**” shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for, or convertible into, Shares.

(p) **Future Reports to the Representatives.** During the period of five years hereafter, the Company will furnish to the Representatives, c/o Jefferies, at 520 Madison Avenue, New York, New York 10022, Attention: Global Head of Syndicate, and Cowen and Company, LLC, 599 Lexington Avenue, New York, NY 10022, Attention: Head of Equity Capital Markets: (i) as soon as practicable after the end of each fiscal year, copies of the Annual Report of the Company containing the balance sheet of the Company as of the close of such fiscal year and statements of income, stockholders’ equity and cash flows for the year then ended and the opinion thereon of the Company’s independent public or certified public accountants; (ii) as soon as practicable after the filing thereof, copies of each proxy statement, Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other report filed by the Company with the Commission or any securities exchange; and (iii) as soon as available, copies of any report or communication of the Company furnished or made available generally to holders of its capital stock; *provided, however*, that the requirements of this Section 3(q) shall be satisfied to the extent that such reports, statement, communications, financial statements or other documents are available on EDGAR.

(q) **Investment Limitation.** The Company shall not invest or otherwise use the proceeds received by the Company from its sale of the Offered Shares in such a manner as would require the Company to register as an investment company under the Investment Company Act.

(r) **No Stabilization or Manipulation; Compliance with Regulation M.** The Company will not take, and will ensure that no affiliate of the Company will take, directly or indirectly, any action designed to or that might cause or result in stabilization or manipulation of the price of the Shares or any reference security with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and the Company will, and shall cause each of its affiliates to, comply with all applicable provisions of Regulation M.

(s) **Enforce Lock-Up Agreements.** During the Lock-up Period, the Company will enforce all agreements between the Company and any of its security holders that restrict or prohibit, expressly or in operation, the offer, sale or transfer of Shares or Related Securities or any of the other actions restricted or prohibited under the terms of the form of Lock-up Agreement. In addition, the Company will direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such "lock-up" agreements for the duration of the periods contemplated in such agreements, including, without limitation, "lock-up" agreements entered into by the Company's officers and directors and stockholders pursuant to Section 6(i) hereof.

(t) **Company to Provide Interim Financial Statements.** Prior to the First Closing Date and each applicable Option Closing Date, the Company will furnish the Underwriters, as soon as they have been prepared by or are available to the Company, a copy of any unaudited interim financial statements of the Company for any period subsequent to the period covered by the most recent financial statements appearing in the Registration Statement and the Prospectus.

(u) **Amendments and Supplements to Permitted Section 5(d) Communications.** If at any time following the distribution of any Permitted Section 5(d) Communication, there occurred or occurs an event or development as a result of which such Permitted Section 5(d) Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Permitted Section 5(d) Communication to eliminate or correct such untrue statement or omission.

(v) **Emerging Growth Company Status.** The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) the time when a prospectus relating to the Offered Shares is not required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) and (ii) the expiration of the Lock-Up Period (as defined herein).

The Representatives, on behalf of the several Underwriters, may, in their sole discretion, waive in writing the performance by the Company of any one or more of the foregoing covenants or extend the time for their performance.

**Section 4. Payment of Expenses.** The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Offered Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Shares, (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Offered Shares to the Underwriters, (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Time of Sale Prospectus, the Prospectus, each free writing prospectus prepared by or on

behalf of, used by, or referred to by the Company, and each preliminary prospectus, each Permitted Section 5(d) Communication, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Underwriters in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Offered Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Representatives, preparing and printing a "Blue Sky Survey" or memorandum and a "Canadian wrapper", and any supplements thereto, advising the Underwriters of such qualifications, registrations and exemptions, (vii) the costs, fees and expenses incurred by the Underwriters in connection with determining their compliance with the rules and regulations of FINRA related to the Underwriters' participation in the offering and distribution of the Offered Shares, including any related filing fees and the legal fees of, and disbursements by, counsel to the Underwriters, (viii) the costs and expenses of the Company relating to investor presentations on any "road show", any Permitted Section 5(d) Communication or any Section 5(d) Oral Communication undertaken in connection with the offering of the Offered Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and any such consultants, and one half of the cost of any aircraft chartered in connection with the road show, with the other half being paid by the Underwriters, (ix) the fees and expenses associated with listing the Offered Shares on Nasdaq and (x) all other fees, costs and expenses of the nature referred to in Item 13 of Part II of the Registration Statement, *provided, however*, that the Company shall not be responsible for any costs, fees and expenses of the Underwriters related to clauses (vi) or (vii) in excess of \$25,000 in the aggregate. Except as provided in this Section 4 or in Section 7, Section 9 or Section 10 hereof, the Underwriters shall pay their own expenses, including the fees and disbursements of their counsel.

**Section 5. Covenant of the Underwriters.** Each Underwriter severally and not jointly covenants with the Company not to take any action that would result in the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not, but for such actions, be required to be filed by the Company under Rule 433(d).

