

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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38601

**LIQUIDIA TECHNOLOGIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

20-1926605

(I.R.S. Employer Identification No.)

419 Davis Drive, Suite 100  
Morrisville, North Carolina

(Address of Principal Executive Offices)

27560

(Zip Code)

Registrant's telephone number, including area code: **(919) 328-4400**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

**Common stock, par value \$0.001 per share**

Name of each exchange on which registered

**NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large Accelerated Filer ☐

Accelerated Filer ☐

Non-accelerated Filer ☒

Smaller Reporting Company ☒

Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter (June 30, 2018) so a calculation of the aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant at such time is not possible.

As of February 22, 2019, there were 15,563,641 shares of the issuer's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Liquidia Technologies, Inc. definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year are incorporated by reference into Part III of this annual report on Form 10-K and certain documents are incorporated by reference into Part IV.



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This annual report on Form 10-K includes our trademarks, trade names and service marks, such as Liquidia, the Liquidia logo and PRINT, or Particle Replication In Non-wetting Templates, which are protected under applicable intellectual property laws and are the property of Liquidia Technologies, Inc. This annual report 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 annual report may appear without the ®, <sup>TM</sup> 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.

## Cautionary Note Regarding Forward-Looking Statements

This annual report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this annual report may be forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, but are also contained elsewhere in this annual report. 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 trial;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidate;
- the clinical utility of our product candidates and their potential advantages compared to other treatments;
- our commercialization, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates and the sufficiency of our current manufacturing facilities to produce development and commercial quantities of our product candidates;
- our ability to establish and maintain collaborations;
- our estimates regarding the market opportunities for our product candidates;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and
- our expected use of proceeds from the initial public 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 annual report 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 annual report 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 annual report. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this annual report on Form 10-K.

*Unless the context otherwise requires, references in this annual report to “we,” “us,” “our” and the “Company” refer to Liquidia Technologies, Inc., a Delaware corporation.*

## PART I

### Item 1. Business.

#### Overview

We are a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using our proprietary PRINT<sup>®</sup> 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<sup>®</sup> (treprostinil, inhaled solution), marketed by 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 January 7, 2019, we enrolled 109 patients in our INSPIRE trial, completing enrollment for the safety portion of the trial. LIQ861 was observed to be well-tolerated at the two-week timepoint. The safety data at the two-week timepoint addresses the FDA's request for inclusion of such data in an NDA submission. During this two-week time period, LIQ861 was evaluated at capsule strengths up to 125 mcg treprostinil with no study-drug related serious adverse events or dose-limiting toxicities observed. 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 are currently focusing our efforts on completing patient enrollment in 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. After review of an initial cohort of patients in our open-label INSPIRE trial we amended the INSPIRE protocol to adjust pharmacokinetic sub-study dosing levels of LIQ861 to more closely match Tyvaso dosing levels on an emitted dose basis. 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 the first quarter of 2019, complete these initial 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 safety portion of the trial. We are currently focusing our efforts on completing patient enrollment in 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 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 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 the first quarter of 2019. We anticipate that the initial Phase 2-enabling toxicology studies will result in LIQ865 being Phase 2-ready by the end of 2019, 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.

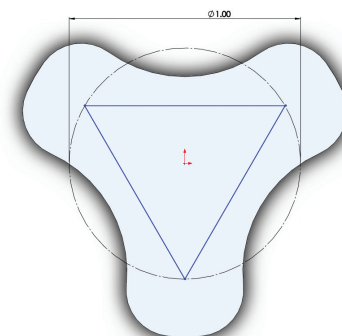
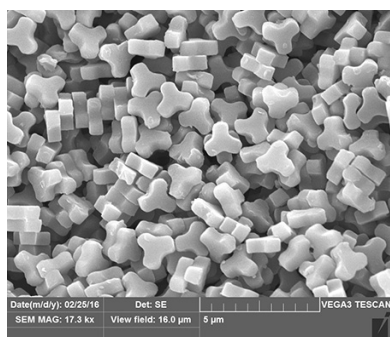
### *Potential Benefits of Our Approach*

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.

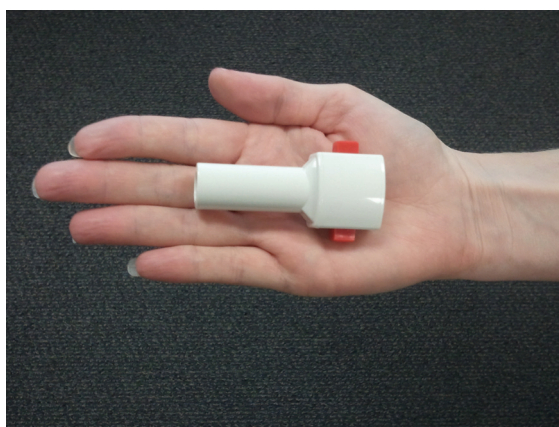
Inspired by a naturally occurring pollen, LIQ861 PRINT particles have a one micrometer trefoil-shape measured by an inscribed one micrometer circle as shown in the figure below. *In vitro* studies suggest that the uniformity of size and shape allow our inhaled particles to target delivery into the lungs 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 Plastiap 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<sup>®</sup>, 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. LIQ861 was observed to be well-tolerated at the two-week timepoint in PAH patients. The safety data at the two-week timepoint addresses the FDA's request for inclusion of such data in an NDA submission. During this two-week time period, LIQ861 was evaluated at capsule strengths up to 125 mcg treprostinil, with no study-drug related serious adverse events or dose-limiting toxicities observed. 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 are currently focusing our efforts on completing patient enrollment in 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. After review of an initial cohort of patients in our open-label INSPIRE trial, we amended the INSPIRE protocol to adjust pharmacokinetics sub-study dosing levels of LIQ861 to more closely match Tyvaso dosing levels on an emitted dose basis. We reported positive interim two-week safety data in January 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. 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 capsule 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.

Estimated TRE Dose from LIQ861				Estimated TRE Dose from Tyvaso	
Capsule (LIQ861 fill wt.)	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	

- (1) LIQ861 capsule treprostinil strength 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.
- (2) 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*

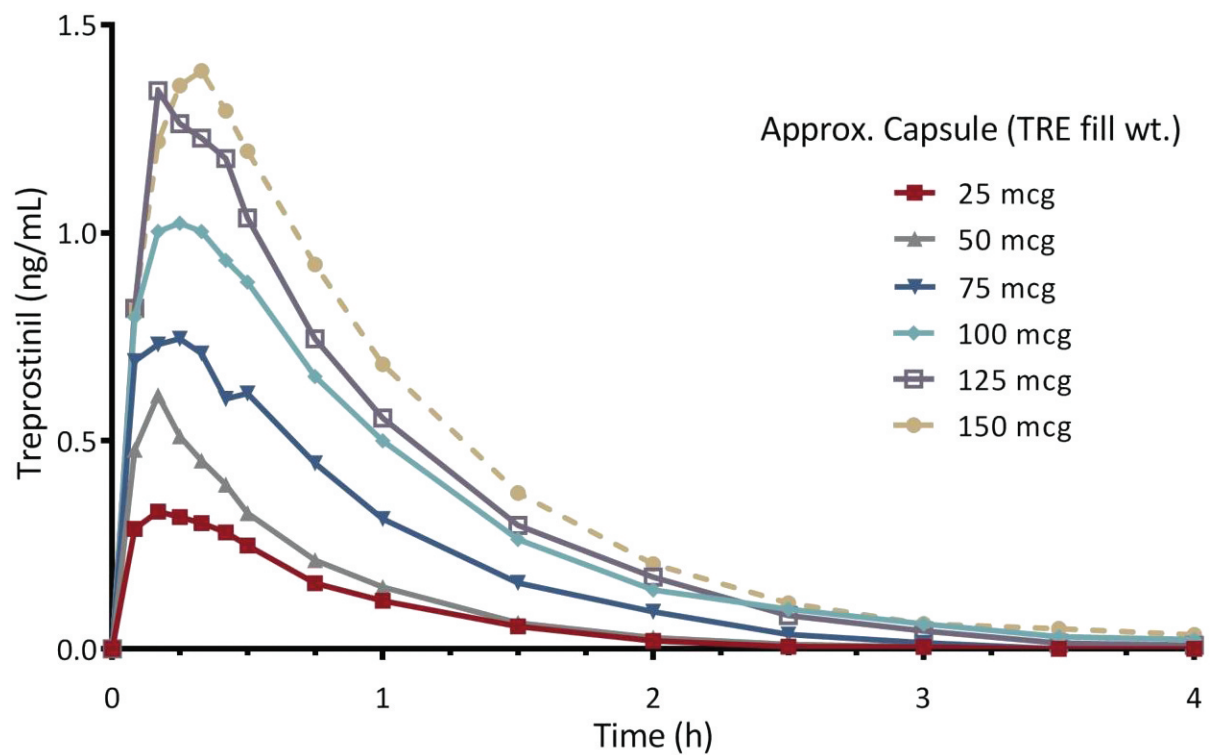
In the Phase 1 clinical trial, we escalated the treprostinil capsule strength of LIQ861 progressively from 25 mcg to 150 mcg. There were no dose-limiting toxicities at the highest dose evaluated. We noted no serious adverse events or deaths and all reported treatment-emergent adverse events, or TEAEs, 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
- $AUC_{\text{Inf}}$  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
<b>C<sub>max</sub> (ng/mL)</b>	0.329	0.572	0.728	1.08	1.19	1.33
<b>T<sub>max</sub> (h)</b>	0.21	0.18	0.25	0.29	0.24	0.31
<b>T<sub>½</sub> (h)</b>	0.507	0.434	0.617	0.722	0.523	0.648
<b>AUC<sub>inf</sub> (h*ng/mL)</b>	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<sup>®</sup>, 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.

LIQ861 was observed to be well-tolerated at the two-week timepoint in PAH patients. The safety data at the two-week timepoint addresses the FDA's request for inclusion of such data in an NDA submission. During this two-week time period, LIQ861 was evaluated at capsule strengths up to 125 mcg treprostinil, with no study-drug related serious adverse events or dose-limiting toxicities observed. Reported TEAEs were mostly mild in nature and consistent with inhaled prostacyclin therapy. As reported on January 7, 2019, the most common TEAEs reported with LIQ861 in  $\geq 4\%$  of the 109 PAH patients were cough (25%), headache (13%), throat irritation (12%), diarrhea (7%), dizziness (6%), oropharyngeal pain (5%) and chest discomfort (5%). Patients have continued to receive treatment beyond two weeks with the first patient dosed in March 2018. Additionally, we have one center dosing a patient above the 150 mcg treprostinil capsule strength. We are currently focusing our efforts on completing patient enrollment in 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. After review of an initial cohort of patients in our open-label INSPIRE trial, we amended the INSPIRE protocol to adjust pharmacokinetics sub-study dosing levels of LIQ861 to more closely match Tyvaso dosing levels on an emitted dose basis. We reported positive interim two-week safety data in January 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*

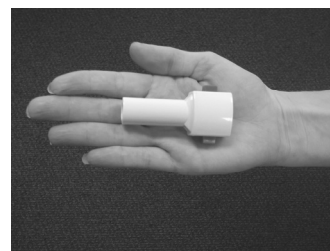
Decision Resources Group estimated that sales for all major PAH drugs in 2017 were more than \$3.7 billion in the United States. Products approved to treat PAH through the prostacyclin deficient pathway generated approximately \$1.4 billion in sales in 2017, of which the prostacyclin analog treprostinil 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.

	<b>Ventavis (iloprost) inhalation solution</b>	<b>Tyvaso (treprostinil) inhalation solution</b>	<b>LIQ861 (treprostinil) dry powder for inhalation (expected)</b>
<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

	Ventavis (iloprost) inhalation solution	Tyvaso (treprostinil) inhalation solution	LIQ861 (treprostinil) dry powder for inhalation (expected)
Supplies required	▪ Ventavis Inhalation System	▪ Tyvaso Inhalation System	▪ Dry powder inhaler
	▪ Power supply	▪ Rechargeable battery	▪ Carrying pouch
	▪ Distilled water	▪ 12V DC adapter	▪ Daily blister pack
	▪ 2 medication chamber assemblies	▪ AC wall plug	▪ Small cleaning brush
	▪ Washing basket	▪ 16 Medicine cups	
	▪ Battery charger	▪ Filter membranes	
	▪ I-neb pouch	▪ Plugs	
	▪ Carry bag	▪ Filter shell	
	▪ Power cord for charger	▪ Dome assembly with baffle plate	
	▪ 2 Spare discs	▪ Inhalation piece	
		▪ Mouthpiece	
		▪ Water level cup	
		▪ Carrying case	
		▪ Distilled water carrier	

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 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 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 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 Uptravi 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.

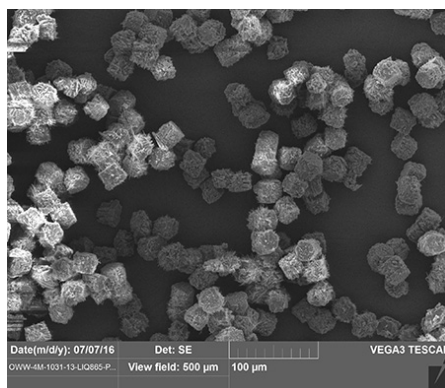
NSAIDs and other non-opioids for pain relief in the post-operative period are also associated with various undesirable side effects. Bleeding and gastrointestinal and renal complications may result from NSAID use. Acetaminophen can cause liver injury or failure with excessive dosing. As a result, we 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 the first quarter of 2019.