**Section 6. Conditions of the Obligations of the Underwriters.** The respective obligations of the several Underwriters hereunder to purchase and pay for the Offered Shares as provided herein on the First Closing Date and, with respect to the Optional Shares, each Option Closing Date, shall be subject to the accuracy of the representations and warranties on the part of the Company set forth in Section 1 hereof as of the date hereof and as of the First Closing Date as though then made and, with respect to the Optional Shares, as of each Option Closing Date as though then made, to the timely performance by the Company of its covenants and other obligations hereunder, and to each of the following additional conditions:

(a) **Comfort Letter.** On the date hereof, the Representatives shall have received from PricewaterhouseCoopers LLP, independent registered public accountants for the Company, a letter dated the date hereof addressed to the Underwriters, in form and substance satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus, and each free writing prospectus, if any.

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(b) **Compliance with Registration Requirements; No Stop Order; No Objection from FINRA.**

(i) The Company shall have filed the Prospectus with the Commission (including the information required by Rule 430A under the Securities Act) in the manner and within the time period required by Rule 424(b) under the Securities Act; or the Company shall have filed a post-effective amendment to the Registration Statement containing the information required by such Rule 430A, and such post-effective amendment shall have become effective.

(ii) No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment to the Registration Statement shall be in effect, and no proceedings for such purpose shall have been instituted or threatened by the Commission.

(iii) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(c) **No Material Adverse Change or Ratings Agency Change.** For the period from and after the date of this Agreement and through and including the First Closing Date and, with respect to any Optional Shares purchased after the First Closing Date, each Option Closing Date:

(i) in the judgment of the Representatives there shall not have occurred any Material Adverse Change; and

(ii) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company by any "nationally recognized statistical rating organization" as that term is used in Rule 15c3-1(c)(2)(vi)(F) under the Exchange Act.

(d) **Opinion of Counsel for the Company.** On each of the First Closing Date and each Option Closing Date the Representatives shall have received the opinion of DLA Piper LLP (US), counsel for the Company, in form and substance satisfactory to the Underwriters, dated as of such date.

(e) **Opinion of Morgan, Lewis & Bockius LLP.** On each of the First Closing Date and each Option Closing Date, the Representatives shall have received the opinion of Morgan, Lewis & Bockius LLP, counsel for the Company with respect to intellectual property matters, in form and substance satisfactory to the Underwriters, dated as of such date.

(f) **Opinion of Counsel for the Underwriters.** On each of the First Closing Date and each Option Closing Date the Representatives shall have received the opinion of Cooley LLP, counsel for the Underwriters in connection with the offer and sale of the Offered Shares, in form and substance satisfactory to the Underwriters, dated as of such date.

(g) **Officers' Certificate.** On each of the First Closing Date and each Option Closing Date, the Representatives shall have received a certificate executed by the Chief Executive Officer or President of the Company and the Chief Financial Officer of the Company, dated as of such date, to the effect set forth in Section 6(b)(ii) and further to the effect that:

(i) for the period from and including the date of this Agreement through and including such date, there has not occurred any Material Adverse Change;

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(ii) the representations, warranties and covenants of the Company set forth in Section 1 of this Agreement are true and correct with the same force and effect as though expressly made on and as of such date; and

(iii) the Company has complied with all the agreements hereunder and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such date.

(h) **Bring-down Comfort Letter.** On each of the First Closing Date and each Option Closing Date the Representatives shall have received from PricewaterhouseCoopers LLP, independent registered public accountants for the Company, a letter dated such date, in form and substance satisfactory to the Representatives, which letter shall: (i) reaffirm the statements made in the letter furnished by them pursuant to Section 6(a), except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the First Closing Date or the applicable Option Closing Date, as the case may be; and (ii) cover certain financial information contained in the Prospectus.

(i) **Lock-Up Agreements.** On or prior to the date hereof, the Company shall have furnished to the Representatives an agreement substantially in the form of Exhibit A hereto from each of the persons listed on Exhibit B hereto, and each such agreement shall be in full force and effect on each of the First Closing Date and each Option Closing Date.

(j) **CFO Certificate.** On the date hereof and each of the First Closing Date and each Option Closing Date, the Representatives shall have received a certificate executed by the Chief Financial Officer of the Company, on behalf of the Company and not in his individual capacity dated as of such date, in form and substance satisfactory to the Underwriters.

(k) **Rule 462(b) Registration Statement.** In the event that a Rule 462(b) Registration Statement is filed in connection with the offering contemplated by this Agreement, such Rule 462(b) Registration Statement shall have been filed with the Commission on the date of this Agreement and shall have become effective automatically upon such filing.

(l) **Approval of Listing.** At the First Closing Date, the Offered Shares shall have been approved for listing on Nasdaq, subject only to official notice of issuance.