#### *Clinical Development*

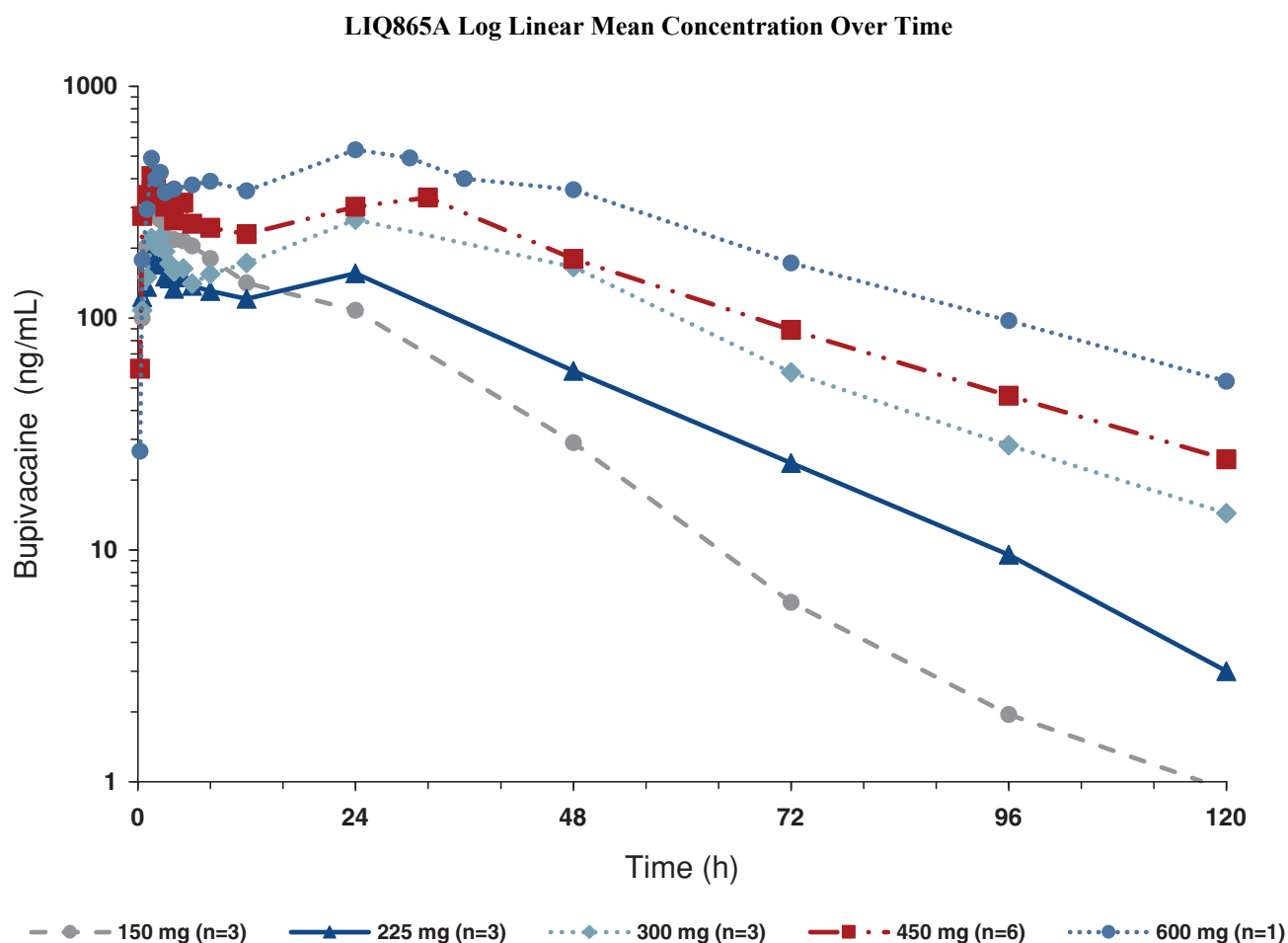
In March 2017, we completed our Phase 1a trial in Denmark to evaluate the safety and tolerability profile of two different PRINT formulations of bupivacaine: LIQ865A, consisting of particles combining bupivacaine and polylactic-glycolic acid, a polymer widely used in sustained-release drug products and 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 the first quarter of 2019, we expect to complete these studies by the end of 2019 and 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 the first quarter of 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*

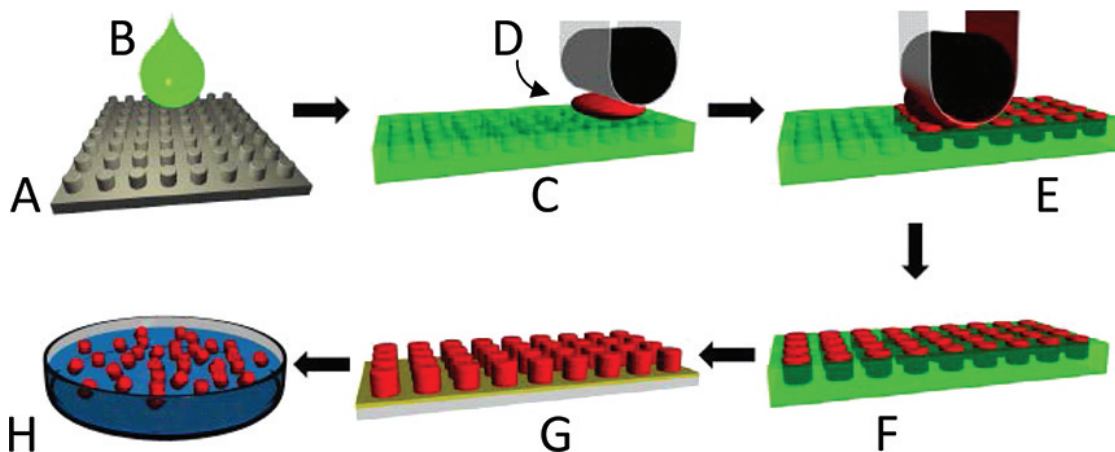
We begin our particle design by procuring a custom designed master template etched with three-dimensional structures, or posts, that will become the eventual shape and size of our drug particles. These three-dimensional structures are then replicated in negative form, through our proprietary processing 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, or LGM Pharma, for treprostinil, the active pharmaceutical ingredient of LIQ861, and we currently rely on a sole supplier, Plastiaple S.p.A., or Plastiaple, for RS00 Model 8 DPI, the DPI used to administer LIQ861. We also rely on a sole supplier, Xcelience LLC (now a Lonza Group Ltd company), or Xcelience, 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 extensive 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.