(m) **Additional Documents.** On or before each of the First Closing Date and each Option Closing Date, the Representatives and counsel for the Underwriters shall have received such information, documents and opinions as they may reasonably request for the purposes of enabling them to pass upon the issuance and sale of the Offered Shares as contemplated herein, or in order to evidence the accuracy of any of the representations and warranties, or the satisfaction of any of the conditions or agreements, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Offered Shares as contemplated herein and in connection with the other transactions contemplated by this Agreement shall be satisfactory in form and substance to the Representatives and counsel for the Underwriters.

If any condition specified in this Section 6 is not satisfied when and as required to be satisfied (unless waived by the Representatives), this Agreement may be terminated by the Representatives by notice from the Representatives to the Company at any time on or prior to the First Closing Date and, with respect to the Optional Shares, at any time on or prior to the applicable Option Closing Date, which termination shall be without liability on the part of any party to any other party, except that Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination.

**Section 7. Reimbursement of Underwriters' Expenses.** If this Agreement is terminated by the Representatives pursuant to Section 6, Section 11 or Section 12, or if the sale to the Underwriters of the Offered Shares on the First Closing Date is not consummated because of any refusal, inability or failure on the part of the Company to perform any agreement herein or to comply with any provision hereof, the Company agrees to reimburse the Representatives and the other Underwriters (or such Underwriters as have terminated this Agreement with respect to themselves), severally, upon demand for all reasonable and documented out-of-pocket expenses that shall have been reasonably incurred by the Representatives and the Underwriters in connection with the proposed purchase and the offering and sale of the Offered Shares, including, but not limited to, fees and disbursements of counsel, printing expenses, travel expenses, postage, facsimile and telephone charges.

**Section 8. Effectiveness of this Agreement.** This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

**Section 9. Indemnification.**

(a) **Indemnification of the Underwriters.** The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors, officers, employees and agents, and each person, if any, who controls any Underwriter within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which such Underwriter or such affiliate, director, officer, employee, agent or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Offered Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Company), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing), or the omission or alleged omission to state therein a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading; or (iii) any act or failure to act or any alleged act or failure to act by any Underwriter in connection with, or relating in any manner to, the Shares or the offering contemplated hereby, and which is included as part of or referred to in any loss, claim, damage, liability or action arising out of or based upon any matter covered by clause (i) or (ii) above; and to reimburse each Underwriter and each such affiliate, director, officer, employee, agent and controlling person for any and all reasonable expenses (including the reasonable fees and disbursements of counsel) as such expenses are incurred by such Underwriter or such affiliate, director, officer, employee, agent or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; *provided, however*, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company by the Representatives in writing expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any such free writing prospectus, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information consists of the information described in Section 9(b) below. The indemnity agreement set forth in this Section 9(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) **Indemnification of the Company, its Directors and Officers.** Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act, against any loss, claim, damage, liability or expense, as incurred, to which the Company, or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus, that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433 of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement) or the omission or alleged omission to state therein a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, such preliminary prospectus, the Time of Sale Prospectus, such free writing prospectus, such Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement), in reliance upon and in conformity with information relating to such Underwriter furnished to the Company by the Representatives in writing expressly for use therein; and to reimburse the Company, or any such director, officer or controlling person for any and all reasonable expenses (including the reasonable fees and disbursements of counsel) as such expenses are incurred by the Company, or any such director, officer or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The Company hereby acknowledges that the only information that the Representatives have furnished to the Company expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing) are the statements set forth in the first sentence of the third paragraph under the caption "Underwriting," the first sentence of the first paragraph under the section entitled "Commission and Expenses," the first sentence of the first paragraph under the section entitled "Stabilization," the first sentence of the first paragraph under the section entitled "Electronic Distribution" and the first paragraph and the first sentence of the second paragraph under the section entitled "Other Activities and Relationships," each under the caption "Underwriting" in the Preliminary Prospectus and the Prospectus. The indemnity agreement set forth in this Section 9(b) shall be in addition to any liabilities that each Underwriter may otherwise have.

(c) **Notifications and Other Indemnification Procedures.** Promptly after receipt by an indemnified party under this Section 9 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 9, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve the indemnifying party from any liability which it may have to any indemnified party to the extent the indemnifying party is not materially prejudiced as a proximate result of such failure and shall not in any event relieve the indemnifying party from any liability that it may have otherwise than on account of this indemnity agreement. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof

with counsel reasonably satisfactory to such indemnified party; *provided, however*, that if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 9 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the Representatives (in the case of counsel for the indemnified parties referred to in Section 9(a) above) or by the Company (in the case of counsel for the indemnified parties referred to in Section 9(b) above) or (ii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

**(d) Settlements.** The indemnifying party under this Section 9 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 9(c) hereof, the indemnifying party shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and does not include an admission of fault or culpability or a failure to act by or on behalf of such indemnified party.

**Section 10. Contribution.** If the indemnification provided for in Section 9 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Offered Shares pursuant to this Agreement or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative

fault of the Company, on the one hand, and the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Offered Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total proceeds from the offering of the Offered Shares pursuant to this Agreement (before deducting expenses) received by the Company, and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth on the front cover page of the Prospectus, bear to the aggregate initial public offering price of the Offered Shares as set forth on such cover. The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriters, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 9(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 9(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 10; *provided, however*, that no additional notice shall be required with respect to any action for which notice has been given under Section 9(c) for purposes of indemnification.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 10 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 10.

Notwithstanding the provisions of this Section 10, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by such Underwriter in connection with the Offered Shares underwritten by it and distributed to the public. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute pursuant to this Section 10 are several, and not joint, in proportion to their respective underwriting commitments as set forth opposite their respective names on Schedule A. For purposes of this Section 10, each affiliate, director, officer, employee and agent of an Underwriter and each person, if any, who controls an Underwriter within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

**Section 11. Default of One or More of the Several Underwriters.** If, on the First Closing Date or any Option Closing Date any one or more of the several Underwriters shall fail or refuse to purchase Offered Shares that it or they have agreed to purchase hereunder on such date, and the aggregate number of Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase does not exceed 10% of the aggregate number of the Offered Shares to be purchased on such date, the Representatives may make arrangements satisfactory to the Company for the purchase of such Offered Shares by other persons, including any of the Underwriters, but if no such arrangements are made by such date, the other Underwriters shall be obligated, severally and not jointly, in the proportions that the number of Firm Shares set forth opposite their respective names on Schedule A bears to the

aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as may be specified by the Representatives with the consent of the non-defaulting Underwriters, to purchase the Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date. If, on the First Closing Date or any Option Closing Date any one or more of the Underwriters shall fail or refuse to purchase Offered Shares and the aggregate number of Offered Shares with respect to which such default occurs exceeds 10% of the aggregate number of Offered Shares to be purchased on such date, and arrangements satisfactory to the Representatives and the Company for the purchase of such Offered Shares are not made within 48 hours after such default, this Agreement shall terminate without liability of any party to any other party except that the provisions of Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination. In any such case either the Representatives or the Company shall have the right to postpone the First Closing Date or the applicable Option Closing Date, as the case may be, but in no event for longer than seven days in order that the required changes, if any, to the Registration Statement and the Prospectus or any other documents or arrangements may be effected.

As used in this Agreement, the term “**Underwriter**” shall be deemed to include any person substituted for a defaulting Underwriter under this Section 11. Any action taken under this Section 11 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

**Section 12. Termination of this Agreement.** Prior to the purchase of the Firm Shares by the Underwriters on the First Closing Date, this Agreement may be terminated by the Representatives by notice given to the Company if at any time: (i) trading or quotation in any of the Company’s securities shall have been suspended or limited by the Commission or by Nasdaq, or trading in securities generally on either Nasdaq or the New York Stock Exchange shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges; (ii) a general banking moratorium shall have been declared by any of federal or New York authorities; (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States’ or international political, financial or economic conditions, as in the judgment of the Representatives is material and adverse and makes it impracticable to market the Offered Shares in the manner and on the terms described in the Time of Sale Prospectus or the Prospectus or to enforce contracts for the sale of securities; (iv) in the judgment of the Representatives there shall have occurred any Material Adverse Change; or (v) the Company shall have sustained a loss by strike, fire, flood, earthquake, accident or other calamity of such character as in the judgment of the Representatives may interfere materially with the conduct of the business and operations of the Company regardless of whether or not such loss shall have been insured. Any termination pursuant to this Section 12 shall be without liability on the part of (a) the Company to any Underwriter, except that the Company shall be obligated to reimburse the expenses of the Representatives and the Underwriters pursuant to Section 4 or Section 7 hereof or (b) any Underwriter to the Company; *provided, however*, that the provisions of Section 9 and Section 10 shall at all times be effective and shall survive such termination.

**Section 13. No Advisory or Fiduciary Relationship.** The Company acknowledges and agrees that (a) the purchase and sale of the Offered Shares pursuant to this Agreement, including the determination of the public offering price of the Offered Shares and any related discounts and commissions, is an arm’s-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering contemplated hereby and the process leading to such transaction, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company

with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company on other matters) and no Underwriter has any obligation to the Company with respect to the offering contemplated hereby except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

**Section 14. Representations and Indemnities to Survive Delivery.** The respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the several Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Offered Shares sold hereunder and any termination of this Agreement.

**Section 15. Notices.** All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Representatives:

Jefferies LLC  
520 Madison Avenue  
New York, New York 10022  
Facsimile: (646) 619-4437  
Attention: General Counsel

Cowen and Company, LLC  
599 Lexington Avenue  
New York, New York 10022  
Facsimile: (646) 562-1124  
Attention: General Counsel

with a copy to:  
(which shall not  
constitute notice)

Cooley LLP  
1299 Pennsylvania Ave NW, Suite 700  
Washington, DC 20004  
Facsimile: (202) 842-7899  
Attention: Brent B. Siler

If to the Company:

Liquidia Technologies, Inc.  
419 Davis Drive, Suite 100  
Morrisville, North Carolina 27560  
Facsimile: (919) 328-4400  
Attention: Neal Fowler

with a copy to:  
(which shall not  
constitute notice)

DLA Piper LLP (US)  
51 John F. Kennedy Parkway, Suite 120  
Short Hills, NJ 07078  
Facsimile: (973) 520-2573  
Attention: Andrew P. Gilbert

Any party hereto may change the address for receipt of communications by giving written notice to the others.