- 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. This law will go into effect in 2021, requiring reporting of payments and transfers made in that same calendar year.
- 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.
- 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.
- 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 50% (and 70% commencing on January 1, 2019) 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".
- 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. Since January 2017, President Trump has signed two 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, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision repealing, 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, amends 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 Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

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. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, 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 has already started the process of soliciting feedback on some of these measures and, at the same, is immediately 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, and 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. Although most of these, and other, proposals will require authorization through additional legislation to become effective, the U.S. Congress and the Trump administration have each indicated that it 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.

## **Corporate Information**

We were 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 annual report, and you should not consider any such information as part of this annual report or in deciding whether to purchase our common stock. This annual report and all of our filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, including copies of annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, are available free of charge through our website on the date we file those materials with, or furnish them to, the U.S. Securities and Exchange Commission, or the SEC. Such filings are also available to the public on the internet at the SEC's website at [www.sec.gov](http://www.sec.gov).

## **Item 1A. 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 annual report, including our financial statements and the related notes, the section entitled "Cautionary Note Regarding Forward-Looking Statements" 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 \$53.1 million and \$29.2 million for the years ended December 31, 2018 and 2017, respectively. We also had negative operating cash flows for the years ended December 31, 2018 and 2017. As of December 31, 2018 and 2017, we had an accumulated deficit of \$167.1 million and \$113.4 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. LIQ861 was observed to be well-tolerated at the two-week timepoint. The safety data at the two-week timepoint addresses the FDA's request for inclusion of such data in an NDA submission. During this two-week time period, LIQ861 was evaluated at capsule strengths up to 125 mcg treprostinil, with no study-drug related serious adverse events or dose-limiting toxicities observed. 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 the first quarter of 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 years ended December 31, 2018 and 2017 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. Future financial statements may also include statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

***We 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, 2018 and 2017, 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 16% and 84%, 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 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 (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, 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 Plastiaple. We also rely on a sole supplier, Xcelience (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 President and Chief Financial Officer, following Mr. Gordon's expected 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 provide sufficient long-term stability of the drug product for approval or for the product candidates to be successfully commercialized;
- 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 interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for our product candidates. Even if we are able to utilize the 505(b)(2) regulatory pathway, a drug approved via this pathway may be subject to the same post-approval limitations, conditions and requirements as any other drug.

In addition, we may face 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;
- 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. This law will go into effect in 2021, requiring reporting of payments and transfers made in that same calendar year;

- 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;
- 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; 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. Since January 2017, President Trump has signed two 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, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the TCJA, includes a provision repealing, 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, amends 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 Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no 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.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. 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 new laws 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. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, 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 has already started the process of soliciting feedback on some of these measures and, at the same, is immediately 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, and 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. Although most of these, and other, proposals will require authorization through additional legislation to become effective, the U.S. Congress and the Trump administration have each indicated that it 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.

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 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 February 15, 2019, 15,560,974 shares of our common stock were outstanding, of which 8,175,269 shares of common stock or 52.5% of our outstanding shares as of February 15, 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 7,385,705 shares held by our stockholders, or 47.5% of our outstanding shares as of February 15, 2019, is currently prohibited or otherwise restricted as a result of securities law provisions entered into by our stockholders with us. 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.

As of February 15, 2019, the holders of 10,184,036 shares, or 65.4% of our outstanding shares as of February 15, 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 any then-current lock-up agreements.

***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 the initial public offering and may not use them effectively.***

We expect to continue to use the net proceeds of the initial public offering to complete our ongoing Phase 3 clinical trial of LIQ861, advance LIQ865 through our planned Phase 2-enabling toxicology studies initiated in 2018, fund operations supporting the development of LIQ861 and LIQ865, continue to broaden out our proprietary PRINT platform and repay outstanding indebtedness in the normal course. Our management will continue to 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 the initial public 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 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 annual report, 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 expected departure of Mr. Gordon, our 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.

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

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned 49.3% of our capital stock as of December 31, 2018. Accordingly, our 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 SEC 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.

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 our 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 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 as of December 31, 2018. No changes to the provisional amounts as of December 31, 2017 were recorded. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

***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.

**Item 1B. Unresolved Staff Comments.**

Not applicable.

**Item 2. Properties.**

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.

### **Item 3. Legal Proceedings.**

We are not currently but may become subject to certain legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, there are currently no claims that would have a material adverse effect on our consolidated financial position, results of operations or cash flows.

### **Item 4. Mine Safety Disclosures.**

Not applicable.

## **PART II**

### **Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

#### ***Market Information***

Our common stock has been listed on Nasdaq Capital Market under the symbol "LQDA" since July 26, 2018. Prior to that date, there was no established public trading market for our common stock. As of February 22, 2019, the closing price of our common stock was \$19.30 per share.

#### ***Holders***

As of February 22, 2019, there were 114 record holders of our common stock, based upon information received from our transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. We estimate that there are more than 1,000 beneficial owners of our common stock.

#### ***Dividend Policy***

We have never paid any cash dividends on our capital stock. We anticipate that we will retain earnings, if any, to support operations and to finance the growth and development of our business. In addition, the terms of our A&R LSA with PWB precludes us from paying cash dividends without the prior written consent of PWB. Therefore, we do not expect to pay cash dividends for the foreseeable future.

#### ***Stock Performance Graph***

Not applicable.

#### ***Sale of Unregistered Securities***

The following sets forth information as to all securities we have sold in 2018 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.

### ***Warrants***

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.

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 March 7, 2018, we granted incentive stock options to 64 employees to purchase an aggregate of 703,330 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 \$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 President and Chief Financial Officer, for 127,576 shares; (iii) Robert Lippe, our Chief Operations Officer, for 43,678 shares; (iv) Dr. Robert Roscigno, our Senior Vice President, Product Development, for 35,656 shares; (v) Dr. Benjamin Maynor, our Senior Vice President, Research and Development, for 41,598 shares; and (vi) Timothy Albury, our Senior Vice President, Chief Accounting Officer, for 30,545 shares.

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.

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 Liquidia Technologies, Inc. Stock Option Plan, as amended, 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.

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 5 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

The information presented in this Item 5 gives effect to a 1-for-16.8273325471348 reverse stock split, which became effective on July 19, 2018.

***Purchases of Equity Securities by the Issuer and Affiliated Purchasers***

We did not repurchase any of our securities during the three months ended December 31, 2018.

**Item 6. Selected Financial Data.**

Not applicable.