**Section 16. Successors.** This Agreement will inure to the benefit of and be binding upon the parties hereto, including any substitute Underwriters pursuant to Section 11 hereof, and to the benefit of the affiliates, directors, officers, employees, agents and controlling persons referred to in Section 9 and Section 10, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term “**successors**” shall not include any purchaser of the Offered Shares as such from any of the Underwriters merely by reason of such purchase.

**Section 17. Partial Unenforceability.** The invalidity or unenforceability of any section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph or provision hereof. If any section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

**Section 18. Governing Law Provisions.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby (“**Related Proceedings**”) may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the “**Specified Courts**”), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a “**Related Judgment**”), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party’s address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

**Section 19. General Provisions.** This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

Each of the parties hereto acknowledges that it is a sophisticated business person who was adequately represented by counsel during negotiations regarding the provisions hereof, including, without limitation, the indemnification provisions of Section 9 and the contribution provisions of Section 10, and is fully informed regarding said provisions. Each of the parties hereto further acknowledges that the provisions of Section 9 and Section 10 hereof fairly allocate the risks in light of the ability of the parties to investigate the Company, its affairs and its business in order to assure that adequate disclosure has been made in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, each free writing prospectus and the Prospectus (and any amendments and supplements to the foregoing), as contemplated by the Securities Act and the Exchange Act.

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms.

Very truly yours,

**LIQUIDIA TECHNOLOGIES, INC.**

By: \_\_\_\_\_

Name:

Title:

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The foregoing Underwriting Agreement is hereby confirmed and accepted by the Representatives in New York, New York as of the date first above written.

**JEFFERIES LLC**  
**COWEN AND COMPANY, LLC**  
Acting individually and as Representatives  
of the several Underwriters named in  
the attached Schedule A.

**JEFFERIES LLC**

By: \_\_\_\_\_

Name:

Title:

**COWEN AND COMPANY, LLC**

By: \_\_\_\_\_

Name:

Title:

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<b>Underwriters</b>	<b>Number of Firm Shares to be Purchased</b>
Jefferies LLC	[•]
Cowen & Company, LLC	[•]
Needham & Company, LLC	[•]
Wedbush PacGrow Healthcare	[•]
Total	[•]

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**Free Writing Prospectuses Included in the Time of Sale Prospectus**

[None.]

**Pricing Information Included in the Time of Sale Prospectus**

Price per share to the public:	\$	[•]
Number of shares being sold by the Company:		[•]
Number of shares potentially issuable pursuant to the option to purchase additional shares:		[•]

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Permitted Section 5(d) Communications

[None.]

Exhibit A

Form of Lock-Up Agreement

Jefferies LLC  
Cowen and Company, LLC  
As Representatives of the Several Underwriters

c/o Jefferies LLC  
520 Madison Avenue  
New York, New York 10022

and

c/o Cowen and Company, LLC  
599 Lexington Avenue  
New York, New York 10022

RE: Liquidia Technologies, Inc. (the "**Company**")

Ladies &amp; Gentlemen:

The undersigned is an owner of shares of common stock, par value \$0.001 per share, of the Company ("**Shares**") or of securities exchangeable or exercisable for Shares. The Company proposes to conduct a public offering of Shares (the "**Offering**") for which Jefferies LLC and Cowen and Company, LLC (each, a "**Representative**" and collectively, the "**Representatives**") will act as the representatives of the underwriters. The undersigned recognizes that the Offering will benefit each of the Company and the undersigned. The undersigned acknowledges that the underwriters are relying on the representations and agreements of the undersigned contained in this letter agreement in conducting the Offering and, at a subsequent date, in entering into an underwriting agreement (the "**Underwriting Agreement**") and other underwriting arrangements with the Company with respect to the Offering.

Annex A sets forth definitions for capitalized terms used in this letter agreement that are not defined in the body of this letter agreement. Those definitions are a part of this letter agreement.

In consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby agrees that, during the Lock-up Period, the undersigned will not (and will cause any Family Member not to), without the prior written consent of the Representatives, which may withhold their consent in their sole discretion:

- Sell or Offer to Sell any Shares or Related Securities currently or hereafter owned either of record or beneficially (as defined in Rule 13d-3 under the Exchange Act) by the undersigned or such Family Member,
- enter into any Swap,
- make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any Shares or Related Securities, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or
- publicly announce any intention to do any of the foregoing.