## Item 7. 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 annual report. This discussion and other parts of this annual report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this annual report, 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.*

### 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 January 7, 2019, we enrolled 109 patients in our INSPIRE trial, completing enrollment for the safety portion of the trial. LIQ861 was observed to be well-tolerated at the two-week timepoint. The safety data at the two-week timepoint addresses the FDA's request for inclusion of such data in an NDA submission. During this two-week time period, LIQ861 was evaluated at capsule strengths up to 125 mcg treprostinil, with no study-drug related serious adverse events or dose-limiting toxicities observed. 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 are currently focusing our efforts on completing patient enrollment in 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. After review of an initial cohort of patients in our open-label INSPIRE trial, we amended the INSPIRE protocol to adjust pharmacokinetics sub-study dosing levels of LIQ861 to more closely match Tyvaso dosing levels on an emitted dose basis. 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 the first quarter of 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 \$53.1 million and \$29.2 million for the years ended December 31, 2018 and 2017, 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 \$2.7 million and \$7.3 million for the years ended December 31, 2018 and 2017, respectively. GSK accounted for \$0.4 million and \$6.1 million for the years ended December 31, 2018 and 2017, respectively, or 16% and 84%, 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 \$0.2 million and \$3.1 million for the years ended December 31, 2018 and 2017, 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 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.

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 as of December 31, 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, 2018 and 2017 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:

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

***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 year 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 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 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.

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

### ***Cash Flows***

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

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

### **Effect of Inflation**

Inflation did not have a significant impact on our net sales, revenues or income from continuing operations in 2018 or 2017.

### **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.

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

### **Item 8. Financial Statements and Supplementary Data.**

Our financial statements required to be filed pursuant to this Item 8 appear in a separate section of this annual report on Form 10-K, beginning on page F-1.

### **Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.**

None.

### **Item 9A. Controls and Procedures.**

#### ***Disclosure Controls and Procedures***

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our principal executive officer and our principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

A control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.



***Management's Annual Report on Internal Control Over Financial Reporting; Attestation Report of the Registered Public Accounting Firm***

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Commencing with the annual report on Form 10-K for our fiscal year ending December 31, 2019, we will include a report of management's assessment regarding internal control over financial reporting.

For as long as we remain an "emerging growth company" we are exempt from the auditor attestation requirement in the assessment of the effectiveness of our internal control over financial reporting.

***Changes in Internal Control Over Financial Reporting***

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

Information required to be disclosed by this Item with respect to our executive officers is incorporated into this annual report on Form 10-K by reference from the section entitled "Executive Officers and Director and Officer Compensation: Executive Officers" contained in our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2018.

Information required to be disclosed by this Item about our Board is incorporated into this annual report on Form 10-K by reference from the section entitled "The Class I Director Election Proposal" contained in our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2018.

Information required to be disclosed by this Item about the Section 16(a) compliance of our directors and executive officers is incorporated into this annual report on Form 10-K by reference from the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" contained in our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2018.

Information required to be disclosed by this Item about our Board, the Audit Committee of our Board, our audit committee financial expert, our code of conduct, as amended, or our Code of Conduct, and other corporate governance matters is incorporated into this annual report on Form 10-K by reference from the section entitled "Liquidia Corporate Governance" contained in our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2018.

The text of our Code of Conduct, which applies to our directors and employees (including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions), is posted in the "Corporate Governance" section of the Investors section of our website, <http://www.liquidia.com/>. A copy of the Code of Conduct can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Conduct that are required to be disclosed pursuant to the rules of the SEC and The Nasdaq Stock Market.

The information presented on our website is not a part of this annual report on Form 10-K and the reference to our website is intended to be an inactive textual reference only.

## **Item 11. Executive Compensation.**

Information required to be disclosed by this Item is incorporated into this annual report on Form 10-K by reference from the section entitled “Executive Officers and Director and Officer Compensation” contained in our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2018.

## **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

Information required to be disclosed by this Item is incorporated into this annual report on Form 10-K by reference from the sections entitled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” contained in our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2018.

## **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required to be disclosed by this Item is incorporated in this annual report on Form 10-K by reference from the sections entitled “Certain Relationships and Related Party Transactions” and “Liquidia Corporate Governance” contained in our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2018.

## **Item 14. Principal Accounting Fees and Services.**

The information required to be disclosed by this Item is incorporated into this annual report on Form 10-K by reference from the section entitled “Principal Accounting Fees and Services” contained in our definitive proxy statement for our 2019 annual meeting of stockholders, which we intend to file within 120 days of the end of our fiscal year ended December 31, 2018.

# **PART IV**

## **Item 15. Exhibits and Financial Statement Schedules.**

### **Financial Statement Schedules**

(a) The following documents are filed as part of this annual report on Form 10-K:

(1) Financial Statements.

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(2) Financial Statement Schedules.  
Required information is included in the footnotes to the financial statements.

(3) Exhibits.  
See Exhibit Index below

(b) The following exhibits are filed as part of this annual report on Form 10-K.

<b>Exhibit No.</b>	<b>Description</b>
3.1	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).
3.2	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).
4.1	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).
4.2	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).
4.3	Seventh Amended and Restated Investors' Rights Agreement, dated as of February 2, 2018, by and among the Company, the Investors party thereto and the Common Holders party thereto (incorporated herein by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).
10.1#*	Liquidia Technologies, Inc. Stock Option Plan (2004), as amended, and forms of award agreements thereunder.
10.2#	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).
10.3#	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).
10.4	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).
10.5	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).
10.6+	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).
10.7+	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).
10.8+	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).
10.9+	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).

- 10.10+ 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).
- 10.11 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).
- 10.12+ 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).
- 10.13+ 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).
- 10.14# 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).
- 10.15# Executive Employment Agreement, dated as of January 22, 2018, by and between the Company and Kevin Gordon, as amended (incorporated herein by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1, filed with the SEC on June 28, 2018).
- 10.16# 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).
- 10.17# 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).
- 10.18# 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).
- 10.19# 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).
- 10.20\* Lease Agreement, dated as of June 29, 2007, by and between the Company and Durham KTP Tech 4, LLC, as amended.
- 23.1\* Consent of PricewaterhouseCoopers LLP, independent Registered Public Accounting Firm.
- 31.1\* Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\*\* Certification of Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\*\* Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101\* The following materials from Liquidia Technologies, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets as of December 31, 2018 and 2017, (ii) Statements of Operations and Comprehensive Loss for the years ended December 31, 2018 and 2017 (iii) Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2018 and 2017, (iv) Statements of Cash Flows for the years ended December 31, 2018 and 2017 and (v) Notes to Financial Statements.

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+ 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.

\* Filed herewith.

\*\* Furnished herewith.

# Indicates management contract or compensatory plan.

(c) Not applicable.

**Item 16. Form 10-K Summary.**

None.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### Liquidia Technologies, Inc.