The foregoing will not apply to the registration of the offer and sale of the Shares, and the sale of the Shares to the underwriters, in each case as contemplated by the Underwriting Agreement. In addition, the foregoing restrictions shall not apply to (i) the establishment or amendment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Shares or Related Securities, *provided* that (x) no public announcement or filing under the Exchange Act shall be permitted with respect to the establishment or amendment of such trading plan, and (y) such plan shall not provide for or permit any transfers, sales or other dispositions during the Lock-up Period, or sales effected pursuant to a trading plan pursuant to Rule 10b5-1 under the Exchange Act that was in effect on the date hereof, *provided* that any filing required or voluntarily made under the Exchange Act shall note that such transaction was conducted pursuant to a pre-established 10b5-1 plan; (ii) the transfer of Shares or Related Securities by gift, or by will or intestate succession to a Family Member or to a trust whose beneficiaries consist exclusively of one or more of the undersigned and/or a Family Member, or to a charitable organization, (iii) transfers by operation of law, including pursuant to a court or regulatory agency order, a qualified domestic relations order or in connection with a divorce settlement, (iv) transfers as a distribution to limited partners, limited liability company members or stockholders of the undersigned, (v) transfers to a corporation, partnership, limited liability company, investment fund or other entity that controls or is controlled by, or is under common control with, the undersigned, or is wholly-owned by the undersigned, or, in the case of an investment fund, that is managed by, or is under common management with, the undersigned (including, for the avoidance of doubt, a fund managed by the same manager or managing member or general partner or management company or by an entity controlling, controlled by, or under common control with such manager or managing member or general partner or management company as the undersigned or who shares a common investment advisor with the undersigned), (vi) transfers of Shares or Related Securities pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of Shares or Related Securities involving a Change of Control of the Company, *provided* that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Shares or Related Securities owned by the undersigned shall remain subject to the restrictions contained in this letter agreement and (vii) transfers of Shares to cover the payment of taxes due upon or consideration required in connection with the vesting, conversion or exercise of securities issued under an equity incentive plan or stock purchase plan of the Company existing on the date hereof and described in the prospectus for which the Offering relates, including the withholding of Shares by, or surrender of Shares to, the Company or pursuant to a “net” or “cashless” exercise or settlement feature, *provided* that if the undersigned is required to make a filing under the Exchange Act, such filing shall include a footnote describing the purpose of the transaction; *provided, however*, that in any such case (except (i), (vi) and (vii)), it shall be a condition to such transfer that:

- each transferee executes and delivers to the Representatives an agreement in form and substance satisfactory to the Representatives stating that such transferee is receiving and holding such Shares and/or Related Securities subject to the provisions of this letter agreement and agrees not to Sell or Offer to Sell such Shares and/or Related Securities, engage in any Swap or engage in any other activities restricted under this letter agreement except in accordance with this letter agreement (as if such transferee had been an original signatory hereto),
- prior to the expiration of the Lock-up Period, no public disclosure or filing under the Exchange Act by any party to the transfer (donor, donee, transferor or transferee) shall be required, or made voluntarily, reporting a reduction in beneficial ownership of Shares in connection with such transfer, and
- any such transfers shall not involve a disposition for value.

“**Change of Control**” shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated

persons (other than an underwriter pursuant to the Offering), of the Company's voting securities if, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity)

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of Shares or Related Securities held by the undersigned and the undersigned's Family Members, if any, except in compliance with the foregoing restrictions.

With respect to the Offering only, the undersigned waives any registration rights relating to registration under the Securities Act of the offer and sale of any Shares and/or any Related Securities owned either of record or beneficially by the undersigned, including any rights to receive notice of the Offering.

The undersigned confirms that the undersigned has not, and has no knowledge that any Family Member has, directly or indirectly, taken any action designed to or that might reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale of the Shares. The undersigned will not, and will cause any Family Member not to take, directly or indirectly, any such action.

Whether or not the Offering occurs as currently contemplated or at all depends on market conditions and other factors. The Offering will only be made pursuant to the Underwriting Agreement, the terms of which are subject to negotiation between the Company and the underwriters.

The undersigned understands that, (i) if the Company notifies the Representatives in writing that it does not intend to proceed with the Offering, (ii) the purchase of the Firm Shares (as defined in the Underwriting Agreement) does not occur by March 31, 2019, or (iii) if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Stock to be sold thereunder, then the undersigned shall be released from all obligations under this letter agreement.

The undersigned hereby represents and warrants that the undersigned has full power, capacity and authority to enter into this letter agreement. This letter agreement is irrevocable and will be binding on the undersigned and the successors, heirs, personal representatives and assigns of the undersigned.

This letter agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

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Signature

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Printed Name of Person Signing

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Title

*(Indicate capacity of person signing if signing as custodian or trustee, or on behalf of an entity)*

**Certain Defined Terms**  
**Used in Lock-up Agreement**

For purposes of the letter agreement to which this Annex A is attached and of which it is made a part:

- “**Call Equivalent Position**” shall have the meaning set forth in Rule 16a-1(b) under the Exchange Act.
- “**Exchange Act**” shall mean the Securities Exchange Act of 1934, as amended.
- “**Family Member**” shall mean the spouse of the undersigned, an immediate family member of the undersigned or an immediate family member of the undersigned’s spouse, in each case living in the undersigned’s household or whose principal residence is the undersigned’s household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or otherwise). “**Immediate family member**” as used above shall have the meaning set forth in Rule 16a-1(e) under the Exchange Act.
- “**Lock-up Period**” shall mean the period beginning on the date hereof and continuing through the close of trading on the date that is 90 days after the date of the Prospectus (as defined in the Underwriting Agreement).
- “**Put Equivalent Position**” shall have the meaning set forth in Rule 16a-1(h) under the Exchange Act.
- “**Related Securities**” shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for or convertible into Shares.
- “**Securities Act**” shall mean the Securities Act of 1933, as amended.
- “**Sell or Offer to Sell**” shall mean to:
  - sell, offer to sell, contract to sell or lend,
  - effect any short sale or establish or increase a Put Equivalent Position or liquidate or decrease any Call Equivalent Position
  - pledge, hypothecate or grant any security interest in, or
  - in any other way transfer or dispose of,in each case whether effected directly or indirectly.
- “**Swap**” shall mean any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise.

Capitalized terms not defined in this Annex A shall have the meanings given to them in the body of this lock-up agreement.

[Attached under separate cover]

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

T: 973-520-2550  
F: 973-520-2551

Attorneys Responsible for Short Hills Office:

Andrew P. Gilbert  
Michael E. Helmer

March 18, 2019

Liquidia Technologies, Inc.  
419 Davis Drive, Suite 100  
Morrisville, North Carolina 27560

**Re: Registration Statement on Form S-1**

Ladies and Gentlemen:

We have acted as counsel to Liquidia Technologies, Inc., a Delaware corporation (the "**Company**"), in connection with a Registration Statement on Form S-1 (as amended and supplemented from time to time, the "**Registration Statement**") initially filed by the Company on March 18, 2019 with the Securities and Exchange Commission (the "**Commission**") under the Securities Act of 1933, as amended (the "**Securities Act**"). The Registration Statement relates to the offer and sale by the Company of up to an aggregate of 3,450,000 shares of the Company's common stock, par value \$0.001 per share, (all such shares, together with any additional shares of such stock that may be issued by the Company pursuant to Rule 462(b) (as prescribed by the Commission pursuant to the Securities Act), the "**Shares**"). We understand that the Shares are to be sold to the underwriters for resale to the public as described in the Registration Statement and pursuant to an underwriting agreement, substantially in the form filed as an exhibit to the Registration Statement, to be entered into by and among the Company and the representatives of the underwriters (the "**Underwriting Agreement**").

As the basis for the opinions hereinafter expressed, we have examined: (i) originals, or copies certified or otherwise identified, of (a) the Registration Statement; (b) certain resolutions of the Board of Directors of the Company; (c) the amended and restated certificate of incorporation of the Company (filed as Exhibit 3.1 to the Registration Statement), and the amended and restated bylaws of the Company (filed as Exhibit 3.2 to the Registration Statement); and (d) such other records, agreements, other instruments and documents as we have deemed necessary or advisable for the purposes of this opinion; and (ii) such statutes, including the Delaware General Corporation Law, and regulations as we have deemed necessary or advisable for the purposes of this opinion. We have not independently verified any factual matter relating to this opinion. As to questions of fact material to this opinion, we have relied upon certificates or comparable documents of public officials and of officers and representatives of the Company.

In our examination of the foregoing documents, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as copies, the authenticity of the originals of such latter documents and the legal competence of all signatories to such documents.

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We express no opinion other than as to the federal laws of the United States of America and the Delaware General Corporation Law (including the statutory provisions, the applicable provisions of the Delaware Constitution and reported judicial decisions interpreting the foregoing).

Based upon the foregoing, and subject to the qualifications, assumptions and limitations stated herein, we are of the opinion that upon payment and delivery of the Shares at the price per share approved by the Pricing Committee of the Board of Directors of the Company, the Shares will be validly issued, fully paid and nonassessable.

In addition to the qualifications set forth above, the foregoing opinion is further qualified as follows:

- (a) The foregoing opinion is rendered as of the date hereof. We assume no obligation to update such opinion to reflect any facts or circumstances that may hereafter come to our attention or changes in the law which may hereafter occur.
- (b) This opinion is limited to the matters set forth herein, and no other opinion should be inferred beyond the matters expressly stated.

We hereby consent to the use of this opinion as an exhibit to the Registration Statement, and we consent to the reference to this firm under the caption "Legal Matters" in the prospectus forming part of the Registration Statement. The giving of this consent, however, does not constitute an admission that we are "experts" within the meaning of Section 11 of the Securities Act or within the category of persons whose consent is required by Section 7 of the Securities Act.