Date: February 26, 2019

By: /s/ Neal Fowler

Name: Neal Fowler

Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

<u>Name</u>	<u>Position</u>	<u>Date</u>
<u>/s/ Neal Fowler</u> Neal Fowler	Director and Chief Executive Officer (Principal Executive Officer)	February 26, 2019
<u>/s/ Kevin Gordon</u> Kevin Gordon	President and Chief Financial Officer (Principal Financial Officer)	February 26, 2019
<u>/s/ Timothy Albury</u> Timothy Albury	Senior Vice President, Chief Accounting Officer (Principal Accounting Officer)	February 26, 2019
<u>/s/ Dr. Stephen Bloch</u> Dr. Stephen Bloch	Chairman of the Board of Directors	February 26, 2019
<u>/s/ Arthur Kirsch</u> Arthur Kirsch	Director	February 26, 2019
<u>/s/ Edward Mathers</u> Edward Mathers	Director	February 26, 2019
<u>/s/ Dr. Seth Rudnick</u> Dr. Seth Rudnick	Director	February 26, 2019
<u>/s/ Raman Singh</u> Raman Singh	Director	February 26, 2019
<u>/s/ Dr. Ralph Snyderman</u> Dr. Ralph Snyderman	Director	February 26, 2019

**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**

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
<b>Assets</b>		
Current assets:		
Cash .....	\$ 39,534,985	\$ 3,418,979
Accounts receivable, less allowance of \$0 and \$48,108, respectively .....	272,557	1,622,179
Prepaid expenses and other current assets .....	219,057	443,460
Total current assets .....	40,026,599	5,484,618
Property, plant and equipment, net .....	8,130,708	8,243,012
Prepaid expenses and other assets .....	1,260,951	1,115,972
Total assets .....	<u>\$ 49,418,258</u>	<u>\$ 14,843,602</u>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable .....	\$ 3,235,949	\$ 4,424,948
Accrued expenses .....	1,459,182	2,785,618
Accrued compensation .....	2,515,519	1,952,505
Accrued interest .....	—	1,408,869
Deferred rent .....	268,599	268,628
Current portion of capital lease obligations .....	452,703	469,798
Current portion of deferred revenue .....	—	3,605,199
Current portion of long-term debt .....	316,906	15,608,349
Total current liabilities .....	8,248,858	30,523,914
Long-term capital lease obligations .....	376,082	510,625
Long-term deferred rent .....	2,406,084	2,612,552
Long-term deferred revenue .....	8,071,920	5,527,296
Long-term debt .....	11,627,643	5,556,782
Deferred financing obligation .....	—	1,341,810
Warrant liabilities .....	—	2,462,859
Total liabilities .....	30,730,587	48,535,838
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock — Series A, \$0.001 par value, 0 and 1,974,430 shares authorized, issued and outstanding as of December 31, 2018 and December 31, 2017, respectively .....	—	1,974
Preferred stock — Series A-1, \$0.001 par value, 0 and 1,834,862 shares authorized, issued and outstanding as of December 31, 2018 and December 31, 2017, respectively .....	—	1,835
Preferred stock — Series B, \$0.001 par value, 0 and 4,620,123 shares authorized as of December 31, 2018 and December 31, 2017, respectively, 0 and 4,496,908 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively .....	—	4,497
Preferred stock — Series C, \$0.001 par value, 0 and 17,102,578 shares authorized, issued and outstanding as of December 31, 2018 and December 31, 2017, respectively .....	—	17,103
Preferred stock — Series C-1, \$0.001 par value, 0 and 91,000,000 shares authorized as of December 31, 2018 and December 31, 2017, respectively, 0 and 17,556,178 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively .....	—	17,556
Preferred stock — Series D, \$0.001 par value, 0 shares authorized, issued and outstanding as of December 31, 2018 and December 31, 2017, respectively .....	—	—
Common stock — Class B (non-voting), \$0.001 par value, 0 and 330,664 shares authorized as of December 31, 2018 and December 31, 2017, respectively, 0 and 19,645 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively .....	—	20
Common stock — \$0.001 par value, 40,000,000 and 175,000,000 shares authorized as of December 31, 2018 and December 31, 2017, respectively, 15,519,469 and 549,952 issued and outstanding as of December 31, 2018 and December 31, 2017, respectively .....	15,520	550
Additional paid-in capital .....	185,726,048	79,677,540
Accumulated deficit .....	(167,053,897)	(113,413,311)
Total stockholders' equity (deficit) .....	18,687,671	(33,692,236)
Total liabilities and stockholders' equity (deficit) .....	<u>\$ 49,418,258</u>	<u>\$ 14,843,602</u>

The accompanying notes are an integral part of these financial statements.

**Liquidia Technologies, Inc.**  
**Statements of Operations and Comprehensive Loss**

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

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, 2018 and 2017**

	Series A		Series A-1		Series B		Series C		Series C-1		Series D		Common Stock		Additional Paid-In Capital		Related Party Note Receivable		Accumulated Deficit		Stockholders' Equity (Deficit)	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Voting Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
<b>Balance as of December 31, 2016</b> . . . . .	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	—	\$ —	533,593	\$ 534	19,645	\$ 20	\$ 66,025,349	\$ (55,000)	\$ (84,259,071)	\$ (18,245,203)	—	—
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 . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Beneficial conversion feature on Convertible Notes . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	55,000	—	—	—	55,000	—
Net loss . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Balance as of December 31, 2017</b> . . . . .	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	—	—	549,952	550	19,645	20	79,677,540	—	(113,413,311)	(29,154,240)	—	—
Adjustment to remove partial shares resulting from reverse split . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	(63)	—	—	—	—	—	—	—	—	—
Cumulative adjustment — adoption of ASC 606 . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Exercise of common stock options . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	119,793	120	—	—	334,591	—	—	(504,727)	—	—
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 . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Initial public offering . . . . .	—	—	—	—	—	—	—	—	—	—	91,147,482	91,147	—	—	—	—	53,893,361	—	—	—	53,893,361	—
Automatic conversion preferred stock and Class B common stock . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	4,833,099	4,833	—	—	53,159,256	—	—	—	53,164,089	—
Reclassification of warrant liabilities . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
IPO financing costs . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Net loss . . . . .	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Balance as of December 31, 2018</b> . . . . .	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	15,519,469	\$ 15,520	—	\$ —	\$ 185,726,048	\$ —	\$ (167,053,897)	\$ 18,687,671	—	—

The accompanying notes are an integral part of these financial statements.

**Liquidia Technologies, Inc.**  
**Statements of Cash Flows**

	<b>For the Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Operating activities</b>		
Net loss . . . . .	\$ (53,135,859)	\$ (29,154,240)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation . . . . .	2,195,075	514,092
Depreciation . . . . .	1,543,667	931,931
Amortization of discount on long-term debt and convertible notes . . . . .	17,550,541	9,837,985
Non-cash interest expense . . . . .	343,103	2,859,102
Non-cash gain on early extinguishment of long-term debt . . . . .	(137,695)	—
Derivative fair value adjustment . . . . .	—	(9,872,990)
Warrant fair value adjustment . . . . .	(277,715)	(2,011,263)
Non-cash rent (income) expense . . . . .	(206,498)	233,449
Lease incentive . . . . .	—	1,981,915
Changes in operating assets and liabilities:		
Accounts receivable . . . . .	1,349,622	(328,458)
Prepaid expenses and other current assets . . . . .	(67,154)	25,206
Other non-current assets . . . . .	2,408,097	(123,249)
Accounts payable . . . . .	(1,281,784)	1,872,852
Accrued expenses . . . . .	(1,055,564)	1,985,263
Accrued compensation . . . . .	563,013	(1,310)
Accrued interest . . . . .	—	(105,036)
Deferred revenue . . . . .	(1,621,384)	(2,935,603)
Net cash used in operating activities . . . . .	<u>(31,830,535)</u>	<u>(24,290,354)</u>
<b>Investing activities</b>		
Purchases of property, plant and equipment . . . . .	(870,943)	(2,544,064)
Net cash used in investing activities . . . . .	<u>(870,943)</u>	<u>(2,544,064)</u>
<b>Financing activities</b>		
Principal payments on capital lease obligations . . . . .	(608,154)	(384,024)
Proceeds from issuance of convertible notes . . . . .	—	27,388,524
Proceeds from issuance of long-term debt . . . . .	11,000,000	4,000,000
Refund of principal payments on long-term debt . . . . .	588,889	—
Principal payments on long-term debt . . . . .	(12,406,010)	(888,890)
Payments for debt issuance costs . . . . .	(397,000)	(1,397,628)
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 . . . . .	335,533	96,703
Net cash provided by financing activities . . . . .	<u>68,817,484</u>	<u>28,814,685</u>
Net increase in cash . . . . .	36,116,006	1,980,267
Cash, beginning of period . . . . .	3,418,979	1,438,712
Cash, end of period . . . . .	<u>\$ 39,534,985</u>	<u>\$ 3,418,979</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest . . . . .	\$ 1,094,532	\$ 313,390
Purchase of equipment with capital leases . . . . .	\$ 456,517	\$ 796,508
Changes in purchases of equipment in accounts payable . . . . .	\$ 25,934	\$ 144,852
Purchase of build-to-suit asset with deferred financing obligation . . . . .	\$ 272,656	\$ 1,341,810
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 . . . . .	\$ 144,993	\$ 41,271
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, 2018 and 2017, was \$0. The initial investment amount recorded represents the Company’s maximum risk of loss related to the identified VIE. As of December 31, 2018 and 2017, 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 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, 2018 and 2017.

### **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 16% and 84% of the Company's revenues for the years ended December 31, 2018 and 2017, respectively, and \$0 or 0% and \$1.1 million or 69% of the Company's accounts receivable as of December 31, 2018 and 2017, respectively.

### **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 - 7 years
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 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:

	Balance at December 31, 2017	Adjustments Due to Topic 606	Balance at January 1, 2018
<b><u>Balance Sheet:</u></b>			
<b><u>Assets</u></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><u>Liabilities</u></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><u>Stockholders' equity (deficit)</u></b>			
Accumulated deficit .....	(113,413,311)	(504,727)	(113,918,038)

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><u>Statement of Operations and Comprehensive Loss:</u></b>			
Revenues .....	\$ 2,706,981	\$ 5,436,630	\$ (2,729,649)
<b><u>Costs and expenses</u></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><u>Balance Sheet:</u></b>			
<b><u>Assets</u></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><u>Liabilities</u></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><u>Stockholders' equity (deficit)</u></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 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 \$365,988 and \$377,623 and were included in Accrued Expenses in the accompanying Balance Sheets as of December 31, 2018 and 2017, respectively.

## 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, 2018 and 2017 does not include the following common stock equivalent shares:

	2018	2017
Preferred Stock .....	—	4,542,665
Stock Options .....	1,658,112	497,329
Warrants .....	170,925	279,281
Total .....	<u>1,829,037</u>	<u>5,319,275</u>

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. For the year ended December 31, 2017, there were no reconciling items between basic and diluted net loss per share.

## Fair Value of Financial Instruments

The carrying values of cash, accounts receivable, and accounts payable at December 31, 2018 and 2017 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, 2018 and 2017:

	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
<b>December 31, 2018</b>				
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>

	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
Total . . . . .	<u>\$ —</u>	<u>\$ 11,408,823</u>	<u>\$ 31,165,127</u>	<u>\$ 23,627,990</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.

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.

## **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, 2018 and 2017 the Company recorded deferred offering costs relating to its financing activities of \$110,365 and \$125,000, 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.

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 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, 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 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.

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.

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.

## **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,	
	2018	2017
Expected dividend yield .....	— %	— %
Risk-free interest rate .....	2.67% - 3.01 %	1.34% - 1.99 %
Volatility .....	78% - 99 %	69% - 100 %
Expected life .....	6.25 years	6.25 years
Weighted-average fair value per share .....	\$ 7.25	\$ 13.97

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.

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 \$10.22 and \$20.36 and per share for the shares issued during the years ended December 31, 2018 and 2017, respectively.

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, 2018 and 2017, stock-based compensation expense for employee stock option awards totaled \$2,195,075 and \$514,092, 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.

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.

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 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, 2018 and 2017:

<b>2018 Revenue Recognized From</b>				
	<b>Non-Refundable Payments</b>		<b>Research and Development</b>	<b>Total</b>
	<b>Milestones</b>	<b>Up-front Payments</b>	<b>Services</b>	
<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> .....	<u>\$ 45,058</u>	<u>\$ 1,168,712</u>	<u>\$ 1,493,211</u>	<u>\$ 2,706,981</u>

<b>2017 Revenue Recognized From</b>				
	<b>Non-Refundable Payments</b>		<b>Research and Development</b>	<b>Total</b>
	<b>Milestones</b>	<b>Up-front Payments</b>	<b>Services</b>	
<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> .....	<u>\$ —</u>	<u>\$ 3,343,216</u>	<u>\$ 3,914,907</u>	<u>\$ 7,258,123</u>

## Deferred Revenue

The Company recognized \$1.2 million of revenue from non-refundable payments under Topic 606 during the year ended December 31, 2018, and \$3.3 million of revenue during the year ended December 31, 2017 under ASC 605, which was included in deferred revenue balances at the beginning of these respective periods.

## 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, 2018, the balances of these unamortized payments included in current and long-term prepaid expenses and other assets was \$0 and \$807,192, respectively. 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.

## 7. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

	2018	2017
Lab and build-to-suit equipment .....	\$ 6,123,194	\$ 3,847,546
Grant equipment .....	1,143,701	1,143,701
Office equipment .....	130,460	123,655
Furniture and fixtures .....	205,051	205,051
Computer equipment .....	799,515	677,569
Leasehold improvements .....	8,878,361	7,218,687
Construction-in-progress .....	155,148	2,830,407
Total property, plant and equipment .....	17,435,430	16,046,616
Accumulated depreciation .....	(9,304,722)	(7,803,604)
Property, plant and equipment, net .....	<u>\$ 8,130,708</u>	<u>\$ 8,243,012</u>

The Company recorded depreciation expense of \$1,543,667 and \$931,931 for the years ended December 31, 2018 and 2017, respectively. Maintenance and repairs are expensed as incurred and were \$153,278 and \$244,885, respectively, for the years ended December 31, 2018 and 2017.