Very truly yours,

/s/ **DLA Piper LLP (US)**

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Registration Statement on Form S-1 of Liquidia Technologies, Inc. of our report dated February 26, 2019, relating to the financial statements of Liquidia Technologies, Inc., which appears in this Registration Statement. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina  
March 18, 2019

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Consent of Decision Resources Group

We hereby consent to (1) the use of and references to our name in the prospectus included in the registration statement on Form S-1 of Liquidia Technologies, Inc. (the "Company") and any amendments thereto (the "Registration Statement"), including, but not limited to, under the "Market and Industry Data," "Prospectus Summary," and "Business" sections, and (2) the filing of this consent as an exhibit to the Registration Statement by the Company for the use of our data and information cited in the above-mentioned sections with data reference points outlined and described expressly within Schedule I hereto only. Any data or information not appearing within Schedule I hereto is not authorized for use and does not form part of this consent exhibit.

The data and information used in the Registration Statement, including, but not limited to, under the "Market and Industry Data," "Prospectus Summary," and "Business" sections and described on Schedule I hereto, are obtained from our materials titled "Research Stream — Disease Landscape and Forecast — All Therapy Areas (Inc. Niche & Rare) (DLSFTA0003)".

By: /s/ Wade Sampson  
Name: Wade Sampson  
Title: Director, Contracts  
DR/Decision Resources, LLC

March 18, 2019

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## Schedule I

Disclosure	Notes
PAH is a rare disease, with an estimated prevalence in the United States expected to be <b>approximately 30,000 patients</b> by 2020.	DRG, Disease Landscape & Forecast, PAH, Market Forecast Assumptions, Nov 2018 [=Epi!G10 = 31,360]
Decision Resources Group, an independent industry research firm, estimated that in <b>2017</b> products containing <b>treprostinil</b> across its three routes of administration (oral, inhaled and parenteral infusion) generated revenue that represented <b>about one-quarter</b> of the approximately <b>\$3.7 billion</b> U.S. market for PAH.	DRG, Disease Landscape & Forecast, PAH, Market Forecast Assumptions, Nov 2018 [='United States'!D7 = \$3,725.6]
As reported by Decision Resources Group, gross revenue in the U.S. market for PAH drug therapies in <b>2017</b> was estimated to be <b>\$3.7 billion</b> .	[= 'United States' SUM(D29,D49,D55,D66) = \$915.0] [\$915.0/\$3,725.6 = 25%]
Decision Resources Group estimated that sales for all major PAH drugs in <b>2017</b> were more than <b>\$3.7 billion</b> in the United States.	
Tyvaso® (treprostinil, inhalation solution), or <b>Tyvaso</b> , the inhaled form of treprostinil marketed by United Therapeutics Corporation in the United States, is the standard of care among the inhaled therapies, with <b>more than 80% of inhaled prostacyclin sales</b> in the United States.	DRG, Disease Landscape & Forecast, PAH, Market Forecast Assumptions, Nov 2018 [='United States'!D49/D48 = \$278/\$327.8 = 85%]
Products approved to treat PAH through the <b>prostacyclin</b> deficient pathway generated approximately <b>\$1.4 billion</b> in sales in <b>2017</b> , of which the prostacyclin analog <b>treprostinil</b> generated the <b>majority</b> from products formulated for continuous infusion, inhalation using a nebulizer and oral delivery, estimated to be approximately <b>\$915 million</b> .	DRG, Disease Landscape & Forecast, PAH, Market Forecast Assumptions, Nov 2018 [='United States'! SUM(D28,D48,D59)=\$1,416.6] [= 'United States' SUM(D29,D49,D55,D66) = \$915.0/\$1,416.6 = 65%]
The combined population of diagnosed prevalent <b>PAH patients</b> in the <b>5EU</b> and <b>Japan</b> was estimated to be <b>approximately 25,000 patients</b> in <b>2017</b> .	DRG, Disease Landscape & Forecast, PAH, Market Forecast Assumptions, Nov 2018 [=Epi!Sum(D226,D262) = 24,622] Japan (7,420), 5EU (17,202)

While considered underdiagnosed and undertreated, the current estimates for diagnosed prevalence of CTEPH are between 2,000 to **6,500 patients** in the **United States** and **more than 10,000 patients** in the **5EU markets and Japan**.

DRG, Disease Landscape & Forecast, PAH, Nov 2018, pg 69

Gall et al Eur Respir Rev 2017; 26:160121, pg 6-7 (see 2015: US 2,000; EU 1,128; Japan 732)

Decision Resources Group reported **that more than 80% of PAH patients on inhaled therapy** in the United States used **Tyvaso** in **2017**.

DRG, Disease Landscape & Forecast, PAH, Market Forecast Assumptions, Nov 2018  
[=United States!\*AF49/AF48]  
[ 2,130/2,434 = 88%]

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