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, 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). As of December 31, 2017, \$1,341,810 was recorded in construction-in-progress with an equal deferred financing obligation.

The following table details the activity of Construction in Progress (“CIP”) in 2018 and 2017 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> .....	<u>\$ 63,351</u>	<u>\$ —</u>	<u>\$ 91,797</u>	<u>\$ 155,148</u>

The Construction in Progress balance includes \$3,925 and \$57,625 of capitalized interest costs for the years ended December 31, 2018 and 2017, respectively.

## 8. Income Taxes

No provision for federal and state income tax expense has been recorded for the years ended December 31, 2018 and 2017 due to the valuation allowance recorded against the net deferred tax asset and recurring losses.

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, 2018 and 2017:

	2018	2017
Non-current deferred income tax assets:		
Tax loss carryforwards . . . . .	\$ 30,239,898	\$ 22,274,378
Deferred revenue . . . . .	1,856,507	2,098,191
Research and development credits . . . . .	2,382,047	2,382,047
Stock-based compensation . . . . .	489,694	277,948
Bad debt . . . . .	—	11,053
Compensation . . . . .	431,649	9,766
Fixed assets . . . . .	160,784	63,570
Patent amortization . . . . .	97,942	106,622
Other . . . . .	669,151	768,936
Valuation allowance . . . . .	(36,327,672)	(27,992,511)
Total non-current deferred income tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2018 and 2017, 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 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, 2018 and 2017 and the amount computed by applying the statutory federal income tax rate to income before income tax are as follows:

	2018		2017	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate . . . . .	\$ (11,158,530)	21.0 %	\$ (9,912,442)	34.0 %
State income taxes, net of federal tax benefit . . . . .	(1,062,492)	2.0 %	(581,901)	2.0
Non-deductible expenses . . . . .	6,810	— %	12,757	(0.1)
Stock-based compensation . . . . .	10,925	— %	153,033	(0.5)
Non-deductible interest expense . . . . .	4,074,501	(7.7)%	3,795,060	(13.0)
Derivative and warrant fair value adjustments . . . . .	(63,873)	0.1 %	(4,040,646)	13.9
Change in federal rate . . . . .	—	— %	14,113,550	(48.4)
Change in state rate . . . . .	(2,842)	— %	371,138	(1.3)
Other . . . . .	(139,660)	0.3 %	24,235	(0.1)
Change in valuation allowance . . . . .	8,335,161	(15.7)%	(3,934,784)	13.5
Provision for income taxes . . . . .	<u>\$ —</u>	<u>0.0 %</u>	<u>\$ —</u>	<u>0.0 %</u>

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, 2018 and 2017, and there were no such interest or penalties recognized during the years ended December 31, 2018 and 2017.

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.

## 9. Related-Party Transactions

For shared services provided by Liquidia to Envisia, Liquidia recorded \$0 and \$105,623, 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, 2018 and 2017, 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.

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.

## 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 \$2,674,683 and \$2,881,180 as of December 31, 2018 and 2017, 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.

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:

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>

Rent expense, including other facility expenses, for the years ended December 31, 2018 and 2017 was \$953,733 and \$1,046,721, 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:

Year ending December 31:	
2019 .....	\$ 464,797
2020 .....	354,739
2021 .....	33,774
Thereafter .....	—
Total minimum lease payments .....	853,310
Less: Amount representing interest .....	(24,525)
Present value of minimum lease payments .....	<u>\$ 828,785</u>

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 \$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, 2018 and 2017, \$0 and \$380,000, 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, 2018 and 2017.

## 11. Long-Term Debt

Long-term debt consisted of the following as of:

	Maturity Date	December 31,	
		2018	2017
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. . . . .		(316,906)	(15,608,349)
Long-term debt, less current portion . . . . .		<u>\$ 11,627,643</u>	<u>\$ 5,556,782</u>

### 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 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 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, 2018 and 2017 was \$0 and \$2,257,684, 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 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).

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 year ended 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 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, 2018 and 2017 are summarized below:

	<b>For the Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Fair value, beginning of period . . . . .	\$ 2,462,859	\$ —
Issuance of warrants . . . . .	—	4,474,122
Change in fair value . . . . .	(277,715)	(2,011,263)
Transfer to additional paid-in capital . . . . .	(2,185,144)	—
Fair value, end of period . . . . .	<u>\$ —</u>	<u>\$ 2,462,859</u>

#### *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 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. 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. 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.

Changes in the values of the derivative liabilities for the years ended December 31, 2018 and 2017 are summarized below:

	<b>For the Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Fair value, beginning of period .....	\$ —	\$ —
Issuance of derivatives .....	—	9,872,990
Change in fair value .....	—	(9,872,990)
Fair value, end of period.....	<u>\$ —</u>	<u>\$ —</u>

#### *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 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:

#### **Year ending December 31:**

2019 .....	\$ 416,989
2020 .....	4,483,486
2021 .....	4,410,660
Thereafter .....	<u>3,000,000</u>
Total .....	12,311,135
Less: Unamortized discount .....	(326,246)
Less: Unamortized debt issuance costs .....	(40,340)
Less: Current portion of long-term debt .....	<u>(316,906)</u>
	<u><u>\$ 11,627,643</u></u>

## **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).

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-226344) of Liquidia Technologies, Inc. of our report dated February 26, 2019 relating to the financial statements which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP  
Raleigh, North Carolina  
February 26, 2019

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neal Fowler, certify that:

1. I have reviewed this annual report on Form 10-K of Liquidia Technologies, Inc. for the year ended December 31, 2018;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 26, 2019

/s/ Neal Fowler

Name: Neal Fowler

Chief Executive Officer

Title: (Principal Executive Officer)

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin Gordon, certify that:

1. I have reviewed this annual report on Form 10-K of Liquidia Technologies, Inc. for the year ended December 31, 2018;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 26, 2019

/s/ Kevin Gordon

Name: Kevin Gordon

Title: President and Chief Financial Officer  
(Principal Financial Officer)

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Liquidia Technologies, Inc., a Delaware corporation (the “Company”), on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Neal Fowler, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 26, 2019

/s/ Neal Fowler

Name: Neal Fowler

Title: Chief Executive Officer  
(Principal Executive Officer)

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Liquidia Technologies, Inc., a Delaware corporation (the “Company”), on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Kevin Gordon, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 26, 2019

/s/ Kevin Gordon

Name: Kevin Gordon

Title: President and Chief Financial Officer  
(Principal Financial Officer)